DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 400, 403, 411, 417, and 423

[CMS–4068–F]

RIN 0938–AN08

Medicare Program; Medicare Prescription Drug Benefit

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule implements the provisions of the Social Security Act (the Act) establishing and regulating the Medicare Prescription Drug Benefit. The new voluntary prescription drug benefit program was enacted into law on December 8, 2003 in section 101 of Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). Although this final rule specifies most of the requirements for implementing the new prescription drug program, readers should note that we are also issuing a closely related rule that concerns Medicare Advantage organizations, which, if they offer coordinated care plans, must offer at least one plan that combines medical coverage under Parts A and B with prescription drug coverage. Readers should also note that separate CMS guidance on many operational details appears or will soon appear on the CMS website, such as materials on formulary review criteria, risk plan and fallback plan solicitations, bid instructions, solvency standards and pricing tools, plan benefit packages.

The addition of a prescription drug benefit to Medicare represents a landmark change to the Medicare program that will significantly improve the health care coverage available to millions of Medicare beneficiaries. The MMA specifies that the prescription drug benefit program will become available to beneficiaries beginning on January 1, 2006.

Generally, coverage for the prescription drug benefit will be provided under private prescription drug plans (PDPs), which will offer only prescription drug coverage, or through Medicare Advantage prescription drug plans (MA PDs), which will offer prescription drug coverage that is integrated with the health care coverage they provide to Medicare beneficiaries under Part C of Medicare. PDPs must offer a basic prescription drug benefit. MA-PDs must offer either a basic benefit or broader coverage for no additional cost. If this required level of coverage is offered, MA-PDs or PDPs, but not fallback PDPs may also offer supplemental benefits through enhanced alternative coverage for an additional premium. All organizations offering drug plans will have flexibility in the design of the prescription drug benefit. Consistent with the MMA, this final rule also provides for subsidy payments to sponsors of qualified retiree prescription drug plans to encourage retention of employer-sponsored benefits.

We are implementing the drug benefit in a way that permits and encourages a range of options for Medicare beneficiaries to augment the standard Medicare coverage. These options include facilitating additional coverage through employer plans, MA-PD plans and high-option PDPs, and through charity organizations and State pharmaceutical assistance programs. See sections II.C, II.J, and II.P, and II.R of this preamble for further details on these issues.

The proposed rule identified options and alternatives to the provisions we proposed and we strongly encouraged comments and ideas on our approach and on alternatives to help us design the Medicare Prescription Drug Benefit Program to operate as effectively and efficiently as possible in meeting the needs of Medicare beneficiaries.

DATES: These regulations are effective on March 22, 2005.

FOR FURTHER INFORMATION CONTACT: Lynn Orlosky (410) 786–9064 or Randy Brauer (410)786–1618 (for issues related to eligibility, elections, enrollment, including auto-enrollment of dual eligible beneficiaries, and creditable coverage).

Melvin Sanders (410) 786–8355 (for issues related to marketing and user fees).

Vanessa Duran (214) 767–6435 (for issues related to benefits and beneficiary protections, including Part D benefit packages, Part D covered drugs, coordination of benefits in claims processing and tracking of true-out-of-pocket costs, pharmacy network access standards, plan information dissemination requirements, and privacy of records).

Craig Miner, RPh. (410) 786–1889 for issues of pharmacy benefit cost and utilization management, formulary development, quality assurance, medication therapy management, and electronic prescribing).

Mark Newsom (410) 786–3198 (for issues of submission, review, negotiation, and approval of risk and limited risk bids for PDPs and MA-PD plans; the calculation of the national average bid amount; determination and collection of enrollee premiums; calculation and payment of direct and reinsurance subsidies and risk-sharing; and retroactive adjustments and reconciliations.)

Jim Owens (410) 786–1582 (for issues of licensing and waiver of licensure, the assumption of financial risk for unsubsidized coverage, and solvency requirements for unlicensed sponsors or sponsors who are not licensed in all States in the region in which it wants to offer a PDP.)

Jim Slade (410) 786–1073 (for issues related to pre-emption of State law) and (for issues related to solicitation, review and approval of fallback prescription drug plan proposals; fallback contract requirements; and enrollee premiums and plan payments specific to fallback plans.)

Christine Hinds (410) 786–4578 (for issues of coordination of Part D plans with providers of other prescription drug coverage including Medicare Advantage plans, State pharmaceutical assistance programs (SPAPs), Medicaid, and other retiree prescription drug plans; also for issues related to eligibility for and payment of subsidies for assistance with premium and cost-sharing amounts for Part D eligible individuals with lower income and resources; for rules for States on eligibility determinations for low-income subsidies and general State payment provisions including the phased-down State contribution to drug benefit costs assumed by Medicare).

Mark Smith (410) 786–8015 (for issues related to conditions necessary to contract with Medicare as a PDP sponsor, as well as contract requirements, intermediate sanctions, termination procedures and change of ownership requirements.)

Jean LeMasurier (410) 786–1091 (for issues related to employer group waivers and options).

Frank Szeflinski (303) 844–7119 (for issues related to cost-based HMOs and CMPS offering Part D coverage.)

John Scott (410) 786–3636 (for issues related to the procedures PDP sponsors must follow with regard to grievances, coverage determinations, and appeals.)

Mark Smith (410) 786–8015 (for issues related to solicitation, review and approval of fallback prescription drug plan proposals; fallback contract requirements; and enrollee premiums and plan payments specific to fallback plans.)

Jim Mayhew (410) 786–9244 (for issues related to the alternative retiree

drug subsidy and other employer-based sponsor options.)

Joanne Sinsheimer (410) 786–4620 (for issues related to physician self-referral prohibitions.)

Brenda Hudson (410) 786–4085 (for issues related to PACE organizations offering Part D coverage.)

Julie Walton (410) 786–4622 or Kathryn McCann (410) 786–7623 (for issues related to provisions on Medicare supplemental (Medigap) policies.)

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In addition, because of the many organizations and terms to which we refer by acronym in this final rule, we are listing these acronyms and their corresponding terms in alphabetical order below:

ABN	Advanced beneficiary notice
ADAP	AIDS Drug Assistance Program
AEP	Annual coordinated election period
AHRQ	Agency for Healthcare Research and Quality
AI/AN	American Indians and Alaska Natives
AIC	Amount in controversy
ALJ	Administrative Law Judge
AMA	American Medical Association
AMCP	Academy of Managed Care Pharmacy
ANCI	American National Standards Institute
AO	Accreditation organization
ASAP	American Society of Automation in Pharmacy
ASHP	American Society of Health Systems Pharmacists
AWP	Average wholesale price
BBA	Balanced Budget Act
BLS	Bureau of Labor Statistics
CAHP	Consumer Assessment of Health Plan
CBI	Confidential business information
CBO	Congressional Budget Office
CCIP	Chronic care improvement programs
CCP	Comprehensive Compliance Program
CFR	Code of Federal Regulations
CHOW	Change of ownership
CMP	competitive medical plan
CMS	Centers for Medicare & Medicaid Services
COB	Coordination of benefit
COBRA	Consolidated Omnibus Budget Reconciliation Act (of 1985)
CPI-PD	Consumer Price Index for Prescription Drugs and Medical Supplies
CPT	Current Procedural Terminology
CY	Calendar year
DAB	Departmental Appeals Board
DHS	Designated health services
DME	Durable medical equipment
DoD	Department of Defense
DOL	Department of Labor
DUR	Drug utilization review
EOB	explanation of benefits
ERISA	Employee Retirement Income Security Act of 1974
ESRD	End stage renal disease
FAR	Federal Acquisition Regulation
FDA	Food and Drug Administration
FEHBP	Federal Employee Health Benefits Program
FFP	Federal financial participation
FOIA	Freedom of Information Act
FQHCs	Federally qualified health centers
FPL	Federal poverty level
FR	FEDERAL REGISTER
FSA	Flexible savings account
FY	Fiscal year
HEDIS	Health plan Employer Data and Information Set
HHS	Department of Health and Human Services
HIC	Health insurance claim
HIPAA	Health Insurance Portability and Accountability Act of 1996
HMO	Health maintenance organization
HPMS	Health Plan Management System
HRA	Health reimbursement account
HRSA	Health Resources and Services Administration
HSA	Health savings account
ICFs/MR	Intermediate care facilities for the mentally retarded
IDIQ	Indefinite duration, indefinite quantity
IEP	Initial enrollment period
IHS	Indian Health Service
IRE	Independent review entity
I/T/U	Indian Tribes and Tribal organizations, and urban Indian organizations
JCHACO	Joint Commission on Accreditation of Health Care Organizations
LIS	Low-income subsidy
LTC	Long term care
MA	Medicare Advantage (formerly Medicare+Choice)
MA-PD	Medicare Advantage prescription drug plans
MAC	Medicare Appeals Council
MAX	Medicaid Analytic extract
MCBS	Medicare Current Beneficiary Survey
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
MSA	Medicare savings account
MSIS	Medicaid Statistical Information System
MSP	Medicare Secondary Payor
MTMP	Medication Therapy Management Program
NAIC	National Association of Insurance Commissioners
NCQA	National Committee for Quality Assurance
NCPDP	National Council for Prescription Drug Programs
NCVHS	National Center for Vital and Health Statistics
NDC	National Drug Code
NHE	National Health Expenditure
NPA	National PACE Association
NPI	National Provider Identifier
OACT	Office of the Actuary (CMS)
OBRA	Omnibus Budget Reconciliation Act
OCR	Office for Civil Rights
OEPI	Open enrollment period for institutionalized individuals
OIG	Office of the Inspector General
OPM	Office of Personnel Management
P&T	Pharmaceutical and therapeutic
PBA	Pharmacy benefit administrator
PBMs	Pharmacy benefit managers
PBP	Plan Benefit Package
PDP	Private prescription drug plan

PDSC	Phased-down State contribution
PFFS	Private fee-for-service plan
PHI	Protected health information
PhRMA	Pharmaceutical Manufacturers and Researchers of America
PPO	Preferred provider organization
PPV	Pharmaceutical Prime Vendor
PSO	Provider-sponsored organization
QDWIs	Qualified disabled and working individuals
QII	Qualified individuals
QIO	Quality Improvement Organization
QMB	Qualified Medicare beneficiaries
REACH	Regional Education About Choices in Health
RHC	Rural Health Center
SCHIP	State Children's Health Insurance Program
SEP	Special enrollment period
SHIP	State health insurance assistance program
SLMB	Special Low-Income Beneficiaries
SOW	Scope of work
SPAP	State Pharmaceutical Assistance Program
SPD	Summary Plan Description
SPOC	Single point of contact
SSA	Social Security Administration
SSI	Supplemental Security Income
SSRI	Selective serotonin reuptake inhibitor
SSSGs	Similarly Sized Subscriber Groups
TANF	Temporary assistance for needy families
TrOOP	True out-of-pocket
U&C	Usual and customary
URAC	Utilization Review Accreditation Commission
USP	U.S. Pharmacopoeia
VA	Department of Veterans Affairs
VDSA	Voluntary data sharing agreement

I. Background

A. Medicare Prescription Drug, Improvement, and Modernization Act of 2003

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) amended Title XVIII of the Social Security Act (the Act) by establishing a new Part D: the Voluntary Prescription Drug Benefit Program. (For ease of reference, we will refer to the new prescription drug benefit program as Part D of Medicare and we will refer to the Medicare Advantage Program described in Part C of title XVIII of the Act -as Part C of Medicare.)

We believe that the new Part D benefit constitutes the most significant change to the Medicare program since its inception in 1965. The addition of outpatient prescription drugs to the Medicare program reflects the Congress' recognition of the fundamental change in recent years in how medical care is delivered in the U.S. It recognizes the vital role of prescription drugs in our health care delivery system, and the need to modernize Medicare to assure their availability to Medicare beneficiaries. This final rule is designed to broaden participation in the new benefit both by organizations that offer prescription drug coverage and by eligible beneficiaries. In conjunction with complementary improvements to the Medicare Advantage program, these changes should significantly increase the coverage and choices available to Medicare beneficiaries.

Effective January 1, 2006, the new program establishes an optional prescription drug benefit for individuals who are entitled to or enrolled in Medicare benefits under Part A and Part B. Beneficiaries who qualify for both Medicare and Medicaid (full-benefit dual eligibles) will automatically receive the Medicare drug benefit unless Medicare has identified the individual as having other creditable coverage through an employer-based prescription drug plan. The statute also provides for assistance with premiums and cost sharing to eligible low-income beneficiaries.

In general, coverage for the new prescription drug benefit will be provided through private prescription drug plans (PDPs) that offer drug-only coverage, or through Medicare Advantage (MA) (formerly known as Medicare+Choice) plans that offer integrated prescription drug and health care coverage (MA-PD plans). PDPs must offer a basic drug benefit. MA-PDs must offer either a basic benefit, or a benefit with broader coverage than the basic benefit, but at no additional cost to the beneficiary. If this required level of coverage is offered, MA-PDs or PDPs, but not fallback plans, may also offer supplemental benefits, called ''enhanced alternative coverage,'' for an additional premium.

All organizations offering drug plans will have flexibility in terms of benefit design, including the authority to establish a formulary to designate specific drugs that will be available, and the ability to have a cost-sharing structure other than the statutorily-defined structure, subject to certain actuarial tests. Most Part D plans also may include supplemental drug coverage such that the total value of the coverage offered exceeds the value of basic prescription drug coverage. The specific sections of the Act that address the prescription drug benefit program are the following:

1860D–1	Eligibility, enrollment, and information.
1860D–2	Prescription drug benefits.
1860D–3	Access to a choice of qualified prescription drug coverage.
1860D–4	Beneficiary protections for qualified prescription drug coverage.
1860D–11	PDP regions; submission of bids; plan approval.
1860D–12	Requirements for and contracts with prescription drug plan (PDP) sponsors.
1860D–13	Premiums; late enrollment penalty.
1860D–14	Premium and cost-sharing subsidies for low-income individuals.
1860D–15	Subsidies for Part D eligible individuals for qualified prescription drug coverage.
1860D–16	Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.
1860D–21	Application to Medicare Advantage program and related managed care programs.
1860D–22	Special rules for employer-sponsored programs.
1860D–23	State pharmaceutical assistance programs.
1860D–24	Coordination requirements for plans providing prescription drug coverage.
1860D–41	Definitions; treatment of references to provisions in Part C.
1860D–42	Miscellaneous provisions.
	Specific sections of the MMA that also relate to the prescription drug benefit program are the following:
Sec. 102	Medicare Advantage Conforming Amendments
Sec. 103	Medicaid Amendments
Sec. 104	Medigap
Sec. 109	Expanding the work of Medicare Quality Improvement Organizations to include Parts C and D.

B. Codification of Regulations

The final provisions set forth here are codified in 42 CFR Part 423–Voluntary Medicare Prescription Drug Benefit. Note that the regulations—

- for Medicare supplemental policies (Medigap) will continue to be located in 42 CFR part 403 (subpart B);
- for exclusions from Medicare and limitations on Medicare payment (the physician self-referral rules) will continue to be located in 42 CFR part 411;
- for managed care organizations that contract with us under cost contracts will continue to be located in 42 CFR part 417, Health Maintenance Organizations, Competitive Medical Plans, and Health Care Prepayment Plans;
- for PACE organizations will continue to be located in 42 CFR part 460.

C. Organizational Overview of Part 423

The regulations set forth in this final rule are codified in the new 42 CFR Part 423–Voluntary Medicare Prescription Drug Benefit. There are a number of places in which statutory provisions in Part D incorporate by reference specific sections in Part C of Medicare (the MA program). The MA regulations appear at 42 CFR Part 422. Since the same organizations that offer MA coordinated care plans will also be required to offer MA-PD plans, we believed it was appropriate to adopt the same organizational structure as part 422. Wherever possible, we modeled the prescription drug regulations on the parallel provisions of the part 422 regulations.

The major subjects covered in each subpart of part 423 are as follows:

Subpart A, General Provisions: Basis and scope of the new part 423, Definitions and discussion of important concepts used throughout part 423, and sponsor cost-sharing in beneficiary education and enrollment-related costs (user fees).

Subpart B, Eligibility, Election, and Enrollment: Eligibility for enrollment in the Part D benefit, enrollment periods, disenrollment, application of the late enrollment penalty, approval of marketing materials and enrollment forms, and the meaning and documentation of creditable coverage. (Please note that other, related topics, are discussed in the following subparts: Subpart P, eligibility and enrollment for low-income individuals; Subpart S, provisions relating to the phase-down of State contributions for dual-eligible drug expenditures; Subpart F, calculation and collection of late enrollment fees; Subpart C, plan disclosure; Subpart Q, eligibility and enrollment for fallback plans; and Subpart T, the definition of a Medicare supplemental (Medigap) policy.)

Subpart C, Benefits and Beneficiary Protections: Prescription drug benefit coverage, service areas, network and out-of-network access, formulary requirements, dissemination of plan information to beneficiaries, and confidentiality of enrollee records. (Please note that actuarial valuation of the coverage offered by plans, as well as the submission of the bid, is discussed in subpart F. Access to negotiated prices is discussed in subpart C, while the reporting of negotiated prices is discussed in subpart G. Formularies are discussed in subpart C, while appeals related to formularies are discussed in subpart M. Incurred costs toward true out-of-pocket (TrOOP expenditures) are discussed in subpart C, while the procedures for determining whether a beneficiary's Part D out-of-pocket costs are actually reimbursed by insurance or another third-party arrangement are discussed in subpart J. Information that plans must disseminate to beneficiaries is discussed in subpart C, while Part D information that CMS must disseminate to beneficiaries is discussed in subpart B.)

Subpart D, Cost Control and Quality Improvement Requirements for Part D Plans: Utilization controls, quality assurance, and medication therapy management, as well as rules related to identifying enrollees for whom medication therapy management is appropriate, consumer satisfaction surveys, and accreditation as a basis for deeming compliance.

Subpart E, Reserved.

Subpart F, Submission of Bids and Monthly Beneficiary Premiums; Plan Approval: Bid submission, the actuarial value of bid components, review and approval of plans, and the calculation and collection of Part D premiums.

Subpart G, Payments to Part D plans for Qualified Prescription Drug Coverage: Data submission, payments and reconciliations for direct subsidies, risk adjustment, reinsurance, and risk-sharing arrangements.

Subpart H, Reserved.

Subpart I, Organization Compliance with State Law and Preemption by Federal Law: Licensure, assumption of financial risk, solvency, and State premium taxes.

Subpart J, Coordination Under Part D With Other Prescription Drug Coverage: Applicability of Part D rules to the Medicare Advantage program, waivers available to facilitate the offering of employer group plans, waivers of part D provisions for PACE plans and 1876 cost plans offering qualified prescription drug coverage, and procedures to facilitate calculation of true out-of-pocket (TrOOP) expenses and coordination of benefits with State pharmaceutical assistance programs and other entities that provide prescription drug coverage. (Please note that subpart C discusses, in more detail, coordination of benefits from the perspective of which prescription drug benefits are covered by Part D and the determination of which incurred beneficiary costs will be counted as TrOOP expenditures. Provisions relating to disenrollment for material misrepresentation by a beneficiary are discussed in subpart B.)

Subpart K, Application Procedures and Contracts with PDP Sponsors: Application procedures and requirements; contract terms; procedures for termination of contracts; reporting by PDP sponsors.

Subpart L, Effect of Change of Ownership or Leasing of Facilities during Term of Contract: Change of ownership of a PDP sponsor; novation agreements; leasing of a PDP sponsor's facilities.

Subpart M, Grievances, Coverage Determinations and Appeals: Coverage determinations by sponsors, exceptions procedures, and all levels of appeals by beneficiaries.

Subpart N, Medicare Contract Determinations and Appeals: Notification by CMS about unfavorable contracting decisions, such as nonrenewals or terminations; reconsiderations; appeals.

Subpart O, Sanctions: Provisions concerning available sanctions for participating organizations.

Subpart P, Premiums and Cost-Sharing Subsidies for Low-Income Individuals: Eligibility determinations and payment calculations for low-income subsidies.

Subpart Q, Guaranteeing Access to a Choice of Coverage (Fallback Plans): Definitions, access requirements, bidding process, and contract requirements for fallback PDPs.

Subpart R, Payments to Sponsors of Retiree Prescription Drug Plans: Provisions for making retiree drug subsidy payments to sponsors of qualified retiree prescription drug plans.

Subpart S, Special Rules for States—Eligibility Determinations for Subsidies and General Payment Provisions: State/Medicaid program's role in determining eligibility for low-income subsidy and other issues related to the Part D benefit.

In addition, in subpart T, this final rule also makes changes to: part 400 relating to definitions of Parts C & D, part 403 relating to Medicare supplemental policies (Medigap), part 411 relating to exclusions from Medicare and limitations on Medicare payment (the physician self-referral rules), part 417 relating to cost-based health maintenance organizations (HMOs), and part 460 relating to PACE organizations.

II. Provisions of the Proposed Rule

We received 7,696 items of correspondence containing comments on the August 2004 proposed rule. Commenters included managed care organizations and other insurance industry representatives, pharmacy benefit management firms, pharmacies and pharmacy education and practice-related organizations, pharmaceutical manufacturers, representatives of physicians and other health care professionals, beneficiary advocacy

groups, representatives of hospitals and other healthcare providers, States, employers and benefits consulting firms, members of the Congress, Indian Health Service, Tribal and Urban Health Programs, American Indians and Alaska Natives, beneficiaries, and others. We also received many comments expressing concerns unrelated to the proposed rule. Some commenters expressed concerns about Medicare unrelated to the Prescription Drug Benefit, while others addressed concerns about health care and health insurance coverage unrelated to Medicare. Because of the volume of comments we received in response to the proposed rule, we will be unable to address comments and concerns that are unrelated to the proposed rule.

Most of the comments addressed multiple issues, often in great detail. Listed below are the areas of the regulation that received the most comments:

- Transition of Coverage for Dual Eligibles from Medicaid to Medicare
- Access to Drugs in Long Term Care Facilities
- Formulary Policies
- Medication Therapy Management Requirements
- Network Access Standards
- Part B/Part D Drug Identification and Coordination
- Dispensing Fees

In this final rule, we address comments received on the proposed rule. For the most part, we will address issues according to the numerical order of the related regulation sections.

A. General Provisions

1. Overview

Section 423.1 of subpart A specified the general statutory authority for the ensuing regulations and indicated that the scope of part 423 is to establish requirements for the Medicare prescription drug benefit program. We proposed key definitions at § 423.4 for terms that appear in multiple sections of part 423.

Consistent with the MMA statute, in many cases we proposed procedures that parallel those in effect under the MA program. Our goal was to maintain consistency between these two programs wherever possible; thus we evaluated the need for parallel changes in the MA final rule when we received comments on provisions that affect both programs.

Comment: Many commenters urged us to finalize regulations by early January—and detailed business requirements soon thereafter. Some also recommended that we make public certain key decisions and data sooner than January in order to promote planning.

Response: We agree that the earliest possible release of program requirements and final rules will facilitate planning and implementation of new business processes required to offer and administer this new program. Consequently we have made numerous draft documents, such as the risk plan solicitation, PDP solvency requirements, formulary review policies, and the actuarial bidding instructions, available for public comment in November and December of 2004 and have expedited the rulemaking process to meet these goals. In response to the lack of specificity regarding the PDP regions in our proposed rule, we conducted extensive outreach in order to obtain public input prior to the publication of our final rule. On December 6, 2004, we announced the establishment of 26 MA regions and 34 PDP regions.

2. Discussion of Important Concepts and Key Definitions (§ 423.4)

a. Introduction

For the most part, the proposed definitions were taken directly from section 1860D–41 of the Act. The definitions set forth in subpart A apply to all of part 423 unless otherwise indicated, and are applicable only for the purposes of part 423. For example, ''insurance risk'' applies only to pharmacies that contract with PDP sponsors under part 423.

Definitions that have a more limited application have not been included in subpart A, but instead are set forth within the relevant subpart of the regulations. For example, in subpart F, we have included all the definitions related to bids and premiums. The detailed definitions and requirements related to prescription drug coverage are included in subpart C, but because of their direct relevance to the bidding process they are also referenced in subpart F.

Following our discussion of important concepts, we provide brief definitions of terms that occur in multiple sections of this preamble and part 423. We believe that it is helpful to define these frequently occurring terms to aid the reader, but that these terms do not require the extended discussion necessary in our section on important concepts.

b. Discussion of Actuarial Equivalence, Creditable Prescription Drug Coverage, PDP Plan Regions, Service Area, and User Fees

- Discussion of the Meaning of Actuarial Equivalence

The concept of actuarial equivalence is applied in several different contexts in Title I of the MMA. In very general terms, actuarial equivalence refers to a determination that, in the aggregate, the dollar value of drug coverage for a set of beneficiaries under one plan can be shown to be equal to the dollar value for those same beneficiaries under another plan. Given the various uses for this term in the Part D provisions, we proposed the following relatively general definition: ''Actuarial equivalence'' means a state of equivalent values demonstrated through the use of generally accepted actuarial principles and in accordance with section 1860D–11(c) of the Act and § 423.265(c)(3) of this part. This concept is discussed in further detail in those sections of this preamble, such as section II.F, where actuarial equivalence comes into play. We will provide further detailed guidance on methods required to demonstrate actuarial equivalence.

Comment: One commenter requested that the definition of actuarial equivalence be refined through examples or more descriptive language.

Response: We agree that it is critical to disclose our requirements for calculation of actuarial values under Part D requirements as fully and as expeditiously as possible to reduce uncertainty on the part of potential plan sponsors. To that end we made available our draft bid preparation rules and processes early in December 2004 for public comment, and we will continue to refine our guidance to bidders through vehicles such as the annual 45-day notice and the CMS website. We have modified our definition to refer to this separate guidance.

- Discussion of the Meaning of Creditable Prescription Drug Coverage

Comments on creditable coverage are addressed in the preamble for subparts B and T.

- Prescription Drug Plan Regions

Prescription drug plan regions are areas in which a contracting PDP sponsor must provide access to covered Part D drugs. Although we included specifications for regions in § 423.112, the regions themselves were not set forth in the proposed rule. To the extent feasible, we tried to establish PDP regions that were consistent with MA regions. The MMA specifically required no fewer than 10 regions and no more than 50 regions, not including the territories. For a further discussion of the PDP regions, see section II.C of this preamble.

Comment: Many commenters expressed concerns about the MA and PDP region decisions. Many argued that

regions should closely mirror existing State insurance markets to maximize participation. Others representing rural constituencies argued for larger regions to encourage offering of coverage in rural areas.

Response: We conducted a market survey and analysis, including an examination of current insurance markets as required in the MMA. Key factors in the survey and analysis included payment rates; eligible population size per region; preferred provider organization (PPO) market penetration; current existence of PPOs, MA plans, or other commercial plans; and presence of PPO providers and primary care providers. Additional factors were also considered, including solvency and licensing requirements, as well as capacity issues. Recognizing the lack of specificity regarding the PDP regions in our proposed rule, we conducted extensive outreach in order to obtain public input prior to the publication of our final decision. On December 6, 2004, we announced the establishment of 26 MA regions and 34 PDP regions. For maps and fact sheets on the regions, please see *http://www.cms.hhs.gov/medicarereform/mmaregions/*.

- Service Area

In the proposed rule we proposed that Medicare beneficiaries would be eligible to enroll in a PDP or an MA-PD plan only if they reside in the PDP's or MA-PD plan's ''Service Area.'' For PDPs the service area is defined as the region or regions for which they must provide access. This is the Region established by CMS either pursuant to proposed § 423.112, or, in the case of fallback plans, the fallback service area pursuant to § 423.859, within which the PDP is responsible for providing access to the Part D drug benefit in accordance with the access standards in proposed § 423.120. Under the MA program, an MA plan's service area is defined in § 422.2. For coordinated care plans, the definition of ''service area'' expressly includes the condition that the service area is an area in which access is provided in accordance with access standards in § 422.112.

We also proposed that for purposes of enrolling in Part D with a PDP, or under an MA-PD plan, the definition of Service Area that governs eligibility to enroll is the area within which the Part D access standards under § 423.120 are met. Beneficiaries in jail or prison do not have access to pharmacies available as required under § 423.120. Therefore, such beneficiaries would not be considered to be in a PDP or MA-PD plan's Service Area for purposes of enrolling in Part D. Incarcerated individuals accordingly would not be assessed a late penalty when they enroll in Part D (either with a PDP or MA-PD plan) upon being released. The same analysis applies with regard to a beneficiary who lives abroad, and does not reside within the boundaries of any PDP Region or MA-PD Service Area. We have modified our definition of service area to clarify our intent as proposed.

Comment: Several commenters asked that we waive the service area requirement for employer group PDP plans.

Response: We agree that we have the authority to waive the service area requirement for employer-sponsored group prescription drug plans, and we plan to do so in appropriate cases. We will provide further details on waivers in separate CMS guidance.

- Sponsor Cost-Sharing in Beneficiary Education and Enrollment Related Costs-User Fees (§ 423.6)

The last section of subpart A proposed regulations implementing the user fees provided for in section 1857(e)(2) of the Act, as incorporated by section 1860D–12(b)(3)(D) of the Act. These fees are currently required of MA plans for the purpose of defraying part of the ongoing costs of the national beneficiary education campaign that includes developing and disseminating print materials, the 1–800–MEDICARE telephone line, community based outreach to support State health insurance assistance programs (SHIPs), and other enrollment and information activities required under section 1851 of the Act and counseling assistance under section 4360 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 103–66).

The MMA expands the user fee to apply to PDP sponsors as well as MA plans. The expansion of the application of user fees recognizes the increased Medicare beneficiary education activities that we would require as part of the new prescription drug benefit. In 2006 and beyond, user fees will help to offset the costs of educating over 41 million beneficiaries about the drug benefit through written materials such as a publication describing the drug benefit, internet sites, and other media. The user fee provisions establish the applicable aggregate contribution portions for PDP sponsors and MA organizations through two calculations.

Comment: Several commenters supported the extension of user fees to PDP sponsors in addition to MA plans. One commenter emphasized the need for Medicare to provide national beneficiary educational materials in accessible formats (including Braille and other languages commonly used by beneficiaries), as well as telecommunications equipment to support beneficiaries with hearing impairments, in order to meet the various needs of Medicare beneficiaries with disabilities. Another commenter urged us to focus beneficiary education efforts on helping beneficiaries make a choice, as opposed to simply describing the array of choices. This commenter also urged us not to overlook the M+C population in its outreach campaign.

Response: We have a long-standing tradition of making our beneficiary education materials accessible in a variety of formats to meet the needs of people with disabilities and special communications barriers. Beneficiary publications on a variety of topics are available in Braille, large print, and audiotape versions, in addition to conventional formats. We expect to continue these practices when educating beneficiaries about MMA topics. In addition, we are finalizing a partnership with the Social Security Administration (SSA) that will allow some of our educational products to be translated into 14 languages (other than English and Spanish) and reach a broader audience.

We are currently planning the development of a range of tools and strategies that will help beneficiaries make a choice that meets their needs. We agree that this action is an essential part of our education process, in addition to building general awareness and understanding. We will address the needs of multiple audiences through our outreach and education efforts, including those with M+C (MA) plans.

c. Definitions of Frequently Occurring Terms

The following definitions were discussed in the preamble to our proposed rule:

Full-benefit dual eligible beneficiary means an individual who meets the criteria established in § 423.772 (Subpart P), regarding coverage under both Part D and Medicaid.

Comment: One commenter asked us to clarify whether individuals eligible for Medicaid at the special income level for long term care qualify as full benefit dual eligibles for a full subsidy.

Response: Yes, all individuals who qualify for Medicaid, including expansion populations and persons eligible for Medicaid in long term care facilities under a State's special income standard which does not exceed 300 percent of the supplemental security income (SSI) payment standard will qualify as full benefit dual eligible beneficiaries eligible for a full subsidy.

Insurance risk means, for a participating pharmacy, risk of the type

commonly assumed only by insurers licensed by a State and does not include payment variations designed to reflect performance-based measures of activities within the control of the pharmacy, such as formulary compliance and generic drug substitutions, nor does it include elements potentially in the control of the pharmacy (for example, labor costs or productivity).

Comment: Several commenters supported our definition of 'insurance risk', including the exclusion of performance-based compensation as this is not commonly viewed as insurance risk.

Response: We will adopt the definition as proposed.

MA means Medicare Advantage, which refers to the program authorized under Part C of Title XVIII of the Act.

MA-PD plan means an MA plan that provides qualified prescription drug coverage.

Medicare prescription drug account means the account created within the Federal Supplementary Medical Insurance Trust Fund for purposes of Medicare Part D.

Part D eligible individual means an individual who is entitled to Medicare benefits under Part A or enrolled in Medicare Part B. For purposes of this part, enrolled under Part B means ''entitled to receive benefits'' under Part B.

Prescription drug plan or *PDP* means prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in § 423.272 and that is offered by a PDP sponsor that has a contract with CMS that meets the contract requirements under subpart K or in the case of fallback PDPs also under subpart Q.

PDP region means a prescription drug plan region as determined by CMS under § 423.112.

PDP sponsor means a nongovernmental entity that is certified under this part as meeting the requirements and standards of this part for that sponsor.

Comment: Several commenters noted that the terms PDP sponsor and MA organization offering an MA-PD plan were not consistently used in the proposed rule to represent distinct and mutually exclusive entities. As a result the proposed rule was not always clear regarding when requirements or options applied only to one or the other entity, or both.

Response: We acknowledge that the terminology regarding sponsors and plans was inconsistently applied. We have revised the language in the final rule accordingly and have also standardized the terms 'Part D plan' and 'Part D plan sponsor' when referring to all plans and sponsors in general. Consequently we have relocated these terms from subpart C to this subpart and clarified that references to ''Part D plans'' in the final rule refer to any or all of MA-PD plans, PDPs, PACE plans and cost plans. Likewise, the term ''Part D plan sponsor'' refers to MA organizations offering MA-PD plans, PDP sponsors, and sponsors of PACE plans and cost plans.

Comment: Several commenters asked that we be flexible in its definition of a non-governmental entity to allow either the creation of State-sponsored entities as PDPs or the selection of a preferred PDP entity for Medicaid dual eligible and SPAP populations.

Response: While we understand and support the goals of minimizing client confusion and facilitating continuity of care, we believe the requirements imposed by sections 1860D–41(13) and 1860D–23(b)(2) of the Act do not allow us to approve State-sponsored PDPs or the selection of preferred PDPs for State populations. We would note, however, that we believe we can waive the non-governmental requirement in section 1860D–41(23) of the Act under the employer waiver authority for States that seek to sponsor Part D plans on behalf of their employees. This is discussed in more detail in subpart J of this rule.

d. Financial Relationships between PDP Sponsors, Health Care Professionals and Pharmaceutical Manufacturers

The financial relationships that exist between or among PDP sponsors, health care professionals (including physicians and pharmacists), or pharmaceutical manufacturers may be subject to the anti-kickback statute and, if the relationship involves a physician, the physician self-referral statute. Nothing in this regulation should be construed as implying that financial relationships described in this final rule meet the requirements of the anti-kickback statute or physician self-referral statute or any other applicable Federal or State law or regulation. All such relationships must comply with applicable laws.

In addition to the provisions in these regulation, under section 6(a)(1) of the Inspector General Act of 1978, as amended, OIG has access to all records, reports, audits, reviews, documents, papers and other materials to which the Department has access that relate to programs and operations for which the Inspector General has responsibilities under the Inspector General Act. The provisions in these regulations do not limit the Office of the Inspector General's (OIG) authority to fulfill the Inspector General's responsibilities under Federal law.''

e. ERISA application and requirements

The rules contained in this rulemaking apply for purposes of Title I of the MMA and no inference should be drawn from anything in this rule regarding the applicability of title I of ERISA. In addition, nothing in this rulemaking should be construed as relieving a plan administrator or other fiduciary of obligations under title I of ERISA.

B. Eligibility and Enrollment

We outlined the eligibility and enrollment requirements for Part D plans in subpart B of the August 2004 proposed rule. We received over 100 comments on this subpart. Below we summarize the provisions of the proposed rule and our final rule and respond to public comments. (Please refer to the proposed rule (69 FR 46637) for a detailed discussion of our proposals.)

1. Eligibility for Part D (§ 423.30)

Section 101 of the MMA established section 1860D–1 of the Act, which includes the eligibility criteria an individual must meet in order to obtain prescription drug coverage and enroll in a Part D plan. Section 1860D–1(a)(3)(A) of the Act defines a ''Part D eligible individual'' as an individual who is entitled to Medicare benefits under Part A or enrolled in Part B. Further, in order to be eligible to enroll in a PDP plan, § 423.30(a) of the proposed rule provided that the individual must reside in the plan's service area, and cannot be enrolled in an MA plan, other than a Medicare savings account (MSA) plan or private fee-for-service (PFFS) plan that does not provide qualified prescription drug coverage. In addition, § 423.4 of the proposed rule provided the definition of service area, which describes that for purposes of eligibility to enroll to receive Part D benefits, certain access standards must be met, hence, making certain individuals ineligible to enroll.

Generally, a Part D eligible individual enrolled in an MA plan that does not provide qualified prescription drug coverage (that is, an MA plan) may not enroll in a PDP. There are, however, exceptions under sections 1860D–1(a)(1)(B)(iii) and (iv) of the Act for individuals who are enrolled in either an MA private fee-for-service plan (as defined in section 1859(b)(2) of the Act) that does not provide qualified prescription drug coverage or an MSA plan (as defined in section 1859(b)(3) of the Act). We provided for these

exceptions in § 423.30(b) of the proposed rule.

Except as provided above, in accordance with section 1860D–1(a)(1)(B)(i) of the Act, and as provided in § 423.30(c) of the proposed rule, a Part D eligible individual who is enrolled in an MA-PD plan must obtain prescription drug coverage through that plan. In order to enroll in an MA-PD plan, a Part D eligible individual must also meet the eligibility and enrollment requirements of the MA-PD plan as provided in § 422.50 through § 422.68 of the proposed rule establishing and regulating the MA program (CMS–4069–P) which was also published August 2004.

Except as otherwise provided below, the final rule adopts the eligibility criteria set forth in § 423.30 of the proposed rule.

Comment: Several commenters requested clarification of the definition of a Part D eligible individual. One commenter stated than a literal reading of the proposed definition appears to say that any individual who is eligible for Medicare but not enrolled could get the Part D benefit, and asks if an individual must enroll in Part A or Part B in order to be eligible for Part D. One commenter indicated that it was unclear how CMS would coordinate Part D eligibility with any retroactive eligibility determinations made by SSA.

Response: Section 1860D–1(a)(3)(A) of the Act defines a ''Part D eligible individual'' as ''an individual who is entitled to benefits under Part A or enrolled under Part B.''

In other context, we generally have interpreted the concept of ''entitled'' to benefits to mean that an individual has met all of the necessary requirements for a benefit (that is, is eligible for the benefit), and has actually applied for and been granted coverage. We believe for purposes of applying the definition of ''Part D eligible individual'' under section 1860D–1(a)(3) of the Act, we believe this interpretation of ''entitlement'' is the appropriate interpretation. Accordingly, we will deem an individual ''entitled'' to Part A, and thus a Part D eligible individual, if the individual is eligible for benefits under Part A, and has actually applied for and been granted coverage under Part A. On the other hand, under our Medicare Part B regulations at part 407, an individual is considered to be ''enrolled'' in Part B when he or she has applied for Part B coverage (or is deemed to have applied). Nevertheless, we do not believe this interpretation of ''enrolled'' in Part B is the correct interpretation of section 1860D–1(a)(3)(A) of the Act, and instead interpret ''enrolled under Part B'' to mean that the individual is entitled to receive benefits under Part B.

When establishing eligibility and enrollment rules for the MA program upon its inception, we adopted a similar interpretation of section 1851(a) (3) of the Act. Section 1851(a) (3) of the Act defined the term ''Medicare+Choice eligible individual'' to mean an individual who is entitled to benefits under part A ''and enrolled under part B.'' As we explained in our proposed rule for the Medicare+Choice program (see 63 FR 34979), we believe that the Congress intended that we provide an individual the opportunity to enroll in the Medicare+Choice program only if entitled to actually receive benefits under Part B in addition to Part A. As we explained, under some situations, an individual may apply for or be deemed to have applied for Part B before he or she is actually entitled to receive coverage. For example, if an individual applies for Part B coverage after he or she reaches age 65, the individual may not actually be entitled to Part B coverage under section 1837 of the Act until one or several months after the month of application and enrollment. If we had interpreted section 1851(a) (3) of the Act to permit individuals to enroll in a Medicare+Choice plan when an individual has only been enrolled in Part B, but is not yet entitled to Part B, he or she could be entitled to the benefits under a Medicare+Choice plan before actually being entitled to Medicare Part B coverage. In order to avoid such a result, we interpreted the language ''enrolled'' in Part B in section 1851(a) (3) of the Act to mean ''entitled'' to Part B.

We similarly will interpret section 1860D–1(a)(3)(A) of the Act as providing that an individuals is eligible for Part D only if the individual is entitled to receive benefits under Part A or Part B. Section 1860D–1(b)(1)(B) of the Act requires us to use rules similar to and coordinated with certain rules for enrollment that govern eligibility for the MA program. Hence, we believe that the Congress intended that we provide an individual the opportunity to enroll in part D only if entitled to actually receive benefits under Part B (or Part A); otherwise an individual would be entitled to receive coverage of Part D drugs under PDP before being entitled to receive benefits under original fee-for-service Medicare.

Our regulations at § 422.2 define an MA eligible individual as someone who meets the requirements of § 422.50, which outlines the various criteria that an individual must meet to be eligible to elect an MA plan, including: entitlement to Parts A and B, residency in a plan's service area, making an enrollment election and agreeing to abide by the rules of the MA plan. We intend to apply a parallel approach to the Part D program. We will amend § 423.4 to define a Part D eligible individual as an individual who meets the requirements at § 423.30, that is, the individual is entitled to Medicare benefits under Part A or enrolled in Part B and lives in the service area of the Part D plan. We clarify, however, that ''enrolled'' in Part B means that the individual not only has applied for and enrolled in Part B, but is also receiving coverage for Part B services, in accordance with part 407.

We have included in § 423.30 to be eligible to enroll in a Part D plan, the individual must also reside in the Part D plan's service area and not be enrolled in another Part D plan.

We have clarified Part D eligibility for those individuals for whom eligibility determinations for Medicare Part A or B have been made retroactively, which results in retroactive entitlement to these programs. The MA statute at section 1851(f) of the Act provides that initial elections shall take effect upon the date the individual becomes entitled to Part A or B, except as the Secretary may provide ''in order to prevent retroactive coverage.'' Under the MA program, an individual who has received a retroactive eligibility determination for Medicare Part A or B is not permitted to enroll in an MA plan retroactively. Again, using section 1860D–1(b)(1)(B) of the Act that directs us to establish rules similar to those in MA, we envision individuals enrolling in a Part D plan prospectively and have revised § 423.30 so that individuals who become entitled to Medicare Part A or Part B benefits for a retroactive effective date are deemed Part D eligible as of the month in which notice of Medicare Part A or Part B entitlement is provided.

Such revisions at § 423.4 and § 423.30 will clarify that an individual is eligible for Part D at the same time an individual is eligible to enroll in Part D.

Comment: Commenters requested clarification on the eligibility of incarcerated individuals. One commenter did not believe that we had the authority to create such exclusion. Another requested clarification of the ability of individuals released from incarceration on probation or parole to enroll in Part D.

Response: In the preamble of the proposed rule, we explained that individuals who are incarcerated likely do not have access to Part D services, as they cannot obtain their prescription drugs from network pharmacies, yet

technically the jail or prison may be located within the larger geographic area encompassing a PDP's service area. As a result, the individual would be subject to a late enrollment penalty for not enrolling in a Part D plan. As a result, we believe that it is appropriate to provide in § 423.4 that a PDP's service area would exclude areas in which incarcerated individuals reside (that is, a correctional facility) and as a result, incarcerated individuals would be ineligible to enroll in a PDP and we have revised the definition to clarify this point. Upon release from incarceration, such as for probation or parole, individuals will be considered eligible for Part D by living in a PDP service area, if they meet other Part D eligibility requirements.

Comment: One commenter suggested that we consider individuals who are residents of a State mental institution to be out of the service area and therefore ineligible for enrollment in a Part D plan.

Response: We would not consider individuals who are residing in a State mental institution to be out of the service area. Medicare beneficiaries residing in such institutions have access to Medicare benefits under Parts A and B and therefore would be entitled to enroll in a Part D plan. However, we do recognize that individuals in a State mental institution may be limited to the pharmacy network contracted with the facility. Therefore, we will provide such individuals a Special Enrollment Period (SEP) to enable them to join the appropriate Part D plan based upon their situation. We will clarify this in guidance following publication of this rule.

Comment: One commenter asked that we clarify § 423.30(c) in the final rule to indicate when an individual in an MA-PD plan can change plans.

Response: The provisions explaining the opportunities for individuals to make PDP enrollment choices are fully set forth at § 423.38 of the final rule. The requirements for MA plans are outlined under § 422.50 through § 422.80.

Comment: One commenter suggested that we permit beneficiaries enrolled in an MA plan to enroll in a PDP or disenroll from the MA plan and enroll in an MA-PD plan.

Response: Section 1860D–1(a)(1) of the Act specifically prohibits an MA plan enrollee from enrolling in a PDP except in the case of enrollees of a MA PFFS plan that does not provide qualified prescription drug coverage or enrollees of an MSA plan. All individuals, including enrollees of MA plans, can enroll in a Part D plan during the established enrollment periods, as described at § 423.38 of the final rule.

2. Enrollment Process (§ 423.32)

Section 1860D–1(b)(1) of the Act requires that we establish a process for the enrollment, disenrollment, termination, and change of enrollment of Part D eligible individuals in prescription drug plans. The statute further requires that this process use rules similar to, and coordinated with, the enrollment, disenrollment, termination, and change of enrollment rules for MA plans under certain provisions of section 1851 of the Act. Thus, we proposed, where possible, to adopt the MA enrollment requirements provided under § 422.50 through § 422.80.

Generally, a Part D eligible individual who wishes to make, change, or discontinue an enrollment during applicable enrollment periods must file an enrollment with the PDP directly. However, we will allow PDPs to use other enrollment mechanisms, as approved by us. In addition, § 423.32 of the final rule provides that beneficiaries will remain enrolled in their PDP without having to actively re-enroll in that PDP at the beginning of each calendar year. Except as otherwise provided below, the final rule adopts the enrollment rules set forth in § 423.34 of the proposed rule.

Comment: Several commenters submitted identical comments on various aspects of the coordination of the enrollment process reflected at both § 423.34(b) and § 423.42(a).

Response: Commenters provided similar comments about the enrollment process at § 423.34(b)(1) of the proposed rule and the coordination of enrollment and disenrollment process at § 423.42(a) of the proposed rule. After reviewing these comments, we recognized that these sections were duplicative and could cause confusion. To address this problem, we have reorganized the following subjects in subpart B into a more logical order: the enrollment process at § 423.32 (previously proposed § 423.34); auto-enrollment process for dual eligible individuals at § 423.34 (previously proposed § 423.34(d); the disenrollment process at § 423.36; the enrollment periods in § 423.38; and the effective dates at § 423.40. We believe that this will simplify and clarify these provisions.

Comment: Several commenters supported the inclusion of regulatory provisions that would permit enrollment through means other than the submission of signed, hard-copy enrollment forms in order to facilitate flexibility for future enrollments. These commenters supported allowing alternative mechanisms for enrollment, particularly electronic enrollments, to enable beneficiaries with access to computers to enroll or disenroll through secure websites established by PDP sponsors. Another commented that we should make the same enrollment mechanisms that are available to Medicare Advantage plans available to PDP sponsors. A few commenters requested clarification as to the ''other mechanisms'' referenced by us in the proposed rule, specifically what types of enrollment are envisioned and the populations to which these ''other mechanisms'' would be applied. One commenter recommended we allow electronic enrollments through a CMS-hosted web site, and that we develop a standard registration process to authenticate the enrollments. Another stated that processing applications via the Internet would require significant systems changes and that the regulation appeared to lack requirements necessary to process applications in such a manner.

Response: We were pleased by the general support for flexibility and creativity in this important part of the enrollment process, and we anticipate working in collaboration with all of our partners to develop enrollment processes that will be convenient, reliable and secure for all beneficiaries. We will adopt this provision as proposed at § 423.32(b), rather than specify or limit the types of alternative enrollment processes that may be used. We will continue to assess the technology available and provide additional operational guidance in the future, including specific systems requirements and other information necessary to implement these processes.

Comment: We received several comments requesting clarification of what parties are authorized to act on behalf of a beneficiary for enrollment purposes. One commenter noted that the regulation does not appear to recognize a beneficiary's ''authorized'' or ''personal'' representative who could be designated to make decisions for individuals and refers to the personal representative definition that we created in subpart P of the proposed rule. Another commenter was concerned that individuals in long-term care facilities do not have a designated surrogate decision maker in place to make such a decision and lack the cognitive capacity to select a PDP. While some commenters stated that we should allow an individual's personal representative to enroll a person into a PDP, others requested that we recognize specific representatives who could effectuate

such an enrollment within the regulatory text (for example, SPAP).

Response: In the regulation, we refer to a Part D eligible ''individual'' who wishes to enroll. An individual who has been appointed as the legal representative to execute such an enrollment on behalf of the beneficiary, in accord with State law, would constitute the ''individual'' for purposes of making the enrollment or disenrollment. As with the Medicare Advantage provisions, we will recognize State laws that authorize persons to effect an enrollment for Medicare beneficiaries. We will include more information on this clarification in future operational guidance.

Comment: Several commenters asked that we clarify that nothing would prevent a person or entity from assisting a beneficiary in completing and submitting his or her application to the PDP, as the MA program allows at § 422.60(c).

Response: We agree and have revised the regulatory language at § 423.32(b) to allow for such assistance, consistent with the MA regulations.

Comment: One commenter suggested that we set forth an appeals process for beneficiaries who are denied enrollment.

Response: Although we agree with the commenter that we should establish a procedure for beneficiaries to dispute enrollment denials, we do not believe that a formal appeals process is necessary. Instead, we intend to address beneficiary complaints regarding enrollment in a similar manner as we have done under the MA program. Under the MA program, individuals are advised through their notice of denial of enrollment that if they disagree with the decision to deny enrollment, they may contact the MA organization. We monitor MA organizations periodically to ensure that they are providing this notification. We also respond to specific inquiries from beneficiaries and investigate possible situations where MA organizations have failed to notify beneficiaries of the process or where an organization may have incorrectly denied a beneficiary's enrollment. If we discover a beneficiary was incorrectly denied enrollment we can require the MA organization to enroll that individual, as provided in our manual instructions. We believe our current process provides adequate remedies to beneficiaries and will therefore establish a similar process for PDPs. We decline to establish a separate appeals process for these denials at this time.

Comment: One commenter requested that we specify in the final rule that PDPs must provide written notice of enrollment decisions to each consumer.

Response: In § 423.32(d) we require PDPs to provide all individuals prompt notice of acceptance or denial of enrollment in the PDP in a format and manner specified by CMS. We will provide specific instructions on the format and manner of these required notices in operational guidance and intend to provide model language and materials for PDPs to use as well. Looking ahead, we believe that beneficiaries may want to receive documents (such as notices) in a variety of formats, rather than just in writing. To that end, we decline to require a specific format in regulation, thereby preserving the flexibility to foster innovation and creativity to satisfy beneficiary and industry expectations in the future.

Comment: One commenter suggested that individuals enrolled in PACE should remain enrolled in the PACE organization for purposes of Part D coverage effective January 1, 2006. Another commenter suggested a similar process be established for cost plans.

Response: Section 1860D–21(f) of the Act provides that a PACE plan may elect to provide qualified prescription drug coverage to its Part D eligible enrollees. Section 1860D–21(e) of the Act establishes a similar directive to cost-based HMO or competitive medical plan (CMP) plans. Discussion of the application of the Part D benefit to both PACE and cost-based HMO or CMP plans can be found under subpart T of the proposed rule. For PACE plans, we stated that PACE plans generally will be treated similar to MA local plans. Applying the appropriate MA rules from § 422.66, PACE enrollees will receive their Part D benefits through the PACE plan if the PACE plan has elected to provide such coverage. Beneficiaries who are enrolled in PACE plans that provide such coverage as of December 31, 2005 will remain enrolled in that plan on January 1, 2006. For cost-based HMO or CMP plans, we state that cost contracts may offer Part D coverage only to individuals also enrolled for Medicare in the cost contract. As a result of the provisions for PACE and cost-based HMO or CMP plans, we revised § 423.32(f) to provide that individuals who are in PACE or cost-based HMO or CMP plans that provide prescription drug coverage on December 31, 2005 will remain enrolled in that plan and be enrolled in the Part D benefit offered through that plan as of January 1, 2006.

3. Enroll Full-Benefit Dual Eligible Individuals (§ 423.34)

In the proposed rule, § 423.34(d) required that full benefit dual eligible individuals who fail to enroll in a PDP or MA-PD during their initial enrollment period would be automatically enrolled into an appropriate Part D plan, specifically a PDP with a Part D premium that does not exceed the low-income premium subsidy amount. When there is more than one available PDP in a region, full benefit dual eligible individuals would be auto-enrolled on a random basis.

All beneficiaries in an MA plan with any prescription drug coverage on December 31, 2005 will be deemed enrolled on January 1, 2006 in an MA-PD plan offered by the same MA organization in accordance with § 422.66(e)(2) and (e)(3) of Title II of the final regulation even if the monthly beneficiary premium exceeds the low-income premium subsidy amount. For full-benefit dual eligible individuals only, the proposed rule provided that those already enrolled in an MA plan without any prescription drug coverage would be auto-enrolled into an MA-PD plan offered by the same organization, and that has a monthly Part D premium that does not exceed the low-income premium subsidy amount. The proposed rule clarified that those auto-enrolled into a Part D plan may affirmatively decline Part D coverage or change Part D plans.

In a related area, § 423.36(c) of the proposed rule provided a SEP for full-benefit dual eligible individuals that permits them to change Part D plans at any time. Separately, there already exists a SEP for full-benefit dual eligible individuals to enroll in or disenroll from a Medicare Advantage plan at any time, and this will be expanded to include MA-PD plans. This SEP is provided in operational guidance (see section 30.4.4–5 of Chapter 2 of the Medicare Managed Care Manual), in accordance with section 1851(e)(4)(D) of the Act, which gives us the authority to provide Special Enrollment Periods for exceptional circumstances. Taken together, the PDP and MA-PD plan SEPs mean a full-benefit dual eligible individual may switch from Original Medicare and a PDP into an MA-PD plan and vice versa; from one PDP to another; and from one MA-PD plan to another MA-PD plan at any time.

We requested comment on two areas: whether we or States should conduct auto-enrollment, and how to address an inherent conflict in the statute, whereby the statute requires auto-enrollment of full-benefit dual eligible individuals

into a Part D plan with a premium that does not exceed the low-income premium subsidy amount, but does not speak to those instances in which an individual is enrolled in an MA organization whose premium for the available MA-PD plan(s) exceeds the low-income premium subsidy amount.

Except as otherwise provided below, the final rule adopts the enrollment rules for full-benefit dual eligible individuals set forth in § 423.34(d) of the propose rule.

Comment: Several commenters supported CMS performing the auto-enrollment function. They viewed it as the most appropriate entity because it is in the best position to randomly assign beneficiaries to MA-PD plans or PDPs in the region, and to establish links with each MA-PD plan or PDP in each region, thereby more efficiently auto-enrolling individuals. Some commenters also suggested that we consider adding an enrollment broker to the process for populations with special health care needs.

A number of other commenters recommended that States either be required or have the option to perform the auto-enrollment function, as they view the States as having more readily available data identifying dual eligible individuals and a vested interest in ensuring these individuals are enrolled in appropriate Part D plans. This option was also viewed as advancing care coordination and ensuring continuity of care. It was noted that these options also present a disincentive for States to maximize enrollment, since the phased-down State contribution payments are tied to the number of Part D eligible individuals enrolled in Part D plans. Commenters also acknowledged that, if we were to afford States the option of conducting the auto-enrollment function, we would have to develop its own systems for auto-enrollment in States that lack the capacity to develop such systems. Commenters supporting this option felt strongly that we should reimburse States for all of their costs related to enrollment activities they are required to perform.

Some commenters recommended that an independent third party coordinate the enrollment process. Those parties could include State and local officials and representatives of nonprofit organizations specializing in care for seniors. One also suggested that the contracted agent would need to be compliant with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy rule and should have no financial incentives regarding a full-benefit dual eligible individual's assignment beyond the contract between it and CMS.

Response: We agree with those who commented that we, or a contractor on our behalf, should perform the auto-enrollment function because we can better ensure consistent, timely implementation. In addition, we would not have to develop and implement a separate administrative structure to oversee auto-enrollment being performed by some or all of the States. Finally, it would likely be more cost effective for us to have a single entity perform auto-enrollment, rather than pay 51 separate entities. For these reasons, we will modify the final regulation to specify that we will conduct the auto-enrollment process.

At this time, we do not envision contracting with an enrollment broker to provide more intensive choice counseling for beneficiaries subject to auto-enrollment. Because the statute makes us ultimately responsible for the auto-enrollment process, we will, at least initially, conduct it ourselves. Instead of hiring a new third party, we believe it would be more effective to partner with existing stakeholders to conduct broad-based outreach and education; provide clear and comprehensive information to beneficiaries; and refer individuals to either the 1–800–MEDICARE toll-free line or to Part D plans for additional information. However, if we decide in the future to contract with an independent enrollment broker, we agree with the commenter that the entity would need to be free of conflicts of interest and comply with HIPAA privacy rules. We note that any delegation to a third party would make the third party a business associate of ours for HIPAA purposes, since the entity would be performing a function on behalf of us.

Comment: Many commenters recommended that we define ''random'' to include auto-enrollment based on beneficiaries' particular drug needs, pharmacy affiliation, or on their classification as a special needs population. Many commenters expressed concerns about how random assignment will impact individuals who are on drug regimens on which they have been previously stabilized. They were concerned that these individuals would be auto-enrolled in a ''low-cost'' plan that may not cover the drugs they need. Without direct access to the coverage they need, this population would have no real choice but to switch medications, even though changing medications can be difficult and lead to adverse health outcomes, reactions, and so on.

Several other commenters expressed similar concerns about individuals who reside in long-term care facilities. In addition, some long-term care facilities require residents to use a pharmacy selected and contracted by the facility. One commenter requested that we define ''random,'' specifically detail how we envision the random process would work, and seek further public comment.

Response: We share the commenters' concerns with ensuring access to necessary prescription drug coverage for vulnerable populations. For ensuring continued access to existing drugs prescribed for an individual, please refer to comments on § 423.120(b) of the final regulation. For ensuring access to long-term care facilities' contracted pharmacies, please refer to comments on § 423.120(a) of the final regulation.

The systems challenges associated with anything other than a random process would be significant, and possibly result in inappropriate assignment or delayed implementation. For example, we have drug utilization data for Medicaid beneficiaries, but there is a time lag in receiving those data. Furthermore, we do not currently have access to information about the pharmacies that contract with long-term care facilities. Finally, we realize that pharmacy affiliation and particular drug needs are only two of the variables that impact a beneficiary's choice of a Part D plan. For example, a beneficiary may also consider cost-sharing, formulary structure, customer service and, in the case of MA-PD plans, whether she or he would want to receive all of her or his Medicare benefits from one organization.

Given these data limitations, and the many and varied reasons for choosing a Part D plan, we do not believe we are in a position to make a judgment about what is best for individual beneficiaries, and decline to change the proposed regulations. However, we will make every effort to ensure that beneficiaries and community organizations receive enough information in time for them to determine the appropriate plan for the beneficiary. The SEP provided for full-benefit dual eligible individuals in the statute and in our final rule at § 423.38(c)(4) also ensures that they can change plans to better accommodate their pharmaceutical needs and pharmacy affiliations.

Comment: One commenter recommended that we establish a bid process whereby PDPs with an expected enrollment by full-benefit dual eligible individuals that is higher than the proportion in the total Medicare eligible population in the relevant PDP region

automatically qualify for inclusion in the auto-enrollment process. The commenter further recommended that, if such a plan has a monthly beneficiary premium above the low-income premium subsidy amount, we should permit a ''waiver'' based on a subsidy or payment of that excess premium by CMS or another entity in order to reduce the premium to an amount equal to or below the low-income premium subsidy amount.

Response: Those plans available for purposes of auto-enrollment are ones that have premiums at or below the low-income premium subsidy amount. This includes fallback plans in areas where they exist. It is our intent to implement the Part D program and adhere to the statute as closely as possible, assuming tenable options are available to do so. In the case of PDPs that serve a disproportionate share of full-benefit dual eligible individuals, and whose premium exceeds the low-income premium subsidy amount, we believe there are tenable options, that is, other PDPs with premiums at or below the low-income premium subsidy amount. However, we note that risk-adjustment should correct for the higher costs incurred by plans with larger proportions of full-benefit dual eligible individuals.

Comment: A few commenters recommended that we not limit the Part D plans available for auto-enrollment to just those plans with premiums below the low-income premium subsidy amount, as this limits full-benefit dual eligible individuals to the ''lowest cost'' plans, which may offer a less generous benefit. The commenters suggested that, regardless of whether these individuals enroll on their own or are auto-enrolled, they should be permitted to enroll in any plan and not be charged any additional premium. At a minimum, a beneficiary's medical provider could attest that a higher premium plan will better meet his or her medical needs and therefore be allowed to enroll in a higher premium plan without the added premium.

Response: We appreciate the commenters' concern that full-benefit dual eligible individuals be able to enroll in the plan best suited for them, not just ''low cost'' plans. We note that a full-benefit dual eligible individual is free to enroll in any Part D plan during the initial enrollment period or annual coordinated election period.

For auto-enrollment, however, section 1860D–1(b)(1)(C) of the Act only permit us to, auto-enroll full-benefit dual eligible individuals into those plans with premiums at or below the low-income premium subsidy amount. In addition, those full-benefit dual eligible individuals randomly auto-enrolled in a particular plan may still choose another plan pursuant to a special enrollment period.

In addition, as we do not have the authority under section 1860D–14(a)(1)(A) of the Act to increase the low-income premium subsidy amount (as defined under section 1860D–14(b)(2)(B) of the Act), full-benefit dual eligible individuals who elect to enroll in a plan with a premium exceeding the low-income premium subsidy amount must pay the difference in premium. We are also precluded under sections 1860D–13(a)(1)(F) and 1854(c) of the Act from requiring or even permitting Part D plans from waiving any premium in excess of the premium subsidy amount, including allowing MA-PD plans to use rebate dollars to reduce the premium only for this portion of their enrolled population.

Comment: We received numerous comments related to the timing of the auto-enrollment process for full-benefit dual eligible individuals. Commenters identified the possibility of a gap in coverage for some of those individuals if the auto-enrollment did not occur until the close of the Initial Enrollment Period on May 15, 2006, since Medicaid coverage of Part D drugs ends several months earlier, on January 1, 2006. They proposed that we require auto-enrollment of these individuals to be completed prior to Medicaid coverage ending on December 31, 2005. Some commenters recommended that the process be completed as early as November 15, 2005, and one commenter suggested starting the 2005 Initial Enrollment Period for full-benefit dual eligible individuals prior to November 15, 2005. Another commenter recommended that auto-enrollment precede Part D eligibility by 6 months, and that Medicaid coverage of Part D drugs be continued until auto-enrollment can be done.

Response: We did not intend to implement a process that would create a gap in drug coverage for full-benefit dual eligible individuals. We do not believe that the Congress intended for such a gap to occur. Therefore, we will modify the final rule so that the auto-enrollment of these individuals will begin as soon as Part D plans with premiums at or below the low-income premium subsidy amount are known prior to January 1, 2006. We will also modify the final rule to provide that those full-benefit Medicaid individuals who become eligible for Medicare after January 1, 2006, will be enrolled as soon as their Medicare Part D eligibility is determined. For the suggestion to start the 2005 Initial Enrollment Period for full-benefit dual eligible individuals before November 15, 2005, we are precluded from doing so, as this date is explicitly identified in section 1860D–1(b)(2)(A) of the Act as the date upon which enrollment in Part D may commence.

Comment: Many other commenters suggested that we delay implementation of the Part D program for full-benefit dual eligible individuals by at least five or six months, and some recommended a year's delay, although the commenters recognized that such a delay would require a legislative change. The commenters' concern was based on the limited time to transition drug coverage for these full-benefit dual eligible individuals from Medicaid to Medicare. The commenters expressed concern about the feasibility of identifying, educating, and enrolling the population of full-benefit dual eligible individuals in time for a smooth transition of drug coverage. Some commenters highlighted the need to ensure adequate time for physicians and patients to navigate administrative barriers and change medications to comply with formularies. One commenter suggested Medicare beneficiaries who currently participate in Medicaid buy-in programs (that is, qualified Medicare beneficiaries (QMB), special low-income beneficiaries (SLMB), and qualified individuals (QI1)) be permitted to keep Medicaid drug coverage after Part D starts.

A few commenters recommended that, assuming Part D coverage begins for full-benefit dual eligible individuals on January 1, 2006, Medicaid coverage of Part D drugs be extended past December 31, 2005, and continued until such time as full-benefit dual eligible individuals are enrolled in Part D.

One commenter recommended that full-benefit dual eligible individuals who are American Indians or Alaska Natives (AI/AN) be exempt from Part D and continue to be eligible for Medicaid drug coverage after January 1, 2006. The commenter argued that this would prevent loss of revenues to pharmacies operated by Indian Health Services (IHS), Tribal Clinics, and Urban Indian Clinics, who may receive lower payments from Part D plans than they currently receive from Medicaid, and eliminate barriers for this population.

Response: As the commenters correctly point out, a delay in the implementation of the Part D program, including auto-enrollment for full-benefit dual eligible individuals would require a change to the statute. Similarly, extending Medicaid coverage of prescription drugs covered under Part D would also require a legislative

change. Absent such changes, we cannot delay implementation, extend Medicaid coverage of Part D drugs, nor can we exclude full-benefit dual eligible individuals who are AI/AN, or participants in Medicaid buy-in programs from Part D.

Comment: A couple of commenters requested clarification about the circumstances under which a beneficiary may affirmatively decline participation in Part D. They expressed concern that individuals with diminished mental faculties may not fully understand the impact of their decision, and that States would likely bear additional costs associated with full-benefit dual eligible individuals whose health deteriorates due to their failure to take necessary medications. One commenter urged that States be able to obtain FFP to provide prescription drug coverage in these instances. Another commenter asserted that permitting a full-benefit dual eligible individual to affirmatively decline enrollment in Part D contradicts numerous statutory and regulatory provisions that require this population's enrollment in Part D. One commenter urged CMS to make disenrollment contingent upon selection of another Part D plan to ensure there is no lapse in coverage. Finally, one commenter suggested expanding the ability to affirmatively decline enrollment in Part D to Medicare beneficiaries who are not auto-enrolled.

Response: The Congress specified that prescription drug coverage under this program is voluntary, and section 1860D–1(b)(1)(C) of the Act specifically stipulates that auto-enrollment does not prevent a full-benefit dual eligible individual from declining or changing such enrollment. Absent any legislative change, we cannot intervene with an individual's right to decline coverage. Nor can we adopt the suggestion to permit Federal financial participation (FFP) for State Medicaid agencies that choose to provide drug coverage for full-benefit dual eligible individuals who affirmatively decline auto-enrollment. Section 1935(d)(1) of the Act stipulates that no FFP is available for any Part D drugs or cost-sharing for Part D drugs for full-benefit dual eligible individuals who are eligible for Part D, even if they are not enrolled in a Part D plan. However, we will be making every effort to ensure that beneficiaries and community organizations have sufficient information to assist individuals in making the most appropriate choices about participating in Part D.

Concerning the comment that we should make disenrollment from a Part D plan contingent upon enrolling in another Part D plan to prevent a coverage gap for full-benefit dual eligibles, we decline to do so in regulation, but will continue to work develop strategies to prevent a coverage gap in this instance.

We decline to expand the ability to affirmatively decline Part D enrollment to individuals who are not auto-enrolled or for whom we do not facilitate enrollment into a Part D plan. This population is comprised of those who are not deemed or determined eligible for the low-income subsidy. If these individuals do not want Part D coverage, they can simply choose not to enroll in a Part D plan.

Comment: One commenter suggested that there should be flexibility for CMS to change the plan into which a beneficiary has been auto-enrolled should the plan no longer meet the needs of the enrollee.

Response: We agree that it would be prudent to retain the flexibility to enroll an individual in subsequent years in a different plan from the one into which we originally enrolled the individual, and have modified the final rule to provide for this. We note that this will require an exception to the maintenance of enrollment provision in § 423.32(e), so we have modified the final rule to provide for one.

We envision this may only be necessary in certain limited circumstances. For example, we may want to consider doing this if the plan's premium in a subsequent year exceeded the low-income premium subsidy amount. We will ensure that beneficiaries are fully notified, and have the option to remain in their original plan. We will examine the need for this as the program evolves and provide operational guidance should we implement it.

Comment: A number of commenters responded to our request in the preamble for solutions to an inherent conflict in the statute. In this instance, the statute requires auto-enrollment of full-benefit dual eligible individuals into a Part D plan with a premium at or below the low-income premium subsidy amount. Section 423.34(d) of the proposed rule stipulated that those in an MA-only plan would be auto-enrolled into an MA-PD plan in the same organization that has a premium that does not exceed the low-income premium subsidy amount. However, there may be instances in which an individual is enrolled in an MA-only plan offered by an MA organization, and all the MA-PD plans in that organizations have premiums that exceed the low-income premium subsidy amount.

We note that most MA enrollees will be deemed to be enrolled into an MA-PD plan in accordance with § 422.66(e)(2) and (e)(3). However, deeming does not address those who elect an MA-only plan that does not offer any drug coverage in 2005, nor qualified prescription drug coverage thereafter.

Several commenters supported auto-enrolling these full-benefit dual eligible individuals into an MA-PD plan offered by the same organization with the lowest Part D premium, even if it was higher than the low-income premium subsidy amount. This would provide seamless continuation of their Medicare benefits through the same organization. Commenters noted that these individuals retain the right to decline Part D coverage, and have a SEP that permits them to change PDPs or MA-PD plans at any time.

One commenter noted that excluding full-benefit duals from auto-enrollment in an MA-PD plan with a premium higher than the low-income premium subsidy amount would give those MA plans an unfair advantage by removing from their risk pool full-benefit dual eligible individuals, who tend to have higher drug utilization.

Response: We agree with commenters' concerns about ensuring continuity of care through the same MA organization, if possible. However, as we discussed in the preamble to the proposed regulation, there is an inherent statutory conflict that would seem to preclude using auto-enrollment authority to accomplish this. Section 1860D–1(b)(1)(C) of the Act directs the Secretary to auto-enroll full-benefit dual eligible individuals who do not enroll in a PDP or MA-PD plan on a random basis into a PDP with a premium at or below the low-income premium subsidy amount; it does not identify an MA-PD plan as an entity into which an individual could be auto-enrolled.

General principles of statutory interpretation requires us to reconcile two seemingly conflicting statutory provisions rather than allowing one provision to effectively nullify the other provision. We had proposed to resolve this by interpreting the reference to ''prescription drug plans'' in section 1860D–1(b)(1)(C) of the Act as including both PDPs and MA-PD plans, thereby allowing auto-enrollment of an MA full-benefit dual eligible individual into an MA-PD offered by the same organization offering his or her MA plan if the premium for such plan did not exceed the low-income premium subsidy amount.

Upon further consideration, we believe there continue to be legal concerns as to whether we have the authority to auto-enroll full-benefit dual eligible individuals into an MA-PD plan. Rather than rely on auto-enrollment authority under section 1860D–1(b)(1)(C) of the Act to ensure continuity of Part D coverage for full-benefit dual eligible individuals enrolled in MA-only plans, we instead will rely on our general authority to establish enrollment procedures under section 1860D–1(b)(1)(A) of the Act to establish a facilitated enrollment process that substantially fulfills the intent of ensuring no prescription drug coverage gap for these individuals.

We will therefore facilitate enrollment into Part D for full-benefit dual eligible individuals enrolled in a MA plan that does not offer qualified prescription drug coverage by assigning them to an MA-PD plan with the lowest premium offered by the same MA organization, even if the plan's MA monthly prescription drug beneficiary premium exceeds the low income premium subsidy amount. We will inform them in advance of this assignment. If the beneficiary fails to affirmatively elect an alternative plan or declines enrollment in Part D, she or he will be enrolled into the plan into which she or he has been assigned. In this instance, a beneficiary's silence would be deemed consent to the enrollment choice we are making on their behalf. We note that the right to affirmatively decline in § 423.34(e), on affirmatively declining Part D enrollment, and the Special Enrollment Period in § 423.38(c)(4), apply equally to all full-benefit dual eligibles, whether they are auto-enrolled or have their enrollment facilitated.

In the case of a full-benefit dual eligible for whom we facilitate enrollment into an MA-PD plan with a premium higher than the low-income premium subsidy amount, we acknowledge that this creates a new financial obligation for the enrollee to pay the balance of the monthly MA monthly prescription drug beneficiary premium not covered by the low-income premium subsidy amount. However, this option best preserves informed enrollee choice, is consistent with statutory intent, respects the beneficiary's initial choice to enroll in an MA plan, and ensures continuity of prescription drug coverage. These individuals will have information about other plan choices available and retain their right to a Special Enrollment Period to choose another plan at any time, as provided by section 1861D–1(b)(3) of the Act for PDPs, and section 1851(e)(4)(D) of the Act and section 30.4.4–5 of Chapter 2 of the Medicare Managed Care Manual for MA-PD plans.

Comment: A few commenters generally supported auto-enrolling full-benefit dual eligible individuals into an MA-PD plan, but urged CMS to find a solution that would ensure no additional costs were imposed on beneficiaries. Some of the commenters that supported auto-enrollment into the MA-PD plan with the lowest Part D premium provided suggestions as to how to minimize the financial impact on beneficiaries. A few suggested that for those who are institutionalized, the excess premium should be considered an incurred medical expense and deducted from their monthly share of cost to the facility. For non-institutionalized beneficiaries, in States with State Pharmacy Assistance Programs (SPAPs), SPAPs should be allowed to pay the balance. For full-benefit dual eligible individuals who are medically needy, the balance should be considered an incurred medical expense contributing towards their spend-down. Otherwise, individuals should be counseled about the premium discrepancy and about the right to disenroll from an MA plan and enroll in Original Medicare with a PDP.

Response: We appreciate these suggestions for minimizing the financial impact on beneficiaries. We intend to highlight the impact of our facilitating enrollment into an MA-PD plan with a premium higher than the low-income premium subsidy amount to these beneficiaries and advise them of their ability to switch plans. We note that under Medicaid, whatever portion of the premium the individual pays would be an incurred medical expense, including any portion of the premium that is paid by the SPAP. Since incurred medical expenses are deducted from income when determining patient liability for an institutionalized individual, and are deducted from income for medically needy spend-down purposes, the commenter's suggestions correctly characterize how Medicaid would treat any premium difference paid by the individual. The commenter is also correct in noting that SPAPs will be allowed to pay the balance for their enrollees, but we note this is an option for all enrollees of an SPAP, not just non-institutionalized enrollees. Since these options are already permitted under the regulatory language in the proposed rule, we will not modify the regulation further to specify them.

Comment: One commenter suggested that we permit MA-PD plans to waive the portion of their premium above the low-income premium subsidy amount. The commenter suggested that explicit authorization by CMS would be a contract amendment, not an inducement to a beneficiary to enroll, which would ensure that the waiver of the excess premium does not implicate the Federal anti-kickback rules or be considered disparate treatment.

Response: We appreciate the intent of the commenter's suggestion. However, we are precluded from permitting MA-PD plans to waive a portion of the Part D premium for a subset of their enrollees by section 1854(c) of the Act, which requires uniform premiums for all enrollees of an MA plan.

Comment: A few commenters urged CMS to prohibit auto-enrollment of full-benefit dual eligible individuals into MA-PD plans. Instead, these MA enrollees should be auto-enrolled into a PDP for their Part D benefit. The commenters note that these beneficiaries could always switch to an MA-PD plan.

Response: Section 1861D–1(a)(1)(B)(ii) of the Act specifies that, with limited exceptions, individuals in an MA plan may not also enroll in a PDP. The only exceptions are those enrolled in a MSA plan, or in a MA private fee-for-service plan or cost-based HMO or CMP that does not offer qualified prescription drug coverage, may enroll in a PDP. Thus, auto-enrolling these individuals into a PDP would require us to also disenroll them from their MA plan, which could be inconsistent with our current MA requirements § 422.66(e), which provide that an individual who elects an MA plan is considered to have continued to have made that election until he or she voluntarily changes that election, or the plan is discontinued or no longer serves the service area.

Comment: Finally, one commenter suggested that if no MA-PD plan is available, or if the Part D premium of the available MA-PD plan exceeds the low-income premium subsidy amount, CMS should auto-enroll these beneficiaries into another organization's MA-PD plan whose premium does not exceed the low-income premium subsidy amount.

Response: For the concern that no MA-PD plan would be available, we note that section 1860D–21(a) of the Act requires all MA organizations to offer at least one MA-PD plan.

Involuntarily disenrolling the individual from his or her MA plan, and auto-enrolling him or her into another MA-PD plan offered by another MA organization, is inconsistent with MA requirements at § 422.66(e) described above.

Comment: A few commenters urged expanding Part D auto-enrollment in the

case of full-benefit dual eligible individuals who are in an organization's Medicaid managed care product, but currently receive Part A and B benefits through Original Medicare. Specifically, the commenters recommended that these beneficiaries be auto-enrolled into an MA-PD plan that is offered under common ownership and control of the organization offering the Medicaid managed care plan.

Response: Please refer to responses to comments on § 422.66(d) in Title II of the final regulation for a discussion on this issue.

Comment: A few commenters proposed that, where a full-benefit dual eligible individual in Original Medicare will be auto-enrolled into a PDP that is affiliated with an MA Special Needs Plan, CMS auto-enroll the individual into the MA Special Needs Plan for their Part A and B benefits, as a way to promote better overall coordination of care. To preserve the beneficiary choice, the commenter suggested the regulation provide an opportunity for the individual to ''opt out'' within some specified period of time (for example, 90 days).

Response: The statute prohibits beneficiaries who have Part D coverage through a PDP from getting their Medicare A and B coverage through an MA-only plan. As a result, we decline to make the suggested change.

Comment: One commenter asked CMS to clarify that, if a full-benefit dual eligible individual is auto-enrolled into an MA-PD plan with a premium higher than the low-income premium subsidy amount, that the State Medicaid program would not be obliged to pay the balance on behalf of the beneficiary.

Response: We confirm that the State Medicaid agency has no obligation to pay any Part D premium in excess of the low-income premium subsidy amount. Further, section 1905(a) of the Act, which provides Federal medical assistance for Medicare cost-sharing (as defined in section 1905(p)(3)(A) of the Act), does not include Part D premiums.

Comment: A few commenters recommended that we consider establishing a process for automatically enrolling or at least facilitating the enrollment into Part D plans all individuals deemed eligible for the full low-income subsidy. In effect, this would expand auto-enrollment to individuals in Medicare Savings Programs. These are individuals for whom State Medicaid agencies pay for Medicare cost sharing, but who are not eligible for comprehensive Medicaid benefits and thus are not considered full-benefit dual eligible individuals. They include QMB, SLMB, and QI1. To the extent that we accept this recommendation, the commenters suggested we also broaden the SEP provision to cover any full subsidy eligible individual who is auto-enrolled in a Part D Plan.

A few commenters advocated expanding auto-enrollment even further to all those who receive the low-income subsidy. This would include not only those deemed eligible for the subsidy, but also those who have to apply and be determined eligible. Auto-enrollment would ensure that these individuals are not subject to a late enrollment penalty.

Response: We agree that there are compelling reasons to promote Part D enrollment of all individuals deemed or determined eligible for the low-income subsidy. These individuals typically are less healthy and often face barriers to care. Effective medication management and prescription drug coverage can lead to reduced inpatient hospital expenditures, making it more cost-effective to provide drug coverage.

Facilitating enrollment into Part D would promote access to drug coverage for these beneficiaries by ensuring that they have drug coverage starting in 2006, while also preserving the voluntary nature of enrollment in Part D. Doing so would also ensure that beneficiaries with limited means would not be liable for a late enrollment penalty for failing to enroll in Part D when first eligible.

We intend to pursue many steps to assist beneficiaries, particularly low-income beneficiaries, in taking advantage of the new Medicare drug coverage. Such steps could include facilitating enrollment into Part D for those beneficiaries. We will provide details in operational guidance to be issued shortly after the publication of the final regulation, including details on the population for whom we will facilitate enrollment. By facilitating enrollment, we mean giving beneficiaries an opportunity to choose a Part D plan first; if they do not choose, we would notify them that we intend to facilitate their enrollment into a specific plan prospectively. If the beneficiary fails to affirmatively elect an alternative plan or declines enrollment in Part D by a given date, she or he would be enrolled into the plan into which she or he has been assigned. In this instance, a beneficiary's silence would be deemed consent to the enrollment choice we are making on their behalf. If we facilitate enrollment in this manner, we would likely follow rules for assigning beneficiaries to Part D plans similar to those for the auto-enrollment and facilitated enrollment process for full-benefit dual eligibles: MA enrollees would be enrolled into an MA-PD plan with the lowest Part D premium; Original Medicare beneficiaries would be enrolled in a PDP with a Part D premium that does not exceed the low-income premium subsidy amount, and, if there is more than one such PDP available, the individual would be randomly enrolled into one of the plans available. In establishing a process for this facilitated enrollment, we would rely upon discretion afforded the Secretary under section 1860D–1(b)(1)(A) of the Act to establish enrollment processes for Part D eligible individuals. Similarly, we would extend some of the same protections afforded the full-benefit dual eligible population who are auto-enrolled to those whose enrollment we facilitate. These protections would include a Special Enrollment Period, the right to affirmatively decline Part D enrollment, and where possible, facilitating enrollment into plans whose premiums do not exceed the low-income premium subsidy amount.

Comment: One commenter suggested expanding auto-enrollment to PACE enrollees, that is, CMS auto-enroll them into their PACE organization for purposes of Part D coverage effective January 1, 2006, unless the PACE enrollee makes another enrollment choice. PACE organizations would provide their enrollees an opportunity to opt out of enrollment in Part D (and, as a result, out of the PACE organization).

Response: We agree that PACE enrollees should not be required to take any additional steps to obtain their Part D benefit through their PACE organization. Individuals who enroll in a PACE organization elect to get all their Medicaid (if eligible for Medicaid) and Medicare benefits through the PACE organization. As noted in response to a similar comment on § 423.32 of the final regulation, we will modify the final regulation to deem individuals enrolled in a PACE organization as of December 31, 2005 to be enrolled with that PACE organization for their Part D benefit as of January 1, 2006. This precludes the need to expand auto-enrollment to PACE enrollees, so we decline to make that change.

Comment: One commenter noted that no provision was made for auto-enrollment of full-benefit dual eligible individuals enrolled in Medicare cost-based HMO or CMPs. The commenter suggested that for full-benefit dual eligible individuals enrolled in a cost-based HMO or CMP, CMS auto-enroll these individuals into the cost-based HMO or CMP for Part D benefits if the cost-based HMO or CMP offers Part D,

even if the Part D premium is higher than the low-income premium subsidy amount. If the cost-based HMO or CMP does not offer Part D benefits, the commenter recommends auto-enrolling the beneficiary into a PDP.

Response: We agree that we should ensure that full-benefit dual eligible individuals, and potentially others eligible for the low-income subsidy who are enrollees of a cost-based HMO or CMP obtain Part D benefits. As noted in response to a similar comment on § 423.32 of the final regulation, we will modify the final regulation to specify that all individuals enrolled in a cost-based HMO or CMP that offers any prescription drug coverage as of December 31, 2005, will be deemed to be enrolled in the cost-based HMO or CMP for Part D benefits as of January 1, 2006, if the cost-based HMO or CMP opts to provide Part D benefits, and regardless of whether the Part D premium exceeds the low-income subsidy amount.

We believe the same legal concerns noted above for auto-enrolling full-benefit dual eligible individuals into MA-PD plans arise for auto-enrolling them into a cost plan HMO or CMP. As a result, we decline to expand auto-enrollment a suggested by this commenter. Instead, we will use a facilitated enrollment process discussed above to accomplish substantially the same end. We will facilitate the enrollment of full-benefit dual eligible individuals enrolled in a cost plan HMO or CMP that offers Part D benefits and who fail to enroll in a Part D plan into the Part D benefits offered by their cost plan HMO or CMP. If the cost plan HMO or CMP does not offer Part D benefits, the individual will be enrolled in a PDP. We may similarly facilitate the enrollment of other cost plan enrollees eligible for the low-income subsidy who fail to elect a Part D plan into the Part D benefit offered by their cost plans.

Comment: One commenter requested clarification as to whether auto-enrollment into a PDP will only occur for Medicare beneficiaries who receive comprehensive health care benefits (full hospital and physician services) from both Medicare and Medicaid, or whether auto-enrollment also applies to Medicare beneficiaries that receive pharmacy-only benefits through Medicaid.

Response: The final rule will limit auto-enrollment to only those dual eligible individuals who receive comprehensive health benefits from both Medicare and Medicaid. As noted above, we may facilitate enrollment of all others deemed or determined eligible for the low-income subsidy into Part D plans. To the extent that a Medicare beneficiary with pharmacy-only Medicaid benefits is in the population whose enrollment we facilitate, we would facilitate that individual's enrollment into a Part D plan.

Comment: One commenter recommended that we explore auto-enrolling residents of long term care facilities who are not full-benefit dual eligible individuals, and permitting these beneficiaries to disenroll or choose another Part D plan. The commenter was especially concerned about residents who lack the cognitive capacity to select a PDP and who do not have a designated surrogate decision-maker in place.

Response: Generally, enrollment in Part D is voluntary. Section 1860D–1(b)(1)(C) of the Act provides for auto-enrollment of full-benefit dual eligible individuals. As noted above, we may facilitate enrollment of others deemed or otherwise determined eligible for the low-income subsidy into Part D plans. To the extent that a resident of a long term care facility is in the population whose enrollment we facilitate, we would facilitate that individual's enrollment into a Part D plan.

Since the Act limits auto-enrollment to full-benefit dual eligible individuals, we decline to auto-enroll long-term care residents who do not receive the low-income subsidy. While we acknowledge that access to prescription drug coverage is critical for this population, we believe they generally have the resources and support to make timely enrollment decisions. We will, however, continue to explore options regarding enrollment for all individuals in long-term care facilities.

Comment: A number of commenters urged CMS to permit SPAPs to act as authorized representatives and enroll some or all of the beneficiaries they serve into the SPAP's preferred PDP. These beneficiaries should be permitted to decline enrollment in the SPAP's preferred PDP or to change to another Part D plan.

Response: With regard to the issue of authorized representatives, we defer to State law, as discussed in response to comments on § 423.32. However, it is important to note that SPAPs that act as the authorized representative for the individual must also comply with the nondiscrimination provisions at § 423.464(e). Please see responses to related comments in subpart J.

Comment: One commenter noted that it appears that a full-benefit dual eligible individual cannot enroll in an MA-PD plan if the individual is not already an MA enrollee. The commenter urged that MA-PD plans that bid at or below the low-income premium subsidy amount should be an enrollment option for all full-benefit dual eligible individuals.

Response: During the Part D initial enrollment period that starts November 15, 2005, full-benefit dual eligible individuals who are in Original Medicare are free to change to an MA-PD plan. Further, we have established in our operational guidance a Special Enrollment Period (SEP) that permits full-benefit dual eligible individuals to enroll in and disenroll from an MA plan at any time, and will extend this SEP to MA-PD plans. This will ensure that MA-PD plans are an option for all full-benefit dual eligible individuals.

As indicated previously, any individual enrolled in a PACE organization as of December 31, 2005 will be deemed to be enrolled with that organization for their Part D benefit as of January 1, 2006.

The chart below provides a summary of the enrollment rules for all beneficiaries, including those with and without the low-income subsidy, in accordance with § 423.32, § 423.34, and § 422.66.

Population	Enrollment Rules
General Medicare Population	(1) A beneficiary who chooses to enroll a Part D plan must do so as follows: Original Medicare ➜ Original Medicare with separate PDP MA Plan without drug coverage ➜ MA-PD plan Medical Savings Account (MSA) Plan ➜ MSA with separate PDP PFFS with Part D ➜ PFFS with Part D Private Fee-For-Service Plan (PFFS) without Part D ➜ PFFS with separate PDP Cost Plan with Part D ➜ Cost plan Part D or cost plan with separate PDP

Population	Enrollment Rules
	Cost Plan without Part D ➜ Cost Plan with separate PDP (2) A beneficiary enrolled in an entity that offers any drug coverage in 2005, CMS deems him or her enrolled as follows* : MA Plan ➜ MA-PD Plan Cost Plan ➜ Cost Plan with Part D PACE Organization ➜ PACE Organization (3) On a case-by-case basis, CMS may allow an MA organization to process ''seamless'' enrollments into the organization's MA-PD plan if individuals are enrolled in a health plan offered by that MA organization that includes prescription drug coverage upon their entitlement to Medicare.
Full-Benefit Dual Eligible Beneficiaries	(1) A beneficiary who chooses to enroll in a Part D Plan follows the same rules as above; otherwise CMS auto-enrolls or facilitates enrollment for him or her as follows: Original Medicare ➜ PDP MSA Plan ➜ PDP PFFS Plan without Part D ➜ PDP Cost Plan with Part D ➜ Cost plan with Part D Cost Plan without Part D ➜ PDP MA-Only Plan ➜ MA-PD Plan (2) For a beneficiary enrolled in an entity that offers any drug coverage in 2005, CMS deems him or her enrolled as follows: MA Plan ➜ MA-PD Plan Cost Plan ➜ Cost Plan with Part D PACE Organization ➜ PACE Organization (3) On a case-by-case basis, CMS may allow an MA organization to process ''seamless'' enrollments into the organization's MA-PD plan if individuals are enrolled in a health plan offered by that MA organization that includes prescription drug coverage upon their entitlement to Medicare.
* Those in an MA Plan without any drug coverage in 2005 will not be deemed into an MA-PD plan, but instead must actively choose one if they want Part D benefits. ** We may facilitate enrollment for other beneficiaries eligible for the low income subsidy; if so, we would likely follow these same rules. For additional detail, please see discussion on: § 423.32—Beneficiary's choice § 422.66(d)(5)—''Seamless'' enrollment on case-by-case basis § 422.66(e)(2)–(3)—Deemed enrollment in 2005 § 423.34—Auto-enrollment and facilitated enrollment	

4. Disenrollment process (§ 423.36)

Section 1860D–1(b)(1)(A) of the Act authorizes us to establish a process to allow disenrollment from prescription drug plans. In the proposed rule, we outlined the rules for a Part D eligible individual who wishes to change or discontinue an enrollment during applicable enrollment periods, including filing a disenrollment with the PDP directly or enrolling in another PDP.

While we initially envision a paper disenrollment process, we retain the flexibility for other secure and convenient mechanisms that we may approve in the future. Any such mechanism will be available at the option of each PDP sponsor. We believe it is important to clarify that, as other mechanisms are approved and implemented, we will require all PDPs offer a minimum standard process, which at this time would be a paper process, along with any optional election mechanism available to prospective enrollees and plan members in conjunction with the paper process. In the future, as technology evolves, another process may be a more appropriate minimum standard. Except as provided below, the final rule adopts the disenrollment rules set forth at § 423.42 of the proposed rule.

Comment: One commenter asked that we clarify whether an enrollment in a different PDP would automatically disenroll the beneficiary from his or her previous PDP effective the first day of enrollment in a new PDP and asked who is responsible for that notification.

Response: We envision creating a process similar to that created for the MA program, under which an individual who is eligible to enroll in another PDP will automatically be disenrolled from the previous PDP upon enrollment in the new PDP. The PDP to which the individual submits an enrollment is required to provide a notice of acceptance or denial, as provided in § 423.32(d). We will notify the previous PDP of the disenrollment and that PDP will inform the individual that he or she has been disenrolled. As for the specifics of the notice requirements, we will issue guidance to PDPs following the publication of this rule.

Comment: One commenter requested that we clarify in the regulations that proper beneficiary protections for retroactive disenrollments are in place for beneficiary requests that are made but not properly acted upon.

Response: We will treat an individual's request for disenrollment that was made but not properly acted upon as if the disenrollment had properly occurred. We will provide guidance to PDPs as to how to handle the processing of such requests, including proper notification to the beneficiary.

Comment: One commenter asked CMS to address the issue for those retirees who enroll in both a PDP and the employer sponsored plan due to their confusion over the variety of new coverage options. The commenter indicated that this not only results in duplicative coverage and unnecessary premium costs. In addition, the commenter was concerned because

many retirees may not be aware that a consequence of enrolling in Part D may be the discontinuation of their employer group benefits, often permanently prevented from ever being able to rejoin the group once he or she enrolls in other coverage, such as Part D. One commenter requested that we allow for retroactive disenrollment from Part D and refund of the Part D premiums for these retirees who enrolled by mistake into a PDP.

Response: We recognize that during the initial enrollment period that some retirees may be confused about how their employer-based coverage may coordinate with Part D coverage. While we feel that establishing a retroactive disenrollment process specifically for this reason would generally be inappropriate, we can establish a process in which we would work with employer group sponsors, PDPs and MA-PDs to educate beneficiaries prior to open enrollment and at the time of enrollment. In addition, we intend to establish a process for the PDPs and MA-PDs to verify an enrollment request for those individuals who have been identified to CMS as having been claimed by an employer group sponsor to receive the employer based subsidy. We will also include information in beneficiary education and enrollment materials targeted to those individuals who already have other prescription drug coverage to provide assistance in determining whether enrollment in Part D would be appropriate for that individual. We will issue operational guidance on this process shortly following publication of the final rule.

5. Part D Enrollment Periods (§ 423.38)

In the proposed rule, as directed by the MMA, we established three coverage enrollment periods: (1) the initial enrollment period (IEP); (2) the annual coordinated election period (AEP); and (3) SEPs. Generally, in accordance with section 1860D–1(b)(2)(B) of the Act, the IEP for Part D is the same as the initial enrollment period established for Part B. In addition, as part of the implementation of the Part D program, and in accordance with section 1860D–1(b)(2)(A) of the Act, we have established an initial enrollment period for Part D from November 15, 2005 until May 15, 2006 for those individuals who are already eligible to enroll in a Part D plan as of November 15, 2005.

In accordance with section 1860D–1(b)(1)(B)(iii) of the Act, the AEP for Part D is concurrent with the annual coordinated election period for the MA program under section 1851(e)(3) of the Act. It is during this annual period in which all PDP plans must open enrollment to Medicare beneficiaries. For coverage beginning in 2006, the annual coordinated election period begins on November 15, 2005 and ends on May 15, 2006. As a result, the initial enrollment period for individuals who are eligible to enroll in a Part D plan as of November 15, 2005 and the annual coordinated election period will run concurrently during this time frame. In accordance with section 1851(e)(3)(B)(iv) of the Act, § 423.36(b)(2) of our proposed rule provides that, for 2007 and subsequent years, the annual coordinated election period will be November 15 through December 31 for coverage beginning on January 1 of the following year.

The MMA also establishes SEPs. SEPs allow an individual to disenroll from one PDP and enroll in another PDP. Similarly, the SEP rules that will apply for individuals in an MA-PD plan will be provided under § 422.62(b). We will include in regulation those SEPs that have been specifically named in the statute. Those SEPs established for exceptional circumstances for PDPs and MA-PDs, as authorized by section 1860D–1(b)(3)(C) of the Act and section 1851(e)(4) for MA-PDs of the Act, respectively, will be provided in our manual instructions. The final rule adopts the enrollment periods as proposed.

Comment: We received several comments regarding SEPs. Several commenters supported the SEPs for exceptional conditions we proposed to provide through manual guidance. Specifically, these include certain SEPs already established in the MA program for circumstances where a plan terminates its contract or the individual changes his or her permanent residence. These commenters also supported an SEP to enroll in a PDP for individuals disenrolling from an MA-PD plan during the MA Open Enrollment Period, and for institutionalized individuals. Other commenters suggested we establish various other SEPs, including the following:

- A subsidy-eligible individual who leaves private prescription drug coverage for any reason, including his or her inability to pay;
- A change in a person's health status that makes a current plan choice no longer suitable to his or her needs;
- Individuals eligible for the low-income subsidy, other than full benefit dual eligible individuals;
- If there are substantial changes to the plan's formulary;
- Individuals with ''life-threatening situations;''
- Individuals whose situations are pharmacologically complex;
- All individuals for the first 18 months of the program as it may be a confusing time;
- All beneficiaries leaving MA plans throughout the year so that they can enroll in a PDP;
- Medicare-eligible retirees whose plan sponsor changes their retiree drug coverage so that it no longer meets the criteria for creditable coverage;
- Individuals enrolled in, or desiring to enroll in PACE, as the PACE program has continuous enrollment and disenrollment; and
- Full benefit dual eligibles at any time, including every time a PDP changes its plan in a way that directly effects these individuals, such as removing a drug from its formulary, changing the co-payment tier for a drug, or denying their appeal concerning a non-formulary drug or an effort to change the co-payment tier.

Response: We appreciate this feedback. As previously mentioned, we have historically included in regulation only those SEPs that have been specifically named in the statute. The SEPs explicitly provided for in statute include an SEP for full-benefit dual eligible individuals, individuals who permanently change their residence so that they no longer reside in their PDP's service area, and individuals enrolled in a PDP whose contract is terminated.

We will issue guidance regarding the above SEPs and other additional SEPs that we choose to establish following publication of the regulation. We intend to establish in this guidance an SEP for those individuals eligible for the low-income subsidy whose enrollment into a Part D plan will be facilitated, individuals in long-term care facilities, individuals enrolled in, or desiring to enroll, in PACE and individuals enrolled in employer group health plans. However, we decline to establish SEPs for other reasons included in the comments described above, because we do not view these circumstances as exceptional. However, we retain the right to establish additional SEPs in the future and will do so in our operational guidance. Furthermore, we may establish SEPs on a case-by-case basis, where warranted by an immediate exceptional circumstance, such as an individual with a life-threatening condition or illness. For the commenter's request that we provide an SEP for the first 18 months of the program, we do not believe that such an SEP is warranted in the circumstances. First, we are committed to ensuring all beneficiaries have adequate information to make informed choices about participating in the Part D program. Second, the statute provides for an

extended AEP and provides a concurrent IEP at the beginning of this program. These extended enrollment periods, in conjunction with the planned education and information campaigns, will provide all beneficiaries with adequate time and information to make an enrollment decision. Therefore, we do not believe that such an SEP is warranted.

Comment: A few commenters recommended that we should provide a SEP to permit those individuals who will receive the low-income subsidy under subpart P but who are not full-benefit dual eligible individuals to change to a plan of their choosing.

Response: We strongly agree that we should permit those individuals who are enrolled or whose enrollment is facilitated by CMS the opportunity to change to a plan of their choosing. Since we are generally limiting in regulation those SEPs specified in statute, we will provide for this SEP in operational guidance.

Comment: One commenter recommends that we change the provision of an SEP for the involuntary loss of creditable coverage to include individuals who lose such coverage due to failure to pay premiums. The commenter believes the provision as proposed is too restrictive and should be modified.

Response: Section 1860D–1(b)(3)(A)(iii) of the Act is clear that disenrollments for failure to pay premiums will be considered a voluntary disenrollment action. We therefore do not believe it appropriate to treat this disenrollment as an exceptional circumstance justifying an SEP.

Comment: One commenter asked if MA-PD plans are required to participate in the AEP.

Response: The MA enrollment periods are discussed in the MA regulations at § 422.62. The AEP applies to both PDP and MA-PD plans.

Comment: One commenter requested clarification of how many times an individual may use an SEP to enroll in a PDP and encouraged CMS to limit the number of times an SEP may be used to enroll.

Response: The duration and applicability of an SEP is specific to each SEP and may vary from one specific circumstance to another. For example, an SEP in the MA program for individuals affected by a plan termination is specific to the circumstances surrounding that specific action and limited in duration. Other SEPs apply more generally to individuals, for example, full-benefit dual eligible dual individuals. We will provide detailed guidance concerning each SEP following the publication of this rule.

Comment: One commenter requested clarification of proposed § 423.36(c)(3) regarding the SEP for individuals whose enrollment or nonenrollment in Part D is caused by an error of a Federal employee or any person authorized by the Federal government to act on its behalf. The commenter suggests that we include all sponsors of Part D plans as ''persons authorized by the Federal Government to act on its behalf.''

Response: We have interpreted this statutorily required SEP to apply to Federal government employees, staff, and contractors hired by the Federal government to perform government duties. We would not consider Part D plans to be performing enrollment functions as a subcontractor on the behalf of CMS; rather, Part D plans must perform certain enrollment functions as requirement of their direct contract with CMS. While it is unlikely that an SEP would be necessary, we will correct any errors made by the plan and not hold the individual liable for the plan's mistake. Thus, we may allow an SEP in individual situations, if appropriate.

Comment: One commenter asked if SEP enrollment in a PDP could be retroactive in order to maintain continuity of care.

Response: An SEP enrollment in a PDP will generally be prospective. We establish the effective date for SEPs and can accommodate unusual circumstances on a case-by-case basis.

Comment: One commenter suggested that we establish an SEP with no late enrollment penalty if a Medigap issuer or other entity fails to provide adequate or accurate notice of whether such coverage is creditable.

Response: Section 423.38(c)(2) of the final rule establishes an SEP for all individuals who are not adequately informed when their creditable prescription drug coverage is lost or changes so that it is no longer creditable prescription drug coverage or that the individual never had such creditable coverage. We believe that these provisions adequately protect an individual who does not receive the required notice from a Medigap issuer or other entity. Regarding the late enrollment penalty, the provision of an SEP is not directly related to, nor does it have a direct effect upon, the imposition of applicable late enrollment penalties. The late enrollment penalty is discussed in more detail at § 423.46 and its relationship to creditable prescription drug coverage is discussed at § 423.56. Specifically, at § 423.56(g) of the final rule we describe the available remedy for an individual who was not adequately informed that their prescription drug coverage is not creditable.

Comment: One commenter believed the enrollment process should ensure that residents of a long-term care facility are enrolled in a PDP that provides access to the pharmacy located in the long-term care facility.

Response: We understand the issue raised by the commenter. Individuals who are in a long-term care facility will be given an SEP to ensure they can choose the PDP that is appropriate for their situation. This will be clarified in guidance following publication of this rule.

6. Effective Dates of Coverage and Change of Coverage (§ 423.40)

Section 1860D–1(b)(1)(B)(iv) of the Act directs us to apply the effective date requirements provided under the MA program at section 1851(f) of the Act. As described above, the three enrollment periods provided under Part D are the IEP, the AEP, and SEP. In the proposed rule, we established the following effective dates for these enrollment periods:

a. Initial Enrollment Period

In accordance with section 1851(f)(1) of the Act, as incorporated into Part D under section 1860D–1(b)(1)(B)(iv) of the Act, an enrollment made during the initial enrollment period will generally be effective the first day of the calendar month following the month in which the individual enrolled in Part D. An enrollment made prior to the month of entitlement to Part A or enrollment in Part B is effective the first day of the month the individual is entitled to Part A or enrolled in Part B. Since the Part D provisions are not effective until January 1, 2006, we clarified that in no case may enrollment in Part D be effective prior to this date. We also clarified that initial enrollments made between November 15 and December 31, 2005 will be effective January 1, 2006. An enrollment made during or after the month of entitlement to Part A or enrollment in Part B is effective the first day of the calendar month following the month in which the enrollment in Part D is made.

b. Annual Coordinated Election Period

In accordance with section 1851(f)(3) of the Act, as incorporated into Part D under section 1860D–1(b)(1)(B)(iv) of the Act, an enrollment made during the annual coordinated election period is effective as of the first day of the following calendar year, that is, January 1st. One exception to this rule occurs during 2006 in the special annual coordinated election period in 2006, in

which elections made between January 1, 2006 though May 15, 2006 will be effective the first day of the calendar month following the month in which the enrollment in Part D is made.

c. Special Enrollment Period

A SEP is effective in a manner that we determine to ensure continuity of health benefits coverage.

The final rule adopts the effective dates as proposed.

Comment: Three commenters suggested that we specify a distinct effective date for the SEPs in the final rule (as described in § 423.38(c) of the proposed rule) to ensure adequate consumer protection. Two commenters suggested adding: ''but no later than the first day of the second calendar month following the month of the request for the enrollment change'' to the end of this section. The third commenter suggested we add: ''changes made before the 20th of the month are effective the first day of the second month following'' the change.

Response: We have outlined the specific effective date requirements for SEPs granted in the MA program in operational guidance and will follow the same process for the Part D program. We believe that in so doing, we retain our ability to react quickly to changes or unforeseen circumstances.

7. Involuntary Disenrollment by the PDP (§ 423.44)

Section 1860D–1(b)(1)(B) of the Act generally directs us to use disenrollment rules similar to those established under section 1851 of the Act. The proposed disenrollment provisions for PDPs were outlined in § 423.44 of our proposed rule, including the basis for disenrollment—both optional and required—and guidance for notice requirements.

Specifically, we proposed at § 423.44(b)(2) that a PDP is required to disenroll an individual who dies, no longer resides in the PDP's service area, loses entitlement or enrollment to Medicare benefits under Part A and is no longer enrolled in Part B, or knowingly misrepresents to the PDP that he or she has received or expects to receive reimbursement for covered Part D drugs through other third-party coverage. The proposed rule also required a PDP to disenroll an individual if the PDP sponsor's contract is terminating.

In addition to providing requirements for mandatory disenrollments, we also provided under § 423.44(d) of our proposed rule that PDPs may disenroll individuals who do not pay monthly premiums or whose behavior is disruptive, consistent with section 1860D–1(b)(1)(B)(v) of the Act.

As with the MA program, PDP sponsors will be required in the final rule to provide proper notice to the beneficiary, as outlined at proposed § 423.44(c), and afford him or her due process in accordance with the procedures outlined in our operational instructions prior to disenrolling the individual. For example, a PDP that wishes to disenroll a beneficiary for disruptive behavior must receive our prior approval and demonstrate to our satisfaction that it has made a good faith effort to resolve the issue prior to requesting the disenrollment. We will review these requests on a case-by-case basis, taking into account all of the facts and circumstances of a particular case, prior to making its decision. PDP sponsors must apply their policies for optional disenrollment for failure to pay premiums and disruptive behavior consistently among individuals enrolled in their plans, unless we permit otherwise, and must do so consistent with applicable laws regarding discrimination on the basis of disability.

Except as otherwise provided below, the final rule adopts the involuntary disenrollment rules set forth in § 423.44 of the proposed rule.

Comment: Several commenters urged CMS to establish a process for individuals to appeal disenrollment decisions. Several commenters believed that individuals should have access to an outside independent review process, especially if these individuals are disenrolled without an SEP. Another commenter stated that involuntary disenrollments must be heavily scrutinized and an appeal right be available on an expedited basis.

Response: As we discussed under a previous comment regarding appeals for enrollment denials, we do not believe that a formal appeals process is necessary. Instead, we intend to address beneficiary complaints regarding disenrollment in a manner addressed under the MA program. Under the MA program, MA plans are required to follow a specific process, which includes notice of potential disenrollment if the individual does not address situation. We currently provide assistance to MA organizations to handle beneficiary inquiries and complaints regarding disenrollment through staff assigned to each MA organization. We envision a similar process being established under the PDP program.

Comment: Several commenters pointed out an error in the numbering of the regulatory text for disruptive behavior at proposed § 423.44(b)(1).

Response: We concur and have corrected the numbering.

Comment: A commenter requested that we clearly define how long an individual would need to reside out of the PDP service area before we would consider the individual as no longer residing in the service area. One commenter did not think that it was reasonable to apply a 6-month time limit to PDPs; PDPs should not be required to disenroll individuals if the PDP can provide individuals access to benefits out of the service area through a PDP in another region, or the PDP's network of pharmacies in other regions, or mail order pharmacies. One commenter believed the decision should be left to the individual as to when he or she has permanently moved out of the PDP service area. A few commenters did not believe that a person's residency should be a factor in a plan's basis for disenrollment. Another commenter stated that a PDP should not be required to disenroll an individual if the PDP meets licensure requirements in the State where the individual has moved and the PDP has a national pharmacy network in place. Another commenter suggested that PDP maintain members if they are an established sponsor and meet certain network adequacy requirements in the region in which the beneficiary moves.

Response: We agree that disenrolling a beneficiary after being temporarily out of the service area for a certain period of time may be less appropriate for PDPs than in the MA program. The MMA directs us to use rules similar to (and coordinated with) the MA residency requirements at section 1851(b)(1)(A) of the Act, which provides that an individual may elect an MA plan only if the plan serves the geographic area in which the individual resides, except as the Secretary may otherwise provide. However, the MA regulation at § 422.74(d)(4) generally provides for disenrollment of an individual if that individual is out of the service area, even temporarily, for 6 months, unless the MA organization offers visitor or traveler benefits that provide for benefits while outside of the service area. We believe that the nature of the prescription drug benefit and the ability for many individuals to access the benefit through mail order or chain drug stores provide greater flexibility in accessing the prescription drug benefit while temporarily being out of the PDP's service area. However, while an individual has greater flexibility to be temporarily outside the service area and still access the PDP benefit, we maintain that the individual must maintain his or her permanent residence within the

PDP's service area to be a member of the PDP. If the PDP learns of a change in the individual's permanent address, the PDP would initiate the disenrollment process. It is, however, an individual's responsibility to notify the PDP if the individual permanently moves out of the service area. We will provide further guidance to PDPs on the process of disenrollment when an individual permanently moves out of the service area following publication of this rule.

Comment: One commenter asked how a PDP will learn of loss of entitlement to Part A or Part B.

Response: We will notify the PDPs of the loss of Part A or B benefits. We will issue detailed operational guidance for PDPs prior to 2006.

Comment: A few commenters requested that we further clarify the provision that an individual who ''knowingly misrepresents to the PDP that he or she has received or expects to receive reimbursement for covered Part D drugs through other third party coverage'' (that is, whether his or her costs are expected to be reimbursed through insurance or otherwise, such as a group health plan) must be disenrolled. These commenters also asked how ''knowingly'' will be determined and what entity would be responsible for investigating such a case. One commenter indicated that a beneficiary should not be penalized for unintended errors or inadvertent omissions, and that many beneficiaries will be confused at the outset about their PDP coverage and how it may coordinate with other insurance.

Response: Section 1860D–2(b)(4)(D)(ii) of the Act provides that ''material misrepresentation'' by an individual as to whether his or her costs are expected to be reimbursed through insurance or otherwise (through a group health plan or other third party payment arrangement) shall be grounds for termination by the PDP. Since section 1860D–2(b)(4)(D)(ii) of the Act also provides that a PDP sponsor may periodically ask Part D eligible individuals about such reimbursement, the statute establishes a penalty for an individual who ''materially'' misrepresents such information. This provision is not intended to disenroll individuals who simply make an error, but instead apply to those individuals who knowingly provide such false information. We would be responsible for reviewing and issuing the final decision on such a case. We plan to issue further guidance on this for PDPs prior to 2006.

Comment: We received several comments on the disenrollment for nonpayment of premium provision, both supporting and opposing inclusion of such a process. Several commenters requested that we clarify the details of disenrollment for nonpayment of premium, including what we view as ''reasonable efforts'' to collect the premium. Several commenters recommended providing a minimum grace period for repayment before permitting disenrollment. One commenter requested that we waive payment of past premiums for full-benefit dual eligible individuals or low-income subsidy individuals. Some commenters believe that it is inappropriate for us to disenroll any individual from Part D for nonpayment of premium. One commenter stated that individuals enrolled in a PACE plan should not be subject to the disenrollment requirements under § 423.44 of the proposed rule.

Response: Section 1860D–1(b)(1)(B)(v) of the Act specifically directs us to apply rules to PDPs that are similar to (and coordinated with) the MA provisions at section 1851(g) of the Act related to disenrollment for nonpayment of premium. While some commenters objected to disenrollment by the PDP on those grounds, we note that such disenrollment is at the PDP sponsor's option and PDP sponsors therefore have the ability to apply this rule to their plan enrollees. In contrast, under Part B, individuals who fail to pay their Part B supplementary medical insurance premiums must be disenrolled from Part B. While we do not review and approve such disenrollments, we maintain that if a PDP chooses the option to disenroll a beneficiary for nonpayment of the premium, we would require that the PDP apply this policy consistently, as we direct, amongst all its members and could not ''waive'' the premium for a certain group of its members. As indicated in the preamble of subpart T of this rule, we will issue additional guidelines that will include a comprehensive listing of Part D waivers applicable to PACE organizations. However, we agree that PACE organizations should not be subject to the disenrollment requirements of § 423.44 as they are duplicative of the PACE disenrollment requirements associated with § 460.164 of the PACE regulation.

Comment: Several commenters recommended that we permit plans to deny reinstatement following disenrollment for failure to pay premiums unless the enrollee pays the outstanding amount that is due. Other commenters stated that PDP should not be required, under any circumstance, to re-enroll individuals who are disenrolled for nonpayment of the premium.

Response: We have provided in the final regulation at § 423.44(d)(1)(iii) that a PDP may decline future enrollment to individuals who have been disenrolled for failure to pay premiums until past due premiums are paid to the PDP. However, we would not allow a PDP to prohibit an individual from enrolling in its plan if the individual has paid all past due premiums to the PDP.

Comment: We received a substantial number of comments on proposed § 423.44(d)(2) to allow PDP sponsors to disenroll individuals who exhibit disruptive behavior.

One commenter supported the definition established in the proposed rule, while several commenters supported the due process safeguards afforded by our approval of disenrollment requests. Two commenters suggested that we provide guidance to PDP sponsors on the symptoms of mental illness and dementia and other personality disorders to distinguish between disruptive behavior and behavior resulting from a medical condition. There were other commenters who asked us to clearly define the terms and requirements for disenrolling a beneficiary for disruptive behavior. These commenters recommended that we include in the final rule such requirements as documentation of a PDP sponsor's effort to provide a reasonable accommodation for individuals with disabilities and sufficient notice of the sponsor's actions during the course of the disenrollment process.

Numerous commenters expressed concern that the proposed definition of disruptive behavior does not adequately protect individuals whose behavior is induced by disability, mental illness, cognitive impairment, or certain prescribed drugs and who rely on prescription drug therapy to stabilize their behavior. Some commenters recommended that we prohibit PDP sponsors from disenrolling certain populations for disruptive behavior, explaining that State Medicaid programs will not be able to claim Federal matching funds for prescription drugs spending on behalf of full-benefit dual eligibles who have been disenrolled by a PDP sponsor. Other commenters suggested that we develop more stringent criteria for PDP sponsors requesting to disenroll a full-benefit dual eligible individual. Several commenters stated that, in cases where an individual is unstable, disruptive behavior could be related to unsuccessful attempts to find the proper medication. There were also a number

of commenters who asserted that we lacked statutory authority to permit PDPs sponsors to disenroll individuals for disruptive behavior. Two commenters questioned the appropriateness of applying a policy of involuntary disenrollment for disruptive behavior to PDPs. One commenter suggested that we allow an individual who is disruptive to designate an authorized representative to access services on his or her behalf.

Response: In the final rule, we aim to strike a balance between allowing PDP sponsors to disenroll individuals who exhibit disruptive behavior and creating adequate protections for individuals who face involuntary disenrollment from a PDP. In accordance with the statute (at section 1860D–1(b)(1)(B)(v) of the Act), we must establish a process that is similar to and coordinated with the process under the MA program that permits MA organizations to disenroll an individual for disruptive behavior. At the same time, we recognize the impact of such a disenrollment on an individual's ability to access prescription drug coverage under the Medicare program, and the need for adequate safeguards for individuals whose disruptive behavior is due to mental illness or a medical condition. Continuity of care for these individuals is essential, especially if they are taking prescription medications that can minimize the debilitating impact of their illness and restore their functioning.

Therefore, in revising our proposed definition of disruptive behavior in § 423.44(d)(2)(i) of the final rule, we focus on behavior that substantially impairs a PDP sponsor's ability to arrange or provide care for the individual or other plan members. Behavior that is related to the use of medical services or compliance (or non-compliance) with medical advice is not disruptive behavior.

We also agree with commenters that arranging or providing care for individuals with mental illness, cognitive impairments such as Alzheimer's disease or other dementias, and medical conditions and treatments that may cause disruptive behavior warrant special consideration, and therefore revise § 423.44(d)(2)(v) to require PDP sponsors to provide a reasonable accommodation to individuals in such exceptional circumstances that we deem necessary. Such accommodation is intended to ensure that the individual can maintain Medicare prescription drug coverage and may include granting an individual a SEP to choose another plan, or requiring the plan to continue the individual's enrollment until the Annual Coordinated Election Period, when the individual has an opportunity to enroll in another plan. We will determine the type of accommodation necessary after a case-by-case review of the needs of all parties involved. This review will be conducted as part of our review and approval of the PDP sponsor's request, as required in regulations at § 423.44(d)(2)(v), and will include expert opinion from our staff with appropriate clinical or medical background.

In addition, we recognize that circumstances may arise where an individual is only able to obtain qualified prescription drug coverage from a fallback prescription drug plan operating in his or her service area. In such instances, allowing a fallback entity to disenroll an individual may create substantial barriers to accessing prescription medications under the Medicare program. Section 1860D–11(g)(4)(B) of the Act grants us authority to establish additional requirements specifically for fallback prescription plans. Under this authority, we reserve the right at § 423.44(d)(2)(vi) to deny a fallback prescription drug plan's request to disenroll an individual for disruptive behavior.

In the proposed rule, we established procedures that PDP sponsors must follow prior to requesting to disenroll a member for disruptive behavior. Under proposed § 423.44(c), a PDP sponsor must give an individual timely notice of the disenrollment, which includes an explanation of the individual's right to a hearing under the PDP's grievance procedures. We further required at proposed § 423.44(d)(2)(ii) a sponsor to make a serious effort to resolve the problems presented by the individual, including the use or attempted use of the organization's grievance procedures. Finally, we established under proposed § 423.44(d)(2)(iii) that a PDP sponsor must document the individual's behavior, its own efforts to resolve the problem, and the use or attempted use of its internal grievance procedures. We are preserving all of these requirements in the final rule at § 423.44(c) and § 423.44(d)(2)(iii) and (d)(2)(iv).

We believe that the final rule achieves the twin goals of permitting involuntary disenrollment based on an individual's disruptive behavior, while also establishing necessary protections for individuals who are subject to our disenrollment rules.

Comment: Several commenters contended that allowing a PDP sponsor to disenroll an individual for disruptive behavior provides an opportunity for PDP sponsors to discriminate against individuals with disabilities, mental illness, Alzheimer's, and other cognitive conditions.

Response: We appreciate the commenters concern about the need to ensure that individuals are not discriminated against on the basis of their disability. However, the Part D plans are not provided the authority to make the decision on such a disenrollment. In addition to establishing safeguards in the final rule for individuals with special needs by requiring PDP sponsors to make reasonable accommodations where we deem necessary, it is CMS who reviews the request for disenrollment and makes the decision to approve or deny the request. In our review, we will include our staff with the appropriate clinical or medical expertise review the case before a final decision is made.

Comment: Several commenters noted that the proposed rule denies protection to individuals who comply with medical advice by trying an on-formulary drug instead of the drug originally prescribed and subsequently experience an adverse reaction that triggers the disruptive behavior. A few commenters asked us to prohibit PDPs from disenrolling an individual because of his or her refusal or inability to adhere to a treatment plan developed by the PDP or other health care professionals associated with the plan.

Response: We agree with the commenters and clarify in the final rule at § 423.44(d)(2)(i) that an individual cannot be considered disruptive if such behavior is related to the use of medical services or compliance (or non-compliance) with medical advice or treatment.

Comment: Two commenters supported the flexibility afforded PDP sponsors by our allowing PDP sponsors to limit re-enrollment for individuals who are disenrolled for disruptive behavior, and one of these commenters specifically asked us to establish criteria for re-enrolling an individual such as a minimum waiting period and a commitment by the individual to discontinue such behavior. On the other hand, there were many commenters who opposed the ability of a PDP sponsor to decline re-enrollment of an individual. These commenters contended that prohibiting an individual from re-enrolling in a PDP for a specified period could cause undue harm and lapses in coverage, especially if the individual is not able to enroll in another PDP. One commenter requested that we specify the maximum period of time that a PDP sponsor may prohibit re-enrollment of

an individual who has been disenrolled for disruptive behavior.

Response: In the proposed rule, we enabled PDP sponsors to request, at their option, the ability to decline future enrollment by an individual who had been disenrolled for disruptive behavior. While we retain this option for PDPs in the final rule, we require these sponsors to request future conditions on re-enrollment as part of their disenrollment request. At the same time, we reserve the right in accordance with § 423.44(d)(2)(v) to review each request on a case-by-case basis. In the review process, we will give due consideration to exceptional circumstances that may warrant reasonable accommodations in addition to the appropriateness of conditions on re-enrollment.

Comment: There were several commenters who objected to the expedited disenrollment process. The commenters noted that the expedited process lacks even the minimal standards and requirements that are in place to protect beneficiaries in these circumstances.

Response: It is our intent to ensure that all individuals facing involuntary disenrollment for disruptive behavior have sufficient opportunity, as provided by the notice requirements, to change their behavior or grieve the PDP sponsor's decision to request involuntary disenrollment from us. We have therefore removed this provision from the final regulation.

Comment: One commenter asked us to clarify whether a full-benefit dual eligible individual who is disenrolled for disruptive behavior is entitled to a SEP.

Response: In accordance with the § 423.38(c)(4), a full-benefit dual eligible individual as defined under section 1935(c)(6) of the Act is entitled to a SEP. A full benefit dual eligible individual who is involuntarily disenrolled for disruptive behavior remains entitled to a Special Enrollment Period.

Comment: We received two comments asking us to adopt an interpretation of nonpayment of cost sharing as disruptive behavior as we had discussed in the preamble of the proposed rule for MA organizations.

Response: We appreciate the feedback provided on the consideration to include nonpayment of cost-sharing as disruptive for the purposes of applying the provisions under disruptive behavior. We will consider these comments in developing guidance for the disruptive behavior provisions.

8. Late Enrollment Penalty (§ 423.46)

Section 1860D–13(b) of the Act establishes late enrollment penalties for beneficiaries who fail to maintain creditable prescription drug coverage for a period of 63 days following the last day of an individual's initial enrollment period and ending on the effective date of enrollment in a Part D plan. We outlined this process for imposing the penalty in the proposed rule. We also proposed that an uncovered month is any month in which an individual does not have creditable coverage at any time during that month. We also reference the calculation of the amount of the penalty, which was described at § 423.286(d)(3) of the proposed rule. The final rule adopts the rules for late enrollment penalties as proposed.

Comment: Several commenters requested that we waive the late enrollment penalty for certain individuals, such as full-benefit dual eligible individuals, subsidy eligible individuals, individuals who are eligible for a special enrollment period and individuals who are involuntarily disenrolled. One commenter asked that State Medicaid programs be allowed to request and obtain such a waiver. Other commenters urged CMS to delay the implementation of the late enrollment penalty for one to two years, or be flexible with the application of the penalty, stating the Part D program was new and complex. Another commenter asked if we would provide any exception to the penalties for exceptional circumstances, such as natural disaster, family death, or clinical justification. A few commenters did not see a late penalty appeals process in the regulation and requested that we add an opportunity to appeal the late penalty.

Response: There is nothing in the statute that would provide us with the authority to waive or delay the late enrollment penalty at any time unless an individual was not adequately informed that his or her prescription drug coverage as described at § 423.56 was not creditable. Only in this limited situation will we be able to deem the individual's prescription drug coverage as creditable, regardless of whether it actually is creditable, so as not to impose the late penalty. Further, it is clear that the statute intended this provision to apply to full-benefit dual eligible individuals since the application of the penalty is specifically referenced in the definition of the full premium subsidy under section 1860D–14(a)(1)(A) of the Act, for which full-benefit dual eligible individuals are eligible. Specifically, section 1860D–14(a)(1)(A) of the Act provides that full subsidy eligible individuals, including full-benefit dual eligible individuals, are responsible for 20 percent of any late enrollment penalty for the first 60 months during which such penalty is imposed. As discussed in the proposed rule, we will develop a process for individuals to apply to CMS for reconsideration of the penalty. We appreciated the feedback that organizations provided on setting up such a process.

Comment: Several commenters asked CMS to clarify that those who do not receive a notice that their prescription drug coverage was not creditable (or received the wrong notice) are not subject to the late enrollment penalty.

Response: As provided in § 423.56(g) of the final rule, an individual who is not adequately informed that his or her prescription drug coverage was not creditable may apply for our review and make a determination if this occurred. If we determine that the individual did not receive adequate notice or received incorrect information, we may deem the individual to have had creditable coverage so that the late enrollment penalty will not be imposed.

Comment: One commenter asked CMS to clarify how the 63-day period would be counted. The commenter recommended from the end of the IEP to the date of the application for the low-income subsidy since individuals may delay a decision until he or she knows whether there will be a subsidy.

Response: The count of the 63-day period will commence the day following the end of the individual's IEP or, once the IEP has passed, the day following the last day of creditable coverage or Part D enrollment (in a PDP or MA-PD plan). The application of the 63-day period will be consistently applied to all individuals, regardless of when an individual may or may not apply for the low-income subsidy.

Comment: One commenter asked how the late enrollment penalty will be coordinated with the late enrollment penalty for Part B.

Response: We are currently developing operational and system requirements to implement the late enrollment penalty process. Additional guidance will be provided to PDPs and individuals with specific information as to how this will occur.

9. Part D Information That CMS Provides to Beneficiaries (§ 423.48)

As provided under section 1860D–1(c)(1) of the Act, we will conduct activities designed to broadly disseminate information about Part D coverage to individuals who are either eligible or prospectively eligible for Part

D benefits. In the proposed rule, we indicated that this information will be made available to beneficiaries at least 30 days prior to their initial enrollment period.

Each organization offering a PDP or MA-PD plan must provide us annually with the information to disseminate to individuals who are currently or prospectively eligible for Part D benefits. The information dissemination activities for Part D will be similar to, and coordinated with, the information dissemination activities that we currently perform for Medicare beneficiaries under sections 1851(d) and 1804 of the Act.

As required under section 1860D–1(c)(3) of the Act, we proposed to include the following comparative information for qualified prescription drug coverage provided by PDPs and MA-PD plans as part of our dissemination of Part D information and our efforts to promote informed beneficiary decisions:

- Benefits and prescription drug formularies;
- Monthly beneficiary premium;
- Quality and performance;
- Beneficiary cost-sharing; and
- Results of consumer satisfaction surveys.

We also proposed to provide information to beneficiaries regarding the methodology we will use for determining late enrollment penalties, as provided in § 423.286(d) of our proposed rule.

In carrying out the annual dissemination of Part D information, we will conduct a significant public information campaign to educate beneficiaries about the new Medicare drug benefit and to ensure the broad dissemination of accurate and timely information. We will work with SSA and the States to ensure that low-income individuals eligible for or currently enrolled in Part D benefits are aware of the additional benefits available to them and how to receive those benefits. In order to maximize the enrollment of Part D eligible individuals, this public information campaign would include outreach, information, mailings, and enrollment assistance with and through appropriate State and Federal agencies, including SHIPs, and will coordinate with other Federal programs providing assistance to low-income individuals. In addition, we will undertake special outreach efforts to disadvantaged and hard-to-reach populations, including targeted efforts among historically underserved populations, and coordinate with a broad array of public, voluntary, private community organizations, plan sponsors and stakeholders serving Medicare beneficiaries to explain the options available under this program. Materials and information will be made available in languages other than English where appropriate.

This information will enable beneficiaries to make informed decisions regarding their Part D coverage options. Organizations offering a PDP or MA-PD plan will be required to provide this information in a format and to use standard terminology that we will specify in further operational guidance.

In the interest of broadly disseminating information that promotes informed decision-making among Part D enrollees and prospective Part D enrollees, as required under Section 1860D–1(c) of the Act, we would extend the price comparison requirements to PDP sponsors and MA organizations offering MA-PD plans and making comparative information about Part D plans' negotiated prices available to beneficiaries through *www.medicare.gov*.

Since the introduction of *www.medicare.gov* in 1998, we have substantially increased the amount of personalized information available to Medicare beneficiaries, making it one of the government's most comprehensive and customer-oriented sites available to the public. The web site hosts twelve separate database applications to help individuals make their own health care decisions. The most significant ones are: the Medicare Personal Plan Finder (which contains costs, benefits, quality, satisfaction and disenrollment measures), Nursing Home Compare (which contains basic characteristics, staffing information and inspection results), the Prescription Drug and Other Assistance Programs application (which contains the most extensive, nationally complete listing of the Medicare-approved discount drug cards, including price comparisons, as well as other government and private programs designed to help with prescription drug costs), and the Medicare Eligibility Tool (which assists users in determining when they are eligible, how to enroll and what they need to consider when joining Medicare). Other tools providing customized results include: the Participating Physician and Supplier Directories, Home Health and Dialysis Facility Compare, Your Medicare Coverage, Helpful Contacts, Publications, and Frequently Asked Questions. By updating all information on the web site at least once a month, the information provided to Medicare beneficiaries via *www.medicare.gov* is the most reliable and consistent information available.

Much of the information available through *www.medicare.gov* is also available via the 1–800–MEDICARE helpline. 1–800–MEDICARE is a major information channel for providing the most personalized and reliable information to people with Medicare. The beneficiary can call 1–800–MEDICARE to find out the most reliable information on public and private programs that offer discounted or free medication, programs that provide help with other health care costs, and Medicare health plans that include prescription drug coverage. The caller can always talk to a live person at 1–800–MEDICARE to get the facts they need. We can also give the beneficiary personalized brochures containing information on their health plan choices, nursing homes and Medicare participating physicians in their area. 1–800–MEDICARE is available 24 hours a day, 7 days a week, to provide the one-on-one service that our Medicare beneficiaries need to make appropriate health care decisions.

The final rule adopts the information requirements set forth in the proposed rule.

Comment: Several commenters were concerned that the web site should reflect accurate information that is presented in an appropriate context and in a way that is useful for beneficiaries to use. Many commenters noted that the web site should provide beneficiaries with the ability to compare plans on the basis of estimating their out-of-pocket spending, including premiums and applicable cost sharing. Several commenters encouraged CMS to rely not only on price as the factor in determining which Part D plan fits beneficiary needs. Another commenter urged CMS to include specific information regarding which drugs are covered by each plan. Other commenters indicated that other information that the beneficiaries would need to consider would be the level of coinsurance, the amount a beneficiary would pay during any period he or she is liable for 100 percent of the cost sharing, whether the drug is on or off the formulary, and other cost management techniques that may apply, such as step therapy and prior authorization. Another commenter stated that we must post prices on its website of retail pharmacies that offer maintenance supplies of medications. One commenter stated that beneficiaries need to know whether the pharmacy is included in the plan's network.

Response: We appreciate this feedback and will consider this when

developing the requirements for the Part D price comparison web tool.

Comment: Another commenter stated that we need to ensure that any website includes price comparisons about generic drugs compared to their innovator brands, as well as generics compared to other brand name drugs in a similar therapeutic class.

Response: This comment will be considered when developing the requirements for the Part D price comparison web tool. As with the current price comparison tool for the Medicare-approved drug discount card program, we include pricing information for both brand and generic drugs.

Comment: One commenter noted that correct information may not be provided to seniors if we require plans to post the maximum price that could be charged, since the maximum price is typically the pharmacy's usual and customary cash price.

Response: It is our understanding that usual and customary pricing data is not readily accessible; therefore, we anticipate posting the maximum negotiated prices for prescription drugs on the website with the understanding that beneficiaries will pay the lower of the negotiated or usual and customary price at the point of sale. It is anticipated that the prices displayed on the website would reflect what enrollees would expect to pay at the point of sale for their prescriptions under the respective plans.

Comment: One commenter asked that we define the process for the information sharing exchange between PDPs and CMS.

Response: The process has not been defined at this time. Once we have developed the data requirements and process for submission of data, we will share this information with all prospective Part D plans.

Comment: Several commenters believe that the price comparison tool should not be a requirement for PDP sponsors or MA organizations offering MA-PD plans.

Response: It is important for beneficiaries to have access to all information in order to make informed choices. We are committed to providing Medicare beneficiaries with information about both PDPs and MA-PD plans through the price comparison tool. Therefore, we will keep this requirement.

Comment: One commenter expressed a general concern with the disclosure of negotiated prices and the negative impact that disclosure of such information could have on competition. The commenter further noted that negotiated prices may be subject to confidentiality agreements. The commenter suggested that we disclose only estimated or average prices and that this information only be posted on the specific website of the Part D plan.

Response: As mentioned previously, it is anticipated that the prices displayed on the website will reflect what enrollees would expect to pay at the point of sale for their prescriptions under the respective plans.

Comment: A commenter stated it was unacceptable for CMS not to provide quality and performance information in the first year or second year of the Part D program.

Response: Quality data will not be available for the first year since this is a new program and historical data will not be available for reporting. For year two, the regulation simply states that if it is impractical to obtain data or if it is not available, it will not be reported; this is not the same as stating that it will not be available for the second plan year. From the perspective of many beneficiaries, cost and availability are the most important quality issues. Hence, we will be able to report timely in response to these issues.

Comment: One commenter urged the agency to work closely with pharmacies to ensure that any price comparison website is understandable and free of errors before it is made public.

Response: Historically, we have worked closely with beneficiaries, stakeholders, partners, and advocacy groups to ensure the information disseminated meets the needs of the Medicare population we serve. We will continue this practice in the development of the website for Part D plan information.

Comment: One commenter stated that we are silent on the notification timeframe for beneficiaries. CMS simply refers to the 30-day notice period. The commenter thinks that beneficiaries will need much more than 30 days to digest all of the information they will receive from CMS to enable them to make informed choices about their Part D coverage. The commenter urges information to be disseminated as soon as possible and urges CMS to plan numerous information campaigns now and involve numerous organizations in developing education activities and materials. Another commenter suggests dissemination activities occur at least 60 days prior to the initial enrollment period for Part D, which begins November 15, 2005.

Response: We are planning outreach and education activities that will occur throughout 2005 and 2006. Detailed information about drug plans and their individual benefit structures will be released as soon as possible after this information is approved. It is impossible to send out plan data any sooner due to submission dates for plan information and the process steps needed to translate the raw data into consumer-friendly information, as well as the print production steps for the publication that will house this comparative information.

Comment: One commenter asked what information we will provide to SSA, SHIPs, and other groups to educate beneficiaries about the late enrollment penalty.

Response: We will provide important details about the penalty associated with late enrollment in the information provided to SSA and SHIPs, as well as in SHIP training materials. In addition, we will develop materials that can be used by employers, unions, partners, advocacy groups and other stakeholders to educate beneficiaries about the late enrollment penalty.

Comment: One commenter stated that we must give greater attention to developing materials and education campaigns focused on informing beneficiaries, especially those with special needs, about the new drug benefit and to help them to enroll in the best plan available.

Response: We are planning a multi-tiered education program to repeatedly reach all beneficiaries. This program will include plans for specific important target audiences, including those with special needs. Mailings and outreach activities to dual eligibles are currently being planned. Education and outreach materials developed for beneficiaries will be thoroughly tested with the target audience.

Comment: Another commenter stated that we should mail, no later than October 15, 2005, standardized, easy-to-understand notices to full-benefit dual eligible individuals that, among other things: inform them of their eligibility to receive the low-income subsidy if they enroll in a PDP; list of choices of health plans, clearly denoting those that meet the benefit premium assistance limit, and contact information for each plan; explain that full-benefit dual eligible individuals will be randomly enrolled in a prescription drug plan at a specified date if they fail to opt out or enroll in a plan themselves; explain how they may change their drug plans if they wish at any time; and inform them of where in their community they can go to get help with enrollment. The commenter also recommended that these notices should be tested for readability by focus groups and experts.

Response: We plan to consumer test beneficiary notices and send out the information noted by the commenter above by October 15, 2005. We are considering using the mailing to inform the full-benefit dual eligible individuals about what plan they will be auto-enrolled in if they fail to elect a Part D plan by December 31, 2005 or affirmatively opt of Part D, and that they have a right to choose to enroll in a different plan.

Comment: One commenter stated that the website should be provided in languages other than English to reflect the language spoken in a PDP service area.

Response: We appreciate this feedback and will consider this when developing the requirements for the website.

Comment: CMS should include in the final rule binding and enforceable standards defining information plans must provide to beneficiaries with various types of disabilities. For example, this information must be available to individuals who are blind or have low-vision. Further, CMS must require PDP internet websites to be accessible for individuals with vision impairments.

Response: Our websites are accessible to people with various disabilities, including those who are blind or have low-vision. Under our marketing requirements in § 423.50, we require Part D plans to demonstrate that marketing resources are allocated to marketing to the vulnerable populations, as well as beneficiaries age 65 and over. It is also important to note that Section 508 of the Rehabilitation Act of 1973 allows individuals with disabilities to access electronic information.

Comment: Commenters stated that the proposed rule focused largely on support through Internet sources and the 1–800 Medicare number, and argued that both are necessary and helpful but insufficient to meet the needs of many duals, as well as those eligible for the low-income subsidy.

Response: Although the basis for information dissemination is through publications, *www.medicare.gov* and 1–800–MEDICARE, we do not plan to solely rely on these resources to reach the population as a whole. We will work closely with SSA, SHIPs, Area Associations on Aging as well as other national stakeholders and partners, to provide assistance to those who may qualify for the low-income subsidy. Through a broad network of support from community based organizations, we will make considerable efforts to reach those beneficiaries who do not have access to the Internet or are uncomfortable calling 1–800–MEDICARE.

Comment: CMS should also make detailed information about PDPs available electronically to others in accessible formats that would enable them to conduct independent analyses about what plan would be best for a particular individual.

Response: Because the actual plan data underlying the price comparison tool is considered proprietary, we do not anticipate making the underlying data available electronically to outside organizations. Since nothing in the MMA addresses disclosure of plan data, the Freedom of Information Act (FOIA) rules apply. FOIA Exemption 4 protects certain confidential commercial information that is submitted to a Federal agency. Determinations about the applicability of FOIA Exemption 4 to plans' pricing data would be made on a case-by-case basis depending on whether the submitter of the data could demonstrate that disclosure of this information would likely cause substantial competitive harm to the submitter's competitive position. If FOIA Exemption 4 is found to protect submitted price information, we cannot disclose this information because to do so would violate the Trade Secrets Act (18 U.S.C. 1905).

Comment: Several commenters stated that we should develop specific outreach and education strategies for vulnerable populations, including disabled Medicare beneficiaries and dual eligibles. Another commenter stated that PDPs should be required to include specific plans for encouraging enrollment of hard-to-reach populations, including individuals with mental illness. Another commenter indicated that outreach efforts must involve community-based groups on a collaborative basis and not just use these groups as conduits for distributing written materials produced by CMS regarding the new benefit. Resources must be provided to enable these groups to educate beneficiaries about their choices and help enroll them. This collaboration with community groups must begin as soon as possible to establish the infrastructure needed once Part D goes into effect.

Response: We are developing an extensive outreach campaign for these individuals and are working closely with U.S. Department of Health and Human Services' Office of Disability to ensure that this important audience is reached.

Comment: One commenter strongly urged CMS to develop a specific plan for facilitating enrollment of beneficiaries with disabilities that incorporates collaborative partnerships with State and local agencies and disability advocacy organizations.

Response: In addition to working closely with the HHS Office of Disability to ensure we reach this group of individuals, we plan to broaden local partner networks though the Regional Education About Choices in Health (REACH) campaign to provide training, information and planning support to provide outreach and assistance to these populations. REACH is a national education and publicity campaign implemented at the local level by our Regional Offices and their partners. The REACH campaign works through partnerships to increase awareness of the Medicare program and resources among hard to reach populations.

Comment: A commenter suggested that we should develop and implement effective outreach strategies utilizing the Medicare Beneficiary Ombudsman authorized under section 923 of the MMA.

Response: Section 923 of the MMA states that, to the extent possible, the Ombudsman shall work with SHIPs to facilitate the provision of information to individuals entitled to benefits under Part A or enrolled under Part B, or both regarding MA plans and changes to those plans. We will ensure that SHIPs receive sufficient training in all aforementioned subjects so that SHIPs can provide information and assistance to beneficiaries referred to them by the Ombudsman. The Ombudsman operational design assumes that 1–800–MEDICARE will refer callers to appropriate sources, including SHIPs, for resolution of complaints and appeals and, when necessary, refer them directly to the Ombudsman as a last resort.

Comment: We received two comments that strongly recommended that we clarify the SHIPs mandate to ensure that they address the needs of individuals with disabilities, including non-elderly individuals.

Response: Section 4360 of the Omnibus Budget Reconciliation Act (OBRA) 1990, which created SHIP, requires that SHIPs provide information, counseling and assistance to Medicare eligible beneficiaries, including beneficiaries with disabilities. All CMS SHIP grant announcements expressly reference beneficiaries with disabilities as intended recipients of SHIP services. In addition, we provide training and information on the special needs and issues related to this population. We agree with the commenters and will clarify the SHIP mandate through the methods described here to address this need.

Comment: One commenter suggested that we partner with and fund community-based disability organizations to conduct outreach, information, and referral activities on the new Part D benefit.

Response: While we agree to partner with these organizations in these activities, funding these groups are subject to available funds in our budget.

Comment: One commenter was concerned about beneficiaries being inundated with marketing and outreach materials. Since many beneficiaries will need counseling on plan selection, this commenter asked for clarification regarding whether counseling will be available, what the States' role will be, and whether there will be Federal financial participation available for such costs.

Response: States that had SPAPs on October 1, 2003 will have Federal assistance available to them through the transitional grant program authorized under section 1860D–23(d) of the Act. These States will use the transitional grant funds to educate SPAP enrollees about the plans that are available to them under part D, as well as provide technical assistance, phone support, counseling, and other activities the SPAP believes will promote the effective coordination of enrollment in Part D. States that do not have a SPAP operational as of October 1, 2003 will not have these transitional funds available to them.

In addition, we will continue to provide grants to the States through the SHIP. SHIP is a national program that offers one-on-one counseling and assistance to people with Medicare and their families. Through grants directed to States, SHIPs provide free counseling and assistance via telephone and face-to-face interactive sessions, public education presentations and programs, and media activities. We expect SHIP counseling to be an important source of information for beneficiaries about Part D.

Comment: One commenter was concerned that the targeted and hands-on outreach, education and decision support and enrollment services, particularly outreach to lower income, rural and disabled beneficiaries is not adequate.

Response: Through the REACH campaign, we plan to broaden local partner networks in order to provide training, information and planning support to provide outreach and assistance to these populations. Through a broad network of support from community-based organizations as well as national stakeholders and partners, considerable effort will be made to reach those beneficiaries who do not have access to the Internet or who are uncomfortable calling 1–800–MEDICARE.

Comment: One commenter stated that we should consider preparing educational materials that would help pharmacists understand the benefits and other material that they can use to educate beneficiaries.

Response: We are working with our provider education staff to develop materials for all providers, including pharmacists, for educational use.

10. Approval of Marketing Materials and Enrollment Forms (§ 423.50)

Section 1860D–1(b)(1)(B)(vi) of the Act directs us to use rules similar to those established under section 1851 of the Act to review PDPs' marketing materials and application forms.

In the proposed rule, we generally replicated the marketing provisions established under § 422.80 for MA plans as appropriate for PDPs. Therefore, we proposed at § 423.50(a) guidance for our review of marketing materials, definition of marketing materials, deemed approval, and standards for PDP marketing. We do recognize that the differences between PDPs and MA plans will require different marketing requirements and we requested comments on this issue. We have drafted the final rule to apply the marketing requirements to all Part D sponsors, although we may waive the Part D provisions in deference to similar MA, PACE and cost plan requirements.

We also proposed to add § 423.50(a)(3) in order to streamline the marketing review process for all PDP sponsors for those materials which pose the lowest risk of confusing or misleading beneficiaries. This aspect of the File and Use program allows the PDP sponsor, prior to distribution, to submit and certify that for certain types of marketing materials it followed all applicable marketing guidelines, or for certain other marketing materials that it used, without modification, proposed model language as specified by CMS.

Except as otherwise provided below, the final rule adopts the marketing rules set forth in § 423.50 of the proposed rule. Although the following area generally applies to Fallback plans, subpart Q specifically addresses issues related Fallback plans.

In addition to marketing materials and enrollment forms, comments provided the opportunity to respond to enrollment issues related to SPAPs, pharmacist and physician marketing to beneficiaries, and organizations marketing additional products in conjunction with PDP services.

Comment: We received several comments on types and quantity of information that should be disseminated to beneficiaries. Many commenters suggested that specific formulary information needs to be provided including specific drugs (top 25–50), pricing and premium information, benefit structure, pharmacy networks, plan availability by region, medication management services offered (and who is eligible for them), appeals and exception process and information on plan performance. Most agreed that this information should be mailed, as well as provided on the Internet and that comparison tables with this information for all plans in a geographic region should be provided so that beneficiaries can compare plans side-by-side. One commenter was concerned that beneficiaries would be overwhelmed with materials and expressed concern about the potential for adverse selection. It was suggested that strict and detailed regulations on marketing be issued to protect beneficiaries. One commenter suggested that we need more detail in the final rule around patient education.

Response: We agree with the commenters that beneficiaries will need information on the Part D plans available in their areas. Our goals in providing information has always been to ensure that beneficiaries have access to timely, accurate and reliable information that helps them make informed health care decisions. Our education and outreach efforts related to Part D are no exception. We will employ multiple tactics, including publications, direct mailings, the Internet (*www.medicare.gov*), toll-free telephone numbers, and localized grassroots partnerships to help beneficiaries access the level of detailed information that they want and need to make their best choice among Part D plans. Our tiered communications approach recognizes that different beneficiaries have varying information needs and what might be an overwhelming level of detail to some individuals may only meet the baseline needs of another. By using multiple, integrated education and outreach approaches and thoroughly market testing our products and messages during development, we are working to strike the best balance of providing the right information at the right time. In addition, we are committed to making sure plans provide clear, accurate information on covered benefits, including formulary, pharmacy networks, and costs. We intend to require such information in guidance rather than specifying the full range of materials in the regulations so that we

can modify our requirements in a timely manner to meet beneficiary needs.

Comment: We received several comments regarding the use of various marketing vehicles to promote PDPs. Several of the commenters supported the distribution of information through websites, 800 numbers, written communications and telemarketing. One commenter stated that marketing should be limited to mail contacts only due to concerns regarding fraud. One commenter stated that the restrictions on marketing need to be expanded due to the potential for fraud. Many commenters opposed telemarketing and one was explicitly against email as well.

Response: Section § 1860(D)(1)(b) of the Act allows for similar marketing rules for the drug benefit as those for MA. We intend to follow this guidance and promote marketing guidelines that are in line with those under the MA program. The MA program supports the use of websites, 800 numbers, mailings, email and telemarketing for plan marketing. By allowing plans multiple routes for marketing, we believe that greater numbers of beneficiaries will be reached and thus enrolled in drug benefit plans. We believe this is an important goal given the penalty for late enrollment in Part D. We understand that this is contrary to what we allowed in the drug discount programs. We did not allow the drug discount card programs to participate in telemarketing practices because many of the drug card sponsors were stand alone start-up companies that did not have a previous history of doing business. We expect that the PDP sponsors will have previous experience administering drug plans, insurance or other lines of similar business, with established reputations, much like MA plans.

Marketing guidelines are in the process of being established, and these will set forth in greater detail what will be expected of the plans. PDP sponsors may be barred from engaging in certain practices if abuses occur. In addition, PDPs will be prohibited from requesting beneficiary identification numbers over the telephone or via email as related to marketing activities.

Comment: One commenter stated that the States should be able to steer its SPAP enrollees toward the most appropriate plan.

Response: Section 1860D–23(b)(2) of the Act defines an SPAP as a State program which, in determining eligibility and the amount of assistance to a Part D eligible individual under the program, provides assistance to such individuals in all Part D plans and does not discriminate based upon the Part D plan in which the individual is enrolled. We further interpreted that provision in the preamble of the proposed regulation such that a SPAP may not designate a preferred PDP, even if the State allows beneficiaries to choose a non-preferred plan and provides for benefits equivalent to that which it also provides for the preferred plan (referred to as wrap-around benefits). We believe that, regardless of whether the SPAP is authorized under State law to make enrollment decisions on behalf of the beneficiary, we interpret using that authority to steer beneficiaries to a preferred PDP or MA-PD plan would be interpreted to violate the non-discrimination provision under section 1860D–23(b)(2) of the Act.

Section 1860D–23(d) of the Act provides for grants to SPAPs, in existence as of October 1, 2003, which were awarded in September of 2004 for fiscal year 2005, for the purpose of educating their members about options to access Medicare drug benefit coverage and about comparing options so they can choose the best value to them. We will reach out to SPAPs with information to help people with Medicare understand their drug plan options. We will also assist SPAPs in adapting this information to ensure that their members understand the way that the new Part D plans coordinate with their SPAP benefit and supporting their members in making informed decisions about drug benefit plan options. Outreach to SPAPs would also include instruction on the educational/outreach/assistance activities SPAPs could pursue while not discriminating against Part D plans.

SPAPs cannot discriminate amongst plans; however, they may provide beneficiaries with comparable education on all of the available Part D plans (PDPs, MA-PD plans, and PACE and cost-based HMO or CMPs offering qualified prescription drug coverage) in terms of the following: which plans have lower premiums after application of any uniform SPAP premium subsidy; which plans offer formularies that cover the drugs utilized by the beneficiaries so that beneficiaries can continue to use the same drugs; which plans offer the drugs used by the beneficiary at the most favorable combination of deductibles, coinsurance/co-pays, and negotiated prices; which plans use the same network pharmacies as the SPAP so that beneficiaries can continue to use the same pharmacy; and which plans (if any) have ID cards that include an emblem or symbol indicating its coordination with the SPAP to facilitate secondary payment at the point of service.

In addition, SPAPs are prohibited from recommending Part D plans based on their financial interest in minimizing their cost of providing coverage that supplements (wraps-around) their members Part D benefits. They are required to mirror our process auto-enrolling full-benefit dual eligible individuals among PDPs on a random basis in the event that members do not actively select a Part D plan during their IEP or after enroll in the SPAP.

Part D plans benefit coordination requirements include establishing procedures to share information with SPAPs on enrollment files, the processing and payment of claims, claims reconciliation reports and whether the beneficiary has satisfied the out-of-pocked limit. Part D plans are encouraged to work with all SPAPs to co-brand the Part D benefits by providing (in its electronic claim response to the pharmacy) information on payment of premiums and coverage, and whether claims should be sent to an SPAP for processing. Plans should also consider including the SPAPs' benefits in marketing and educational materials to beneficiaries, which includes SPAP benefit information, eligibility criteria, order of party payment, and a phone number for SPAP enrollment and claims payment information.

Comment: Two commenters were concerned that SPAP beneficiaries will be confused by materials and decline enrollment if premiums, deductibles and coverage gaps are discussed since SPAP participants were never required to pay these amounts. It was also stated that marketing materials for this population should include coordination of benefit (COB) information.

Response: We expect that SPAPS will provide information to beneficiaries on their drug plan choices in their States. We expect that plans will work cooperatively with SPAPs to co-brand materials, when appropriate, to ensure that beneficiaries are provided with comprehensive, appropriate, coordinated information that will facilitate education and understanding of their benefits. Requirements for coordination of benefits with other providers of prescription drug coverage are described under § 423.464 (e). We expect Part D plans to work with SPAPs on coordination of benefit activities to ensure that beneficiaries are provided seamless care that is easily understandable.

Comment: We received multiple comments regarding the specific requirements for marketing materials. Many commenters agreed that marketing materials should be available in Spanish and in other languages that

are in the plan's service area. Two commenters stated that marketing materials should be developed at an appropriate health literacy level. Two commenters stated that the information will need to be adapted for the blind/low vision, those with cognitive disabilities, in Braille, large print and on audio or computer disks. It was also stated that there should be a requirement that the Internet site be accessible for the visually impaired and that interpreters and alternative communication methods should be mandated. Another commenter stated that a subpart should be devoted to notice requirements.

Response: We agree that there are special needs of beneficiaries that will need to be provided for. The regulation currently dictates that marketing materials need to be available in low-literacy formats. While we do not require materials to be available in other languages, it is highly encouraged. In addition, basic enrollee information should be developed to accommodate the visually impaired. Call centers must be able to accommodate non-English speaking/reading beneficiaries. Plan sponsors should have appropriate individuals or translation services available to call center personnel to answer questions that beneficiaries may have concerning aspects of the drug benefit. We are working on developing guidance shortly following publication of the final rule that is similar to the MA requirements to ensure appropriate information is available to beneficiaries.

Comment: Several commenters stated that marketing materials should be consistent with other Medicare programs.

Response: We are currently developing additional marketing guidelines and expect them to be similar to other Medicare programs (for example, the MA and the Medicare-approved prescription drug discount card programs), to the extent possible, in order to reduce the administrative burden for plans that participate in these programs.

Comment: We received many conflicting comments regarding whether providers (pharmacists and physicians) should be allowed to market to beneficiaries. This includes the display of materials from Part D sponsors as well as verbally steering beneficiaries to particular plans. Several commenters were in support of pharmacies marketing MA/PD and PDPs; some of these commenters stated that equal attention should be provided to all plans in the particular area. In addition, some commenters specifically mentioned that they were in support of physicians marketing Part D plans.

Other commenters were against marketing of Part D plans in the pharmacy setting; three specifically mentioned the prohibition of physicians from marketing to beneficiaries. Most stated that the reasons for their positions were that physicians or pharmacists could steer a beneficiary to inappropriate Part D plans.

Response: Both the MA and the Medicare-approved prescription drug discount card programs allow some provider marketing to occur. Our position is that it is appropriate to allow providers and pharmacies to market to beneficiaries. This marketing provides beneficiaries with access to information about the options available to them under Part D that they may not have received through other sources because beneficiaries often look to their health care professionals to provide them with complete information regarding their health care choices. Therefore, we believe that providers and pharmacies should provide prospective enrollees with information on the full range of options available to them under Part D. This process is similar to the process followed for the discount drug card program, where pharmacies may provide information on where beneficiaries may get complete information regarding all the Medicare-approved discount cards available in the region in their service area. We would require Part D sponsors that want their network pharmacies to provide marketing materials to prospective enrollees to include in their contracts language requiring the pharmacies Part D eligible individuals with information on all Part D options available in the service area. This requirement would be specified in the further guidance issued by CMS. Any remuneration offered to providers in exchange for providing to patients information about particular Part D plans must comply with applicable Federal and State laws on fraud and abuse.

Comment: Two commenters stated that Part D sponsors should be prohibited from using Medicare discount card enrollee and applicant information to provide leads for marketing their Part D plans.

Response: We acknowledge the importance of beneficiary privacy, and the marketing limitations that drug cards operate in accordance with section 1860D–31(h)(7) of the Act. The drug card provisions under section 1860D–31 of the Act contemplate a transition from the drug card program to Part D, and we are considering what will be the specific drug card responsibilities of drug card sponsors during transition. From that understanding we will assess whether PDP sponsors currently offering a drug card may use of beneficiary drug card information to market their Part D plans and we will provide further guidance to the drug card sponsors and Part D sponsors at a later time. We note, however, that the HIPAA Privacy Rules may limit the ability of drug card sponsors to disclose their enrollees' information to un-affiliated Part D sponsors.

Comment: One commenter suggested that the File & Use program should be delayed one year until we have more experience with evaluating the practice of the PDPs, and that the term ''performance requirements'' needs to be defined.

Response: We will define the eligibility and performance requirements associated with the File & Use program in further guidance.

Comment: There was concern over the amount of time that was stated was necessary for a review of PDP and MA-PD marketing materials. Some suggestions included decreasing the time of this review from 45 days to 30 days, and instituting a 10-day review period for resubmitted materials. In addition, if unaltered model materials were used, the review should be limited to 10 days.

Response: We agree that that timelines for reviewing marketing materials should be shortened. However, we intend on maintaining the proposed timelines for Part D marketing materials as defined in the statute. We will work to develop a review process that is as efficient as possible. We will develop a range of model materials for Part D sponsors.

Comment: We also received a comment that the amount of materials that must be individually approved should be limited. There was also concern that we may not have enough staff to review the materials and that the process needs to be open, fair and constructive.

Response: We will develop a range of model materials for Part D sponsors to choose from to improve efficiency of the marketing review process. Materials that utilize ''model language'', without modification, are subject to a streamlined review process. We will work to develop a review process that is as efficient and effective as possible utilizing standardized criteria to review the materials.

Comment: Two commenters stated that it is unacceptable that marketing materials are deemed approved if we fail to approve them within the time

period and materials should be reviewed multiple times for multiple regions.

Response: It is a statutory requirement that we approve marketing materials within 45 days or that they are then deemed approved. In developing sub regulatory marketing guidance and processes, we will work to ensure that our reviews are completed within the statutory timeframe.

Comment: Commenters stated that guidelines for CMS review under § 423.5(c)(i),(ii), and (iii) of the proposed rule need to be more specific. These sections lay out the information that Part D plans need to provide to beneficiaries.

Response: We will provide greater detail in the sub regulatory guidance in order to facilitate any necessary future changes that would need to be made.

Comment: Many commenters gave input as to whether additional products, such as financial services, should be marketed to Medicare beneficiaries in conjunction with the Part D benefit. Several of the organizations expressed their concerns over the fact that beneficiaries may be confused with receiving additional information for other products and services in conjunction with information about the Part D benefit. The major concern is that beneficiaries would choose not to participate in Part D because they did not like some of the other products or that they may mistakenly believe that we have approved these products. One commenter suggested that individuals must actively agree to receive marketing materials other than enrollment materials. Some commenters suggested that financial institutions should not be encouraged to participate as PDPs, since the potential for abuse, as in selection of healthier beneficiaries into plans and avoidance of financial services to less healthy individuals, is enormous.

Some health plans commented that they are in favor of allowing PDP sponsors to market additional health-related and non-health-related products to beneficiaries. These products could be provided for an additional fee or at no additional cost to the beneficiary. The belief is that the additional tools could help beneficiaries manage their expenses and financial securities. One organization also stated that if PDP sponsors are permitted to provide these additional products, than MA-PD plans should be allowed to similarly provide these additional products.

Response: We do not want to restrict beneficiaries from receiving materials about of health-related and non-health-related services that may be of benefit to them in managing their health or payments for health care. All organizations that are qualified to be a Part D sponsor are encouraged to participate in providing services under Part D. In situations where plans want to use or disclose protected health information (PHI), for purposes of marketing these other products or services, for example beneficiary enrollment information, Part D plans must comply with the HIPAA Privacy Rule and obtain a written authorization from the beneficiary prior to using the beneficiary's PHI to market non-health-related products and services. In other cases where Part D plans implement general marketing mailings that do not use beneficiary PHI, we would not object to plans providing such information to beneficiaries as long as the information is not contingent upon PHI to do so. For example, a plan may obtain a general mailing list from a non-related marketing vendor to mail materials to all individuals over age 65 in a geographic area to promote its products. The use of beneficiary names and addresses obtained from a plan and used for mailings to beneficiaries only, would presumably use PHI. Consequently, plans could not market non-health-related products through mailings using beneficiary information absent authorization.

Comment: One commenter recommended that any Part D sponsor offering other health coverage to its Part D plan enrollees be required to provide anti-duplication notices like those that are required under the National Association of Insurance Commissioners (NAIC) model regulation for Medigap policies. The purpose of these anti-duplication notices is to advise Medicare beneficiaries as to whether other non-Medigap types of coverage being offered to them might duplicate coverage they already have under Medicare.

Response: The disclosure statements that are required under the NAIC model regulation for Medigap policies were adopted by the NAIC pursuant to anti-duplication provisions contained in section 171(d) of the Social Security Act Amendments of 1994 (SSAA'94–Pub. L. 103–432) that amended section 1882(d)(3)(A) of the Act. These statements apply to all issuers of health insurance coverage that is offered to Medicare beneficiaries that is neither a Medigap policy nor a type of coverage that is listed as exempt from this requirement in a **Federal Register** notice that CMS [then HCFA] published on June 12, 1995. Section 171(d) required CMS to either publish the disclosure statements developed by the NAIC or publish its own. The FR notice through which CMS accepted the 10 separate disclosure statements developed by the NAIC for the various types of coverage commonly offered to Medicare beneficiaries contained a list of types of policies not requiring disclosure statements (See 60 FR 30880).

Among the types of coverage not requiring the use of a disclosure statement were managed care organizations with Medicare contracts under section 1876 of the Act. The notice went on to explain that these types of policies are exempt because ''these plans do not 'duplicate' Medicare benefits; rather their purpose is to actually provide all covered Medicare benefits directly to enrolled beneficiaries.'' In 1995, cost and risk managed care organizations with contracts under section 1876 of the Act were the primary alternative to fee-for-service Medicare. Medicare+Choice plans were authorized by the Balanced Budget Act (BBA) in 1997, and the program has now been renamed Medicare Advantage by MMA. MMA also provided for private prescription drug plans (PDPs) to contract to deliver Medicare prescription drug benefits under Medicare Part D. Because Part D plans will actually provide all covered Medicare drug benefits directly to enrolled beneficiaries, we wish to clarify that these entities will not have to provide anti-duplication notices for their provision of coverage pursuant to their Medicare Part D contracts. However, if Part D plans choose to market to their enrollees other (non-Medigap) health insurance products that are not part of their contracts under Part D, these other types of health insurance products will have to bear the disclosure statements required by section 1882(d)(3)(A) (vi) of the Act and the NAIC model regulation unless the other coverage comes within one of the specified exemptions.

11. Information Provided to PDP sponsors and MA Organizations

Section 1860D–1(b)(4)(A) of the Act authorizes us to provide information about Part D eligible individuals to PDP sponsors and MA organizations to facilitate the marketing and enrollment of beneficiaries in their PDP and MA-PD plans. This information is intended to ensure participation in the Part D program, as well as to reduce costs to those plans.

In the final rule, it is not necessary to provide regulatory text implementing this provision; however, we intend to provide additional guidance shortly following publication of this rule, as explained below.

Comment: We received several comments on this MMA provision. Several of the commenters supported the provision of such information to organizations, with a few offering to work with CMS to develop guidance and ensure that the appropriate beneficiary protections are in place. Many who supported this initiative believed that, at a minimum, the name, address, and telephone number of the individual should be provided. Another commenter believed that the statute permits organizations to contact beneficiaries through written, electronic, or phone communication. Another commenter stated that the individual's dual eligible or low-income subsidy status should also be provided. The commenter also noted that we should provide the information to organizations upon request, as opposed to being limited to only receiving such information at certain times of the year. The commenter also believed that the statute would permit PDP sponsors to obtain marketing information on low-income and dual eligible individuals directly from States and SPAPs.

Several commenters also opposed such information being provided to organizations. One commenter believed that providing such information to Part D competitors would generate more problems and ''incite'' more negative beneficiary reaction that would outweigh any value in enhancing beneficiary outreach. Other commenters were concerned that such information would be used to ''cherry pick'' healthier and less expensive beneficiaries. Several commenters noted that if we were to provide such information to organizations, such information should be limited to the minimum amount necessary. They stated that certain information, such as health or financial information or telephone numbers should not be provided. Further, beneficiaries should be given the option to request that we not share their information with plans. Several commenters did not believe that PDPs or MA-PD plans should be able to use the information for telemarketing purposes. Another commenter indicated that we should only disclose information to the plan if the plan's marketing material contains formulary and drug pricing information and is accompanied by an application form.

Response: We decline to provide specifics on the provision of this information at this time but reserves the right to provide this information to plans in the future. We will develop further guidance on this issue shortly after publication of this rule.

12. Procedures to Determine and Document Creditable Status of Prescription Drug Coverage (§ 423.56)

Section 1860D–13(b)(6) of the Act identifies certain entities, which we describe in our proposed rule that must disclose whether the prescription drug coverage that they provide to their members who are Part D eligible is creditable prescription drug coverage.

Sections 1860D–13(b)(4) (A) through (G) of the Act lists seven forms of potential creditable prescription drug coverage: Coverage under a PDP or under an MA-PD plan; Medicaid; a group health plan (including coverage provided by a Federal or a nonfederal government plan and by a church plan for its employees); a State pharmaceutical assistance program; veterans' coverage of prescription drugs, prescription drug coverage under a Medigap policy; and military coverage (including Tricare). Many of these terms are defined elsewhere in Federal regulations; some of them are under the jurisdiction of other Federal agencies.

In addition to the forms of creditable coverage identified in sections 1860D–13(b)(4) (A)-(G) of the Act, section 1860D–13(b)(4)(H) of the Act provides the Secretary with the flexibility to identify ''other coverage'' that could be considered to be creditable prescription drug coverage. We proposed, at § 423.56, to expand the list of types of creditable prescription drug coverage.

As discussed in § 423.46 of the proposed rule, upon becoming eligible for Part D, beneficiaries must decide whether to enroll in Part D, or forego that opportunity and face a possible financial penalty should they later decide to enroll. Beneficiaries who decide not to enroll in Part D because they have creditable prescription drug coverage will not face such a penalty if they later decide to enroll in Part D.

According to section 1860D–13(b)(5) of the Act, an enrollee who would otherwise be subject to a late enrollment penalty may avoid the penalty if his or her previous coverage met the standards of ''creditable prescription drug coverage''. Under section 1860D–13(b)(5) of the Act, previous coverage will only meet those standards ''if the coverage is determined (in a manner specified by the Secretary) to provide coverage of the cost of prescription drugs the actuarial value of which (as defined by the Secretary) to the individual equals or exceeds the actuarial value of standard prescription drug coverage.''

In the proposed rule, we interpreted ''to the individual'' in this case as being to the average individual under the plan, as opposed to the sponsor of the plan. For purposes of determining creditable coverage, we proposed a ''gross'' test: will the expected plan payout on average be at least equal to the expected plan payout under the standard benefit? We also proposed at § 423.56(c) that any entity seeking to offer coverage of the type described in § 423.56 must attest to the actuarial equivalence (or non-equivalence) of its prescription drug coverage in their notice to Medicare beneficiaries and in a submission to CMS, and must maintain documentation of the actuarial analysis and assumptions supporting the attestation.

In coordination with the provisions regarding the late enrollment penalty, we proposed at § 423.56 to establish a process under which these entities will disclose the creditable status of their prescription drug coverage to us and to each part D eligible beneficiary enrolled in such coverage.

Section 1860D–13(b)(6)(C) of the Act, implemented at § 423.56(g) of the proposed rule, provides that an individual who was not adequately informed that his or her prescription drug coverage was not creditable prescription drug coverage may apply to CMS to have such coverage treated as creditable prescription drug coverage for purposes of not having the late penalty imposed.

Comment: One commenter stated that Medicaid should not be considered creditable prescription drug coverage, for the purposes of Part D, because no Medicaid benefit for Part D covered prescription drugs is available to Part D eligible beneficiaries.

Response: All entities listed under § 423.56(b), except PDPs and MA-PDs under (b)(1) and PACE plans and cost-based HMOs and CMPs offering qualified prescription drug coverage, must provide notice to both CMS and its members whether the prescription drug coverage provided is or is not creditable. The purpose of the notice of creditable coverage is to ensure that individuals are aware of whether such coverage is creditable prescription drug coverage and its implication to the late enrollment penalty.

Medicaid is prohibited from providing Part D drugs to full-benefit dual eligible individuals. However, since there may be other individuals who are not receiving the full range of benefits from Medicaid but who will continue to receive some drug coverage from the State, these individuals must also receive this notice providing status of the coverage.

Comment: One commenter requested that we include SPAP in the definition

of types of coverage that may be creditable.

Response: The proposed rule at § 423.56(b)(4) includes SPAPs as potentially creditable. Section 1860D–13(b)(4)(D) of the Act specifies these programs, as described in section 1860D–23(b) of the Act, as such. To ensure this concept is clear, we will revise § 423.56(b)(4) to include the acronym ''SPAP.''

Comment: We received a comment indicating that the value of prescription drug coverage under PACE will likely equal or exceed the actuarial value of Part D standard prescription drug coverage as a result of existing requirements in sections § 460.90 and § 460.92 of the PACE regulation. The commenter recommended incorporating PACE into the CMS definition of creditable prescription drug coverage found in § 423.56(a).

Response: We agree with the commenter and have incorporated PACE into the definition of potentially creditable prescription drug coverage found in § 423.56(b). Additional discussion of the applicability to Part D benefits and requirements to PACE are outlined in subpart T of the final rule.

Comment: A few commenters inquired about the actuarial equivalence test that the entities listed will be required to meet, since the actuarial equivalence reference in § 423.265 refers to bid submissions. Commenters supported both the concept of ''gross'' test and an ''aggregate test'' for calculation of the actuarial equivalence for plans, including group health plans which offer several benefit packages to determine if the prescription drug coverage is creditable.

Response: The basic actuarial equivalence value test for the determination of creditable coverage of alternative coverage is determined by calculating whether the expected plan payout on average will be at least equal to the expected plan payout under defined prescription drug coverage (gross test). We believe Section 1860D–22(a)(2) of the Act is subject to two reasonable interpretations of calculating the creditable coverage test (gross test). Under the first interpretation, the actuarial equivalence standard for determining creditable coverage would be applied to the alternative coverage as a whole, and under the second interpretation the actuarial standard would be applied for each benefit option (including separate cost-sharing arrangements) within a single group health plan. Whereas our proposed rule required plans to apply the actuarial equivalence standard at the aggregate level, for the final rule we instead require plans to apply the actuarial equivalence standard to each benefit option within its plan.

Our rationale for revising the actuarial equivalence test is to ensure that beneficiaries are adequately informed that their coverage is or is not creditable prescription drug coverage. A sponsor may offer many different benefit options to beneficiaries. One of those benefit options may not pass the gross test but be included in an overall (or ''aggregate'') text. As a result, this would leave beneficiaries in certain benefit options with a determination that their coverage is creditable, when in actuality it is not. For example, a sponsor has a group in which richer benefits are offered, compared to another group that has more limited benefits. If the sponsor would aggregate the two benefits together, the lower benefit will end up as ''creditable'' when the benefit packages are averaged together.

We will issue guidance on the aspects of actuarial equivalence shortly following publication of the final rule.

Comment: One commenter asked if any coverage that is less than full pharmacy benefits could be considered creditable prescription drug coverage, such as coverage for maintenance or coverage of specific disease-only drugs.

Response: We believe that the definition of creditable prescription drug coverage would prohibit us from concluding that such coverage is creditable. To be creditable prescription drug coverage, the coverage must equal or exceed the actuarial value of defined standard prescription drug coverage, as we will define in guidance referenced in the previous response. It is likely that coverage of a very limited scope such as the commenter refers will not likely meet our actuarial equivalence test.

Comment: In response to our request for comments on other forms of coverage that may potentially be considered creditable, two commenters requested that we cost-based HMOs and CMPs authorized under section 1876 of the Act as potential providers of creditable prescription drug coverage. Both commenters also suggest that we include a provision allowing CMS to designate other types of coverage as potentially creditable prescription drug coverage in the future without requiring such an addition be accomplished through the rule making process. Another commenter suggested that coverage provided by State high risk insurance pools also be included in the types of coverage that may be creditable.

Response: We agree with these suggestions and have revised § 423.56(b) to include cost-based HMOs and CMPs and coverage offered by State high risk pools, as defined under the HIPAA regulations at § 146.113(a)(1)(vii), as well as a provision permitting CMS to recognize other types of coverage as potentially creditable prescription drug coverage, which we would do so in separate guidance as determined necessary.

Comment: Several commenters supported permitting the disclosure of the creditable prescription drug status of coverage through the inclusion of this information in already existing beneficiary materials, such as Summary Plan Descriptions (SPDs), or annual notices. One commenter suggested that because beneficiaries are already familiar with these documents, they provide a more recognizable and familiar avenue for this important information. On the other hand, several commenters supported requiring all notices of the creditable status of coverage to ''stand alone;'' that is; to be provided separately in a specific notice to each individual. Some commenters expressed concern that if this disclosure were not highlighted in a separate notice, the important message could go unnoticed and inadvertently subject an individual to the late enrollment penalty. Another commenter suggested that all notices be linked to ERISA disclosure documents (that is, SPDs), and to HIPAA or COBRA required notices. One commenter suggested that notice of creditable status could be incorporated into already existing beneficiary information materials, while notice of non-creditable status should stand alone. Lastly, a commenter requested that we specify the elements that would be required to be included in these notices.

Response: We specifically requested comment on the disclosure of creditable prescription drug notice requirements and appreciate the feedback received. Based on the comments we received we believe that linking the notice of creditable status to other required documents is an acceptable vehicle provided it is conspicuous and includes standard information elements. This approach appropriately recognizes the importance and familiarity of materials that beneficiaries currently receive regarding coverage they have. Further, we believe that it is important to encourage compliance with the provision of these notices by eliminating duplication and the undue burden associated with it. To that end, we have revised § 423.56(c) to allow notices of creditable and non-creditable status to be provided in the same manner, and will provide specific guidance following the publication of the rule. This guidance will require that

a notice of creditable and non-creditable status be provided, at minimum, prominently with other beneficiary information materials, and will include model language for both types of notices.

We may specify different requirements for those entities identified at § 423.56(b) that are required to provide these notices, where appropriate, to reduce beneficiary confusion and minimize administrative burden. For example, as explained in our discussion of § 423.34 above, we intend to notify full benefit dual eligible individuals that they are eligible for the low-income subsidy. This notice will also inform individuals that Medicaid will no longer cover those prescription drugs covered under Part D and that any additional prescription drug coverage provided by Medicaid would not be creditable coverage under Part D. Including this information in the same notice will avoid duplication of effort and possible beneficiary confusion.

Comment: Several commenters felt that requiring an attestation by group health plans of actuarial equivalence for creditable coverage when the sponsor of such coverage elects not to enroll in the retiree drug subsidy program under subpart R was an unnecessary cost and an administrative burden. The commenters believed that for those employer groups that offer prescription drug coverage to active employees who might be Part D eligible individuals, such coverage should be assumed to be ''creditable'' and should only have to provide notices to those qualified retirees and dependents who are Part D eligible individuals. The commenters also suggested that notices could be published in summary plan descriptions, on employer website and via e-mail.

Response: Section 1860D–13(b)(6)(B) of the Act requires specific entities that offer prescription drug coverage to provide notices to all Part D eligible individuals enrolled in their plans regarding whether such prescription drug coverage is creditable. This would include sponsors (as defined under § 423.880) not electing the Retiree Drug Subsidy, as described in subpart R. A notice of creditable or non-creditable coverage must be provided to active Medicare eligible employees and Medicare eligible dependents so that a late enrollment penalty will not be imposed when the beneficiary enrolls in Part D coverage.

We will provide further guidance on a simplified method of determining creditable coverage for those sponsors not electing the retiree drug subsidy.

We will also provide guidance to sponsors on the form, manner, and timing of such notice requirements, following publication of this final rule. Notices may be provided, at minimum, prominently with other plan participant information materials (for example, summary plan descriptions, or HIPAA notices) that the sponsor is required to provide as long as it is conspicuous and includes standard information elements as determined in our guidance. This approach appropriately recognizes the importance and familiarity of materials that beneficiaries currently receive regarding coverage they have.

Comment: Many commenters responded to our request for comments on the timing of the delivery of creditable coverage status notices to Part D eligible individuals. Several of these commenters suggested that the initial notice should be required to be delivered prior to the commencement of the AEP which begins on November 15, 2005. One commenter suggested that notices also be issued at least 60 days prior to the effective date of any change to current coverage. Another commenter suggested that entities required to deliver these notices should do so within 30 to 45 days of the end of Part D enrollment periods.

Response: We appreciate the feedback we received regarding the timing of notices to disclose creditable prescription drug coverage. We agree that, in order to ensure beneficiaries are making informed choices regarding enrollment in Part D, notice must be provided to all Part D eligible individuals each year prior to the commencement of the AEP, which begins on November 15th. We also believe there are three other key times when notice must be provided: (1) prior to the commencement of the individual's initial enrollment period in Part D; (2) prior to the effective date of enrollment in such coverage or any change in creditable status of that coverage; and, (3) upon request by the beneficiary. We will revise § 423.56(f) to require that notice be provided, at minimum, at these 4 times.

Comment: One commenter requested that we clarify the meaning of the words in § 423.56(b) of the proposed rule ''with the exception of PDPs and MA-PD plans.'' for the duty to furnish notices of creditable coverage to beneficiaries. The commenter also requested clarification of the duty of Cost plans offered under section 1876 of the Act that provide qualified prescription drug coverage to furnish such notice. Lastly, the commenter asked us to clarify if the provision at § 423.56(d) of the proposed rule regarding the disclosure of creditable status to CMS applies to any entity that is exempted from notice requirements according to § 423.56(b).

Response: It is our view that the practical need for disclosure of creditable status notices is directly related to a beneficiary's understanding of their options related to enrolling in Part D and any consequences should they choose not to, such as the late enrollment penalty. It also provides the beneficiary with information about how their coverage compares to what is available under a Part D plan. Beneficiaries enrolled in a PDP, MA-PD plan, PACE plan or cost plan that provides qualified prescription drug coverage are enrolled in Part D, and therefore not subject to any consequence of choosing not to enroll. Including these types of coverage in the list of coverage that may be considered creditable ensures that at no time could a beneficiary who has maintained enrollment in a legitimate Part D plan be subject to the late enrollment penalty for the same time period. However, sending notice of creditable status seems superfluous since, as these plans are Part D plans, the creditable status is automatic.

The statute at 1860D–13(b)(6)(B) of the Act exempts PDP sponsors and MA organizations from providing notice of creditable coverage to its members. Since sections 1860D–21(e) and (f) of the Act provide that we treat cost-based HMO and CMPs and PACE organizations that elect to provide qualified prescription drug coverage similar to MA-PD local plans, such cost-based HMO and CMP and PACE organizations offering qualified prescription drug coverage will also be excepted from this notice requirement. We will revise the notice requirements under § 423.56(c) to reflect that PACE plans and 1876 Cost plans offering qualified prescription drug coverage as excepted entities from the notice requirements under § 423.56(c). We also note that PACE plans and section 1876 of the Act cost plans that do not offer qualified prescription drug coverage must provide notices, as required. To ensure that Part D plan members understand their options, we will ensure that an explanation of the late enrollment penalty and the concept of creditable coverage are included in plan documents.

Similarly, a requirement for organizations that provide Part D benefits to submit separate notice would be duplicative by their nature as CMS approved Part D plans, they are creditable. We will revise § 423.56(e) to clarify that all entities providing CMS-approved Part D coverage do not have

to disclose creditable status of Part D coverage to us under this paragraph.

Comment: One commenter suggests that we consider ways that entities could provide the required notice of creditable status to beneficiaries and CMS via electronic means.

Response: We recognize that most plan documents have been historically provided to beneficiaries in hard-copy (that is, paper) but know from the comments received from plan sponsors and business advocates that participants are receiving plan information through other electronic means, such as websites and e-mail. Most beneficiaries are probably accustomed to receiving materials in one of these manners. We feel that paper documents have better ensured that the beneficiary receives and understands the information. In addition, paper documents will provide beneficiaries a hard copy that they can present whenever needed to show proof of creditable coverage. Since beneficiaries may already be choosing to receive information electronically, we will explore this option as we develop operational guidance for creditable notice requirements.

As for entities notifying us of the creditable status of their coverage, we will describe the form and manner in which entities disclose this information to us in operational guidance and will consider various options for entities to do so.

C. Voluntary Prescription Benefits and Beneficiary Protections

1. Overview and Definitions (§ 423.100)

Proposed subpart C of part 423 implemented sections 1860D–2, 1860D–4(a), 1860D–4(b), 1860D–4(i), 1860D–4(k), 1860D 11(a), 1860D–21(a), 1860D–21(c)(3), and 1860D 21(d)(2) of the Act. This subpart set forth requirements regarding—

- Definitions for terms that are frequently used in this subpart.
- The benefits offered by Part D sponsors.
- The establishment of prescription drug plan service areas.
- Access standards with regard to covered Part D drugs.
- Part D sponsor formularies.
- Information dissemination by Part D sponsors.
- Disclosure to beneficiaries of pricing information for generic versions of covered Part D drugs.
- Privacy, confidentiality, and accuracy of PDP sponsors' beneficiary records.

Below we summarize the provisions of subpart C and respond to public comments. (Please refer to the proposed rule (69 FR 46646) for a detailed discussion of our proposals.)

a. Part D Drug

The definition of a covered Part D drug in § 423.100 of our proposed rule closely followed the statutory definition in section 1860D–2(e) of the Act. According to this definition, a covered Part D drug was available only by prescription, approved by the Food and Drug Administration (FDA), used and sold in the United States, and used for a medically accepted indication (as defined in section 1927(k)(6) of the Act). A covered Part D drug included prescription drugs, biological products, insulin as described in specified paragraphs of section 1927(k) of the Act, and vaccines licensed under section 351 of the Public Health Service Act. The definition also included ''medical supplies associated with the injection of insulin (as defined in regulations of the Secretary).'' We proposed to define those medical supplies to include syringes, needles, alcohol swabs, and gauze.

In accordance with section 1860D–2(e)(2) of the Act, the definition of a covered Part D drug specifically excluded drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under section 1927(d)(2) of the Act, with the exception of smoking cessation agents. In accordance with section 1927(d)(2) of the Act, the drugs or classes of drugs that may currently be excluded or otherwise restricted under Medicaid include: (1) agents when used for anorexia, weight loss, or weight gain; (2) agents when used to promote fertility; (3) agents when used for cosmetic purposes or hair growth; (4) agents when used for the symptomatic relief of cough and colds; (5) prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations; (6) nonprescription drugs; (7) outpatient drugs for which the manufacturer seeks to require that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee as a condition of sale; (8) barbiturates; and (9) benzodiazepines.

The definition of a covered Part D drug also excluded any drug for which, as prescribed and dispensed or administered to an individual, payment would be available under Parts A or B of Medicare for that individual (even though a deductible may apply).

Except as otherwise provided below, the final rule adopts the definition of ''covered Part D drug'' set forth in § 423.100 of the proposed rule.

Comment: Several commenters were confused about the distinction between drugs that may be covered under Part D given the definition of the term ''covered Part D drug'' in section 1860D–2(e) of the Act and those drugs that are actually included on a Part D plan's formulary.

Response: In order to clarify when we are referring to a drug that may be covered under Part D and one that not only is covered by Part D but is also included on a particular Part D plan's formulary, we refer to drugs that may be covered under Part D, consistent with the definition of the term ''covered Part D drug'' in section 1860d–2(e) of the Act, simply as ''Part D drugs.'' We use the term ''covered Part D drug'' to refer to a drug that not only is a Part D drug, but that is included in a Part D plan's formulary or treated (through a coverage determination or appeal described in subpart M of this preamble) as being included in a Part D plan's formulary, and is obtained at a network pharmacy or at an out-of-network pharmacy in accordance with § 423.124 of our final rule. Both terms are defined in § 423.100 of our final rule.

Comment: One commenter recommended that we consider expanding the definition of ''medically accepted indication'' beyond the FDA-approved indications to include uses in official compendia or research. Another commenter was concerned that the definition of ''medically accepted indication'' may allow Part D sponsors to limit their payments for use of Part D drugs solely to FDA-approved indications even though clinical standards allow for alternative uses. Another commenter was concerned that pharmacists will be penalized for dispensing prescriptions that are prescribed for an indication that is not a medically accepted indication. This commenter indicated that pharmacists cannot be expected to contact each physician for each prescription in question to determine if the drug is being prescribed for a medically-accepted indication.

Response: To qualify as a Part D drug, a drug or biological must be used for a medically accepted indication, as defined under section 1927(k)(6) of the Act. This definition states that a medically accepted indication means not only any use for a covered outpatient drug which is FDA-approved, but also a use which is supported by one or more citations included or approved for inclusion in any of the compendia listed in section 1927(g)(1)(B)(i) of the Act-the American Hospital Formulary Service Drug Information, United States

Pharmacopoeia-Drug Information, the DRUGDEX Information System, and American Medical Association Drug Evaluations. We cannot extend the meaning of ''medically accepted indication'' to cover uses in research, as one commenter notes, since the definition of ''medically accepted indication'' in section 1927(k)(6) of the Act does not include the reference in section 1927(g)(1)(B)(ii) of the Act to peer-reviewed medical literature. Thus, a ''medically accepted indication'' is limited by statute to a use for a covered outpatient drug which is approved by the FDA, or the use of which is supported by one or more citations in the compendia listed above. It will be Part D plans' responsibility to ensure that covered Part D drugs are prescribed for a medically accepted indication; plans may, for example, rely on utilization management policies and procedures (which we will review as part of our comprehensive review of Part D plan benefits) to ensure that drugs are prescribed and used for medically accepted indications. We clarify that pharmacists will not be required to contact each physician to verify whether a prescription is being used for other than a medically accepted indication.

Comment: Some commenters recommended including coverage for all EPA-recommended disposal methods and disposal solutions as part of the definition of ''medical supplies associated with injection of insulin''. The commenters noted that proper disposal of needles and lancets are necessary to patient safety and important to public health. Some commenters requested that the definition include lancets, blood glucose test strips, glucometers, syringes, and needles. One commenter suggested that gauze not be included.

Response: We are interpreting the term ''medical supplies associated with the injection of insulin'' in section 1860D–2(e)(1)(B) of the Act as comprising syringes, needles, alcohol swabs, gauze, and insulin delivery devices not otherwise covered by Part B, such as insulin pens, pen supplies, and needle-free syringes. Given that section 1860D–2(e)(2)(B) of the Act excludes products covered by Part B from the definition of a Part D drug, test strips and lancets, which are covered under Part B, cannot be covered under Part D. While we recognize the importance of needle disposal systems, we also do not consider the systems to be directly associated with injection. Thus, these devices fall outside of our interpretation of medical supplies associated with the injection of insulin.

We note that it is our intention to narrowly construe further Part D plan determinations of what constitutes ''medical supplies associated with the injection of insulin'' in order to ensure that such determinations are consistent with the examples we have provided, and that they do not lead to an inappropriate expansion of the Part D benefit.

Comment: Some commenters asked for clarification on coverage of smoking cessation products, specifically regarding whether over-the-counter products will be covered under Part D. Another commenter suggested that in order to cover smoking cessation products, Part D plans should require proof of smoking cessation classes.

Response: Section 1860D–2(e)(1)(A) of the Act specifies that a Part D drug is a drug that may be dispensed only upon a prescription. Although section 1860D–2(e)(1)(B) of the Act specifically allows smoking cessation agents to be covered under Part D, such agents must not otherwise be excluded from coverage under Part D. Over-the-counter smoking cessation products (for example, gum and most patches), by virtue of being not being drugs that may be dispensed only upon a prescription, therefore cannot be considered Part D drugs, even though they are smoking cessation products. Smoking cessation products that may be dispensed only upon a prescription, however (for example, some patches, oral inhalants, nasal sprays, and Zyban), may be considered Part D drugs provided they meet all other applicable requirements under the definition of a Part D drug in § 423.100 of the final rule. We do not have the authority to require Part D plans to condition coverage of permissible smoking cessation agents on proof of smoking cessation classes.

Comment: One commenter requested clarification in the final rule that Part D plans are not prohibited from providing drugs on the exclusion list (under section 1927(d)(2) of the Act, other than smoking cessation drugs) if they are provided through an enhanced benefit.

Response: As provided in § 423.104(f)(1)(ii)(A) of our final rule and in accordance with section 1860D–2(a)(2)(A)(ii) of the Act, Part D plans may only provide coverage of drugs that are specifically excluded as Part D drugs under section 1860D–2(e)(2)(A) of the Act, that is, drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under section 1927(d)(2) of the Act, with the exception of smoking cessation agents—if they do so as supplemental benefits through enhanced alternative coverage and if they would otherwise meet the definition of a Part D drug under section 1860D–2(e)(1) of the Act, but for the application of section 1860D–2(e)(2)(A) of the Act.

Comment: Many commenters urged us to remove benzodiazepines from the exclusion list indicating the multiple therapeutic uses of this drug. One commenter was concerned that excluding drugs such as these from the Part D benefit would force health care providers to alter how they treat patients based on which medications are Part D drugs. Many commenters noted that benzodiazepines serve as valuable therapy for anxiety disorders, bipolar disorder, Parkinson's disease, seizures, and other conditions. Some commenters noted that excluding drugs such as benzodiazepines that are inexpensive, first-line therapies would require more expensive drugs to be prescribed simply because they are covered. Some commenters were concerned about the dangers of beneficiary withdrawal from benzodiazepines if these drugs are not covered under Part D. Some commenters were concerned about loss of drug coverage for benzodiazepines for dual eligibles, especially because benzodiazepines are covered in many States. Many commenters also urged us to remove barbiturates from the exclusion list, citing similar reasons as those listed for benzodiazepines.

Some commenters urged us to make an exception for vitamins used under special circumstances, specifically with ESRD patients. Another commenter was concerned about the exclusion of renal vitamins under Part D and requested that we allow the coverage of water-soluble vitamins lost during dialysis to be covered under Part D. Another commenter noted that prescription vitamins are relatively inexpensive.

Some commenters requested coverage of over-the-counter medications for beneficiaries with certain conditions. One commenter asked us to reconsider excluding over-the-counter drugs that were formerly prescription-only drugs and now have over-the-counter status. Another commenter recommended including a provision allowing over-the-counter drugs to be covered if prescribed in the same manner as a prescription item. Another commenter asked us to consider over-the-counter drugs and medications for unintended weight loss as a covered drug under Part D. One commenter suggested that we amend the exclusion for ''agents used for symptomatic relief of cough or cold'' to ''non-prescription agents used for symptomatic relief of cough or cold''.

Response: Section 1860D–2(e)(2) of the Act clearly requires us to exclude certain drugs from the definition of a Part D drug. According to the statute, the definition of a Part D drug specifically excludes certain drugs or classes of drugs that may be excluded from Medicaid coverage under section 1927(d)(2) of the Act, including agents when used for anorexia, weight loss, or gain; agents when used for cosmetic purposes or hair growth; agents when used for symptomatic relief of cough and colds; prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations; outpatient drugs for which the manufacturer seeks to require that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee as a condition of sale; nonprescription drugs; barbiturates; and benzodiazepines. We have no flexibility to allow Part D coverage of any of these drugs, including over-the-counter drugs used to treat certain medical conditions, except as provided in § 423.104(f)(1)(ii)(A) of the final rule, which permits Part D plans to provide coverage of drugs that otherwise meet the definition of a Part D drug under section 1860D–2(e)(1) of the Act and are not otherwise excluded under section 1860D–2(e)(2)(B) of the Act, if they do so as supplemental benefits through enhanced alternative coverage. We also note that insurance or otherwise, group health plans, or third party payment arrangements (including States under Medicaid and State Pharmaceutical Assistance Programs) may, at their discretion, provide Part D enrollees with supplemental coverage for drugs excluded from coverage under Part D.

Comment: One commenter said that many of the categories of excludable drugs in section 1927(d)(2) of the Act refer to drugs when used for a specific purpose and that it is inappropriate to simply exclude these drugs when they may be covered depending on the specific clinical use. This commenter recommended that that we provide coverage for potentially excludable drugs when they are prescribed for a clinical use not covered by section 1927(d)(2) of the Act. Two examples provided were ''weight loss agents'' when used not for cosmetic purposes, but for the treatment of morbid obesity, and decongestant combination products, which while commonly prescribed to treat coughs and colds, could be used for the treatment of allergic conditions.

Response: Drugs that are excluded from coverage under Part D when used as agents for certain conditions may be considered covered when used to treat other conditions not specifically excluded by section 1927(d)(2) of the Act, provided they otherwise meet the requirements of section 1860D–2(e)(1) of the Act and are not otherwise excluded under section 1860D–2(e)(2)(B) of the Act. To the extent this is the case, and a drug is dispensed for a ''medically accepted indication'' as described in the statute, weight loss agents may be covered for the treatment of morbid obesity, and decongestant products for example, may be covered when used to treat allergies. However, we clarify that Part D plans may establish utilization management processes in order to ensure that such drugs are being prescribed for medically accepted indications that are not excluded under section 1927(d)(2) of the Act (for example, decongestant products when used for ''symptomatic relief of coughs and colds'').

Comment: One commenter suggested excluding drugs that have non-prescription drug alternatives available as Part D drugs. Two commenters supported excluding drugs that are ''lifestyle'' drugs such as Viagra, Levitra, and Cialis.

Response: We do not have the authority to exclude the drugs if they meet all the criteria of a Part D drug as provided under section 1860D–2(e)(1) of the of the Act and are not otherwise excluded under section 1860D–2(e)(2) of the Act. However, we clarify that Part D plans may subject these drugs to utilization management processes provided we do not find such processes to discourage enrollment by certain Part D enrollees as part of the benefits package review we will conduct (and which is discussed in detail elsewhere in this preamble).

Comment: One commenter supports the current statutory language regarding the manufacturer tying arrangements exclusion, whereas another commenter supports expanding this prohibition but does not specify how we should expand it. One commenter opposes any CMS effort to mandate the interactions between Part D plans and pharmaceutical manufacturers, and another asks us to affirm that this exclusion will not interfere with Part D plan decisions to cover drugs/diagnostic test combinations if manufacturers do not require the purchase of the combinations. Yet another commenter points out that the tying arrangement exclusion would exclude drugs from Part D coverage that are tied to one pharmacy system because of requirements for patient monitoring.

Response: We appreciate the clarification provided by the various commenters. We are not expanding the manufacturer tying arrangement exclusion of coverage under Part D in our final rule. We believe that existing Federal fraud and abuse laws, including the anti-kickback statute at section 1128B(b) of the Act, as well as the civil monetary penalty provision at Section 1128A(a)(5) of the Act, provide clear guidance regarding what are and are not inappropriate manufacturer tying arrangements. Manufacturers remain responsible for ensuring that they do not engage in any tying arrangements that violate the anti-kickback statute or, where applicable, the civil monetary penalty provision prohibiting inducements to beneficiaries.

Comment: Some commenters asked for clarification on which vaccines are covered under the Part D benefit and suggested that we provide additional guidance on how non-Part B vaccines are to be covered under Part D, including administrative fees. Another commenter requested that we strongly encourage Part D plans to include all vaccines that are not covered under Part B on their formularies.

Response: The definition of a Part D drug in section 1860D–2(e) of the Act clarifies that Part D may cover a biological product described in sections 1927(k)(2)(B)(i) to (k)(2)(B)(iii) of the Act—to include a vaccine licensed under section 351 of the Public Health Service Act. Since section 1860D–2(e)(2)(B) of the Act excludes an otherwise covered Part D drug from coverage under Part D ''if payment for such drug as so prescribed and dispensed or administered with respect to that individual is available (or would be available but for the application of a deductible) under Part A or B for that individual,'' certain drugs and vaccines would be covered under Part D only to the extent they are not covered under Part B.

In addition to excluding Part B vaccines from coverage under Part D, section 1860D–2(e)(3) of the Act provides that a Part D plan may exclude from coverage covered Part D drugs for which payment may not be made under section 1862(a) of the Act if applied to Part D. Section 1862(a)(1)(A) generally excludes from payment items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, except those vaccines identified in section 1862(a)(1)(B) of the Act as covered Part B vaccines. Section 1862(a)(1)(A) of the Act, however, excepts from this rule vaccines covered under Part B. Therefore, if these provisions are read literally, Part D plans would be permitted to exclude

from coverage preventative vaccines that are covered Part D drugs because they are not ''reasonable and necessary for the diagnosis or treatment of an illness or injury.''

However, we argue that whereas section 1862(a)(1)(B) of the Act requires coverage under Part B of covered Part B vaccines, by analogy, section 1862(a)(1)(B) of the Act as applied to Part D should be read as requiring coverage under Part D of vaccines that are covered Part D drugs. This argument is buttressed by the fact that the Congress specifically defined Part D drugs under section 1860D–2(e)(1) of the Act to include vaccines. Moreover, section 1860D–2(e)(3) of the Act references all of section 1862(a) of the Act, and the only way to give meaning to the reference to section 1862(a)(1)(B) of the Act is to extend the provision to permit coverage of Part D vaccines. In other words, if section 1862(a)(1)(B) of the Act as applied to Part D were read literally as only permitting coverage of Part B vaccines, the reference in section 1860D–2(e)(3)(A) of the Act to section 1862(a)(1)(B) of the Act would be rendered meaningless.

Building on the argument that by analogy section 1862(a)(1)(B) of the Act should be extended to Part D so as to require coverage of non-Part B vaccines under Part D, the standard under Part D should reflect a standard similar to section 1862(a)(1)(b) of the Act but adapted to apply to preventative vaccines. Therefore, we believe such standard should be vaccines that are ''reasonable and necessary for the prevention of illness.'' Plans will need to develop explicit criteria that can be applied on a case-by-case basis to determine that the administration of Part D vaccine is ''reasonable and necessary'' and that the Part D vaccine is therefore a covered Part D drug. Presumably these will comply with any widely accepted practice guidelines. If widely accepted practice guidelines are not available for certain vaccines, Part D plans will need to develop criteria that they can support with sound clinical reasoning.

Currently, most vaccines of interest to the Medicare population are covered under Part B. Although Part B makes only three exceptions (influenza, pneumococcal, and hepatitis B vaccines for high risk patients) to its rule requiring injury or direct exposure, these three exceptions probably account for the majority of vaccinations needed by an elderly population. Since many of the remaining vaccines on the market are administered during childhood, we do not expect that Part D will cover a large number of vaccines. However, as more vaccines are developed and practice guidelines develop, Part D plans might face a growing burden with supplying vaccinations to significant numbers of their Part D patient populations. Therefore, the ability of Part D plans to limit payment to those situations that are ''reasonable and necessary for the prevention of illness'' will become more and more important.

Given the definition of dispensing fees we have incorporated in the final rule, the costs of Part D-covered vaccine administration could not be covered as part of a dispensing fee. Neither could those costs be covered as separate administrative fees, since as discussed elsewhere in this preamble, other than medication therapy management programs (described in subpart D), we do not expect medical or clinical services to be included in administrative fees.

As discussed in subpart J, Part D-covered vaccines administered in a physician's office will be covered under the out-of-network access rules at § 423.124 of our final rule. The costs of vaccine administration may be included in physician fees under Part B since Part B pays for the medically necessary administration of non-covered drugs and biologicals. However, there is currently no ready mechanism for physicians to bill Part D plans for Part D-covered vaccine costs. In the short-term, we will require that a Part D enrollee self-pay the physician for the Part D-covered vaccine cost and submit a paper claim for reimbursement by his or her Part D plan. This approach is consistent with how beneficiaries accessing covered Part D drugs at an out-of-network pharmacy will be reimbursed by Part D plans for costs associated with those drugs. Once Part D is implemented, we will get a better sense for the actual volume of Part D-covered vaccines (and other covered Part D drugs appropriately dispensed and administered in a physician's office) and the need and most appropriate mechanisms for any automatic cross-over procedures such that physicians could submit claims for reimbursement of Part D-covered vaccine ingredient costs directly to the appropriate Part B carrier. Any such automatic cross-over procedures would mean that beneficiaries would not have to submit paper claims and, instead, physicians could submit a single claim for reimbursement of both the Part D-covered vaccine ingredient costs and the administration fee directly to the appropriate Part B carrier, which would forward the Part D charge to the appropriate Part D plan.

Comment: One commenter asked that we cover individually compounded medications or combinations of medications. Another commenter stated that we should not consider compounded drugs as meeting the definition of a Part D drug, as it is contrary to the definition in the MMA and would put patients at risk.

Response: Historically, extemporaneous compounding has filled an important role in pharmacy practice and continues to be an important part of contemporary pharmacy practice. While less than one percent of prescriptions are compounded, these compounded prescriptions often provide medically necessary drug therapies that would otherwise be unavailable to patients. Compounding also provides many independent pharmacies with the opportunity to offer services that competitively differentiate them from the chain industry. In addition, compounded prescription drug products are frequently reimbursed under commercial prescription drug benefit plans. Therefore, excluding compounded prescription drug products from Medicare Part D would be a significant change from current pharmacy practice.

Section 1860D–2(e)(1)(A) of the Act defines a Part D drug as including a drug that may be dispensed only upon a prescription and that is described in section 1927(k)(2)(A)(i), (A)(ii) or (A)(iii) of the Act. As a matter of simplification, we refer to these products as ''FDA approved prescription drug products,'' and note that, as used in this part of the preamble, that term incorporates the non-FDA approved drug products specifically described under sections 1927(k)(2)(A)(ii) and (A)(iii) of the Act.

Compounded prescription drug products may contain: (1) all FDA approved prescription drug products; (2) some FDA approved prescription drug products; or (3) all non-FDA approved drug products. While the strictest reading of section 1927(k)(2) of the Act appears to indicate that non-FDA approved compounded prescription drug products are not Part D drugs, we believe that FDA-approved prescription drug product components of a non-FDA approved compounded prescription drug product could be considered to be Part D drugs. The definition of a Part D drug is not based on the final form of the drug as dispensed to the beneficiary; rather, section 1860D–2(e)(1)(A) of the Act speaks to a drug ''that may be dispensed'' only upon a prescription and that meets the requirements of section 1927(k)(2) of the Act. Therefore,

the FDA approved component can satisfy section 1860D–2(e)(1)(A) of the Act even if the finished product does not. Although reimbursement must be limited to the FDA approved prescription drug components (that is, no reimbursement is available for compounded products containing only products that are not approved by the FDA, or otherwise described under sections 1927(k)(2)(A)(ii) and (A)(iii) of the Act, or only over-the-counter products), these usually account for the most significant drug costs and, accordingly, current commercial practice often limits reimbursement to the most expensive component only. In addition, the labor costs associated with mixing a compounded drug product that contains at least one FDA approved prescription drug component can be included in dispensing fees (as defined in § 423.100 of our final rule).

Comment: Two commenters suggested covering medical foods under the Part D benefit because medical foods contain vitamins and nutrition that are beneficial to beneficiaries with certain diseases such as End Stage Renal Disease (ESRD). Another commenter asked that we cover parenteral nutrition therapy.

Response: It is not clear what the commenter meant by ''medical foods.'' If ''medical foods'' refers to products that are vitamins and mineral products, these are excluded from the definition of Part D drugs and are not a covered Part D benefit. In addition, enteral nutrients are not regulated as drugs by the FDA and are therefore not covered under Part D.

On the other hand, parenteral nutrition frequently contains primary components such as amino acids, nitrogen products, and dextrose mixtures that are regulated by the FDA as drugs and therefore meets the definition of a Part D drug if prescribed for a medically accepted indication and not otherwise excluded under section 1860D–2(e)(2) of the Act. Vitamins and minerals added to parenteral nutrition are not be considered Part D drugs, and costs associated with these vitamins or minerals cannot be paid for under Part D.

Part D plans would only need to include parenteral nutrition coverage for reasonable and necessary medically accepted indications that are not covered under Parts A or B. These situations would likely involve long-term care facility or home infusion patients who do not qualify for Part B coverage under the prosthetic benefit provision for permanent dysfunction of the alimentary tract. This could include temporary situations in which patients are unable to swallow or absorb nutrients from the alimentary tract, either for physical or cognitive reasons. We are currently unable to estimate the potential impact of such coverage on Part D expenditures. However, Part D plans will need to establish appropriate policies and procedures in order to limit Part D coverage of parenteral nutrition to patients with medically accepted indications that are not otherwise covered by Parts A or B. In addition, we note that Part D plans are not responsible for the costs of supplies and equipment related to parenteral nutrition therapy.

Comment: One commenter suggested additional supplies to consider for Part D coverage: spacers and aerochambers for administration of inhalation products, devices for administration of eye drops, and flushing supplies (for example, saline and heparin for home infusion therapy).

Response: Section 1860D–2(e)(1) of the Act provides us with authority to deem medical supplies to be Part D drugs to the extent they are associated with the injection of insulin. Thus, the supplies mentioned by this commenter cannot be covered under Part D, as they are not associated with the injection of insulin. We clarify that although heparin is a Part D drug, a heparin flush is not used to treat a patient for a medically accepted indication, but rather to dissolve possible blood clots around an infusion line. Therefore, heparin's use in this instance is not therapeutic but is, instead, necessary to make durable medical equipment work. It would therefore not be a Part D drug when used in a heparin flush.

Comment: One commenter recommended that Part D drugs should include liquid, chewable, transdermal and other special dosage forms and delivery mechanisms to accommodate swallowing limitations and intravenous medications, such as antibiotics.

Response: The definition of a Part D drug at section 1860D–2(e) of the Act places no limitations on drug dosage forms and delivery mechanisms provided that a drug or biological product is not otherwise excluded by the statute. We expect Part D plans to provide an adequate benefit that includes coverage of special dosage forms and delivery mechanisms to fit the needs of all their enrollees.

Comment: Several commenters supported our proposed framework for Part D coverage wrapping around Part B coverage at the individual level. However, other commenters recommended that drugs currently covered under Part B be excluded from coverage under Part D until the mandated study on the transitioning of Part B prescription drug coverage into Part D is released. Another commenter recommended that individual drugs be paid by either Part B or Part D in all circumstances.

Response: The statutory definition of the term ''covered Part D drug'' would, under section 1860D–2(e)(2)(B) of the Act, exclude any drug for which, as dispensed and administered to an individual, payment would be available under Parts A or B of Medicare for that individual (even though a deductible may apply). By including the language ''as so prescribed and dispensed or administered,'' section 1860D–2(e)(2)(B) of the Act makes a distinction between what would be paid for under Part D as opposed to Part B. This language indicates that the Congress was aware that some drugs could qualify for payment under Part B in some circumstances and Part D in others, depending on the way those drugs are dispensed or administered. Given the statutory definition of the term ''covered Part D drug'', we cannot preclude drugs that may be covered under Part B under some circumstances (for example, when they are furnished ''incident to'' a physician's service), but that are not covered under Part B under other circumstances, from being covered under Part D under such other circumstances (for example, because they are self-administered by the patient at home). Such a policy would require statutory changes by the Congress. The various issues raised by the drugs covered under Part B for the administration of the Part D drug benefit will be addressed in our report mandated by section 1860D–42(c) of the Act.

Comment: We solicited comments concerning any drugs that may require special guidance with regard to their coverage under Part D, and any gaps that may exist in the combined ''Part D & B'' coverage package. A number of commenters requested that we further clarify the relationship between drugs covered under Medicare Part B and drugs that will be covered under Part D. These commenters would like us to clarify how Part D plans can recognize Part B covered drugs since no universal list exists, Part B coverage differs by patient and situation, and Part B coverage policies differ regionally. They raise concerns about appropriately limiting coverage of drugs under Part D while achieving our goal of wrapping around Medicare Part B to the greatest extent possible.

Response: We acknowledge that there are numerous complexities involved in the distinction between drugs covered

under Parts B and D, as well as with wrapping around existing drug coverage under Part B. Nevertheless, section 1860D–2(e)(2)(B) of the Act states that Part D plans must exclude any drug that would otherwise be considered a Part D drug for which, as so prescribed and dispensed or administered to that individual, payment would be available under Parts A or B (even though a deductible may apply). Furthermore, we believe that the language ''as so prescribed and dispensed or administered'' indicates the Congress's awareness that the determination regarding whether a particular drug is covered under Part B or Part D could differ on a case-by-case basis.

Despite the complexities, we believe Part D plans can best wrap around existing Part B coverage under Part D by understanding the scope of the definition of covered Part D drug, becoming familiar with the general categories of Part B covered drugs, and planning for potential Part B interactions that are likely to be encountered in specific settings with regard to some of these categories.

Part D drugs are not limited to typical outpatient prescription drugs. The definition includes injectable prescription drugs (for example, intramuscular, intravenous, and infusible drugs, as well as vaccines). Some Part D plans may lack experience with covering the drugs under an outpatient prescription drug benefit program because they are more commonly covered under commercial medical benefits, as opposed to commercial prescription drug benefits.

The implementation of the Part D benefit does not alter coverage or associated rules for drugs currently covered under Part B. Part B covers drugs in a variety of settings. In almost all of these settings the question of whether coverage should be provided under Part D will not arise since the drugs are being provided in the context of a service or procedure. For a limited number of categories, however, pharmacists and infusion providers will have to determine whether to bill Part B or Part D, and Part D sponsors will need to confirm whether Part D is being billed correctly. In some cases, this determination can be made on the basis of the drug. For example, in the case of oral anti-cancer drugs, there is a list of drugs covered under Part B based on certain statutory criteria. All other oral anti-cancer drugs will be covered under Part D, provided they otherwise meet the definition of a Part D drug. In other cases, the pharmacist or infusion provider would need information about the member in order to bill appropriately. For example, in the case of drugs used in immunosuppressive therapy, Part B should be billed in the case of a beneficiary whose transplant has been covered by Medicare. Part D should make payment in all other instances. We will provide more information and guidance on the relation between Part B and Part D coverage in separate guidance to Part D plans.

Based upon the definition of the term ''Part D drug'' and the general categories of coverage under Part B, we believe that Part D plans could implement utilization management strategies to identify potential Part B drug coverage overlap for individuals and verify appropriate coverage accordingly. For example, if a Part D beneficiary were filling a retail prescription for an antiemetic, prior authorization could be used to ensure that the drug is not covered by Part B. Similarly, prior authorization could be used to flag drugs dispensed via home infusion that are covered under the Part B durable medical equipment policy. Plans will need to ensure that they do not cover any drugs which, as prescribed and dispensed or administered, are covered under Part B in a specific region under its local medical review policy (LMRP).

We clarify that MA organizations must follow fee-for-service coverage rules as provided in section 1852(a)(1) of the Act in determining whether to pay for a drug under its Part A/Part B or Part D benefits. Payment for injectable drugs that Medicare considers to be usually not self-administered should be paid under the Part A or Part B benefits if provided in a physician's office, and under Part D if dispensed by a network pharmacy. Even if an MA plan offers coverage under Part D of an injectable drug that Medicare considers to be usually not self-administered (for example, Avonex) the plan cannot deny coverage of this drug under its Part A or Part B benefits when furnished in a physician's office.

Comment: Several commenters noted that excluding Part B drugs from coverage under Part D regardless of whether the consumer is enrolled in Part B is seriously detrimental to consumers who enroll in Part B but who cannot effectuate their enrollment for many months due to the Part B enrollment timeframes. Consumers without Part B coverage, but who intend to enroll, could enroll in Part D in April of 2006 but would not be able to gain coverage for Part B drugs until 15 months later (enrollment in January effective in July). These commenters argue that we should make an exception for beneficiaries in this predicament such that their Part D plans could cover Part B drugs. This is especially important for full-benefit dual eligible individuals in this situation, since they would be unable to fall back on Medicaid to obtain coverage for Part B-covered medications. They recommend that Part D plans be required to cover Part B medications for a consumer for up to 15 months (the maximum amount of time it could take to effectuate an enrollment under Part B).

Response: Section 1860D–2(e)(2)(B) of the Act specifies that a drug prescribed to a Part D eligible individual that would otherwise qualify as a Part D drug cannot be considered a covered Part D drug if payment for such drug ''... is available (or would be available but for the application of a deductible) under part A or B for that individual.'' We interpreted this to mean that if payment could be available under Part A or Part B to the individual for such drug, then it will not be covered under Part D. Thus, for all Part D eligible individuals, drugs covered under Parts A and B are available if they choose to pay the appropriate premiums.

This will be the case even if a beneficiary has Part A, but not Part B, or vice versa, since, as we explain in subpart F of this preamble and at § 423.265(c) of the Act, Part D sponsors must offer a uniform benefit package in order to carry out the Congress's intent in section 1860D–13(a)(1)(F) of the Act. If Part B covered drugs were included in the Part D benefit package only for those enrollees without Part B, but not for others, it would not be possible for Part D sponsors to offer uniform benefit packages for a uniform premium to all enrollees. In addition, we believe that payment for a drug under Part A or B is available to any individual who could sign up for Parts A or B, regardless of whether they actually enrolled or are waiting to be enrolled, as these commenters describe. All individuals who are entitled to premium-free Part A are eligible to enroll in Part B. This includes individuals who are entitled to Part A based on age, disability, and ESRD. All individuals who are entitled to Part B only are age 65 or older and, in almost all instances, not eligible for premium-free Part A. However, they are eligible to buy into Part A for a premium.

Comment: Some commenters recommended that we introduce more consistent coverage rules by adopting national standards rather than relying on local carriers for coverage and payment decisions.

Response: Policies with regard to coverage of infusible drugs covered as DME supplies are uniform across the

country. Some differences do exist between carriers with regard to which injectable drugs will be covered under Part B ''incident to'' a physician service. These differences in coverage in a physician's office setting, however, should not impact whether a Part D plan will cover a prescription for an injectable drug presented at a participating pharmacy. The statute does not exclude ''all drugs'' covered under Medicare, but rather, drugs when Medicare coverage under Part B is available ''as so prescribed and dispensed or administered.''

Comment: One commenter asked about the interface between the hospice benefit and Part D, specifically whether we anticipated that Part D would account for or impact the delivery of hospice drugs.

Response: As provided in section 1861(dd)(1) of the Act, the hospice benefit covers all medications related to a beneficiary's terminal illness. There is no change in Medicare coverage of these drugs. However, all other medications provided to the beneficiary are currently paid for either out-of-pocket or by private insurance. These drugs could now be covered by Part D plans on either a primary or secondary basis depending on the presence or nature of other insurance. Given the life expectancy of beneficiaries receiving hospice benefits, we do not expect this to be a large expense for Part D plans.

b. Dispensing Fees

The MMA does not define the term ''dispensing fee,'' although the terms ''dispensing fee'' and ''dispense'' appear several times throughout the MMA. Because the statute is ambiguous on the meaning of ''dispensing fee,'' in the proposed rule we did not propose a specific definition of ''dispensing fee,'' but instead offered three different options we believed would be reasonable, permissible definitions of the term and invited comments on which option would be most appropriate under Part D.

- Option 1: The dispensing fee will include only those activities related to the transfer of possession of the covered Part D drug from the pharmacy to the beneficiary, including charges associated with mixing drugs, delivery, and overhead. The dispensing fee will not include any activities beyond the point of sale (that is, pharmacy follow-up phone calls) or any activities for entities other than the pharmacy.
- Option 2: The dispensing fee will include the activities included in Option 1, but in addition will include amounts for the supplies and equipment necessary for the drugs to be provided in a State in which they can be effectively administered.
- Option 3: The dispensing fee will include the activities in Option 2, but in addition will include activities associated with ensuring proper ongoing administration of the drugs, such as the professional services of skilled nursing visits and ongoing monitoring by a clinical pharmacist.

We also requested comments regarding any implications for our proposed options for defining dispensing fees vis-à-vis the administration of other drugs (for example, vaccines and injectable long-acting antipsychotic drugs).

Comment: The majority of commenters favored Option 1 claiming that this definition is consistent with current industry practice regarding dispensing fees. Several said that professional services involved in providing medications should more appropriately be covered under Parts A and B, and another commenter opined that Options 2 and 3 were burdensome for Part D sponsors. Another commenter expressed concern that what is currently covered under Part B should not be shifted to Part D through the dispensing fees. Other commenters stated that, although they supported Option 1, they believed that the definition proposed for Option 1 was too narrow. One commenter suggested that pharmacists are required to provide patient counseling for Medicaid patients under OBRA 1990 and that they should be reimbursed for those efforts. They also felt that the definition of what it means to dispense a drug should be clarified. One commenter argued that supplies, equipment and professional services needed to deliver a drug should be covered under ancillary fees negotiated between pharmacies and Part D plans and should not be included in dispensing fees. Another commenter pointed out that requiring PBMs to pay for professional services, as contemplated under Option 3, would require them to renegotiate tens of thousands of contracts with the pharmacies in their networks.

Several commenters supported Option 2. One commenter focused on medication packaging and the need to cover packaging specifically designed for the cognitively impaired or those with physical impairments.

Other commenters favored adoption of Option 3. Some of these commenters argued that the Congress meant for home infusion to be covered and that failure to pay for the supplies, equipment and services involved in delivering home infusion drugs was tantamount to failure to cover the drug itself. Since Part D specifically covers those drugs, (antibiotics, pain management, chemotherapy, parenteral nutrition, immune globulin and other infused drugs) they argued that we must require that dispensing fees cover the resources needed to deliver them. Other commenters argued that new treatment modalities were allowing patients to remain at home, a cost-effective setting, to receive their medications, and that some patients might not be able to receive their medications at home should the definition of dispensing fee fail to cover the service, equipment, and supplies needed to deliver the medications in the home setting. One commenter specifically noted the need to cover supplies and services surrounding infusion of long-term anti-psychotic medications in community mental health centers. Two commenters focused on the need to pay for physician services involved in home infusion of certain drugs given that many infections and adverse events take place in this setting. Direct physician supervision of these services is required to mitigate these potential problems.

Other commenters argued for Part D plan flexibility in establishing dispensing fees that would be appropriate for the setting and medication at issue, allowing each Part D plan to define dispensing fee. One commenter thought that Part D plans should be allowed to use tiered dispensing fees to encourage the use of generic drugs. One commenter indicated that point of sale systems in place today already support multiple variations of dispensing fees based on drug or amount of effort required to prepare or administer medication and such systems could handle the multiple variations for the drug benefit. Another commenter specified that the transmission standard should be the National Council of Prescription Drug Program's Telecommunication Standard Version 5.1.

Response: We agree with the majority of commenters that Option 1—including only those activities related to the transfer of possession of the covered Part D drug from the pharmacy to the beneficiary, including charges associated with mixing drugs, delivery, and overhead is the most appropriate definition of the term ''dispensing fees'' for Part D, and we have included a definition of dispensing fees in § 423.100 of our final rule consistent with Option 1.

Although we recognize that Options 2 or 3 would eliminate current gaps in coverage relative to home infused drugs, such approaches would also extend the definition of dispensing fee beyond the

mere transfer of possession of the drug, and certainly beyond what we believe to have been Congressional intent regarding the scope of an outpatient drug benefit. The inclusion of professional services in the definition of dispensing fees is also problematic given the potential for double billing with regard to some of the skilled nursing costs associated with home infusion. In many cases, these skilled nursing costs are separately billable to Part A, Medicaid, or supplemental insurance, and we are concerned about Part D supplanting these other sources of payment.

We believe Option 1 represents the best reading of the statute, since it will limit dispensing fees to a transfer of possession of the drug and will not include any fees associated with administering the drug. We also note that where the Congress wished for us to include the cost of supplies under Part D, it specifically directed us to do so (for example, by requiring that the supplies associated with the injection of insulin be included in the definition of the term Part D drug).

Even though some commenters suggest that the supplies, equipment, and services associated with Options 2 and 3 could be paid for through a separate fee or additional compensation to home infusion and other providers, we caution that such separate administrative fees would not be allowed under Part D. Other than medication therapy management programs, as described in section 1860D–4(c)(2) of the Act, we do not expect medical or clinical services to be included in administrative fees. Please refer to the subpart G preamble discussion of the types of costs that Part D plans may include as administrative costs in their bids. Thus, the costs for professional services associated with home infusion could not be included in the premium bid. In addition, professional services, including those associated with home infusion, may not be included in Part D plan supplemental coverage, given that section 1860D–2(a)(2) of the Act defines supplemental coverage as consisting of: (1) a reduction in the deductible, coinsurance percentage, initial coverage limit, or any combination thereof; or (2) coverage of drugs that are excluded from the definition of a ''Part D drug'' because of the application of section 1927(d)(2) or (3) of the Act.

Provided that Part D plans include only those activities allowed under our definition of dispensing fees in the dispensing fees negotiated with network pharmacies and offer standard contracting terms and conditions to all pharmacies, we note that Part D plans have the flexibility to vary the actual dispensing fee paid to pharmacies. For example, Part D plans may need to increase the dispensing fees paid to rural or long-term care pharmacies in order to obtain their participation in networks and meet the pharmacy access standards.

As detailed elsewhere in this preamble, Part D plans will be required to ensure adequate access to home infusion services as part of their pharmacy network access standards. Thus, enrollees will have access to home infusion services, though they may have to pay for supplies, equipment, and professional services out-of-pocket particularly if they are enrolled in a Part D plan and have no source of supplemental coverage.

As we noted in the proposed rule, our definition of dispensing fees under Part D will not carry over to Part B of the Medicare program. Section 1842(o)(2) of the Act gives the Secretary discretionary authority to pay a dispensing fee to a licensed pharmacy that furnishes certain covered Part B drugs and biologicals to Medicare beneficiaries. While the term ''dispensing fee'' is not defined in section 1842(o)(2) of the Act, the considerations under Medicare Part B, a more comprehensive health insurance product that has separate payment mechanisms for durable medical equipment and professional services, are different from those under Part D.

Comment: Some commenters did not support a particular option for defining the term ''dispensing fees,'' but were more concerned about including certain activities in the definition of dispensing fees (for example, staff, equipment, automation, facilities overhead, time inputting information into a computer, resolving problems with PBMs and prescribing practitioners, counseling the patient, waste disposal, turning the medication over to the patient, particularly when it involved home delivery, and actually packaging the medications). Many of these commenters noted that pharmacists merit a small profit and that dispensing fees should not be specifically designed simply to meet costs. Others felt that terms used in the proposed options were too vague. Specifically, they wanted the meaning of dispensing to be defined to include the costs they outlined. They also wanted to account for the level of complexity and include clear definitions of reconstituting, mixing and compounding drugs, which they believe involve very different equipment, skill and time resources.

Response: We have defined the term ''dispensing fees'' in § 423.100 of our final rule to include reasonable pharmacy costs associated with ensuring that possession of the appropriate covered Part D drug is transferred to a Part D enrollee. We specify that reasonable pharmacy costs may include costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing quality assurance activities consistent with § 423.153(c)(2) of our final rule, measurement or mixing of the covered Part D drug, filling the container, physically providing the completed prescription to the Part D enrollee, delivery costs, special packaging costs, and overhead costs associated with maintaining the facility and equipment necessary to operate the pharmacy. We clarify that in using the term ''reasonable'' pharmacy costs, our intent is to convey that such costs be appropriate for the typical beneficiary in that pharmacy setting. We believe that our definition clarifies commenters' concerns about the inclusion of some overhead costs, time spent inputting information into a computer and resolving problems with PBMs and prescribing practitioners, transferring the medication to the patient, and special packaging costs.

We clarify that reasonable delivery costs include only those costs appropriate for the typical beneficiary in a particular pharmacy setting. Thus, while it would be appropriate for Part D plans to reimburse long-term care, mail-order, and home infusion pharmacies for home delivery costs via the dispensing fee, this would not be the case for retail pharmacies (where the term ''delivery'' would be limited to the transfer of a covered Part D drug from the pharmacist to the patient at the point of sale) because the typical retail customer does not require home delivery. While retail pharmacies may offer home delivery services, Part D plans may not reimburse those pharmacies for these costs, and the delivery cost must be borne by the beneficiary.

As concerns patient counseling, dispensing fees for covered Part D drugs may include pharmacy costs associated with quality assurance activities consistent with § 423.153(c)(2) of our final rule. Section 423.153(c)(1) of our final rule requires Part D plans to represent that pharmacists in their network pharmacies comply with minimum standards for pharmacy practice established by the States. Since almost all States have established requirements for pharmacy practice

related to counseling, we believe that the offer of counseling that pharmacists currently provide their customers will continue consistent with current pharmacy practice in compliance with State requirements. .Any pharmacist counseling activities in addition to those established by the States will have to be negotiated and paid for separately under Part D plans' medication therapy management programs (discussed in greater detail elsewhere in this preamble).

As provided in section 1860D–11(i) of the Act, we cannot intervene in negotiations between pharmacies and Part D plans. Thus, the extent to which Part D plans reimburse pharmacies for their entire dispensing costs (or even in excess of their dispensing costs) will depend on the outcome of those negotiations. In addition, we clarify that we expect Part D plans and pharmacies to account for pharmacy profit as part of negotiated prices—either as part of overhead costs accounted for in dispensing fees or in the reimbursement rates for ingredient costs negotiated with pharmacies.

We clarify that we interpret the term ''mixing'' as used in our definition of the term ''dispensing fees'' to encompass reconstituting and compounding of covered Part D drugs. Further, we note that Part D plans have the flexibility to pay differential dispensing fees to pharmacies based on higher labor costs—for example, for a compounded product relative to a non-compounded covered Part D drug. Plans could also used differential dispensing fees to encourage the use of generics over brand-name drugs as appropriate.

Comment: Another commenter wanted dispensing fees for non-profit entities to reflect their preferred acquisition costs, arguing that without this, Part D would be assisting tax-exempt non-profit competitors of small business pharmacies.

Response: As mentioned previously, we have defined the term ''dispensing fees'' in § 423.100 of our final rule to include pharmacy costs associated with ensuring that possession of the appropriate covered Part D drug is transferred to a Part D enrollee. Plans may wish to consider non-profit entities' preferred acquisition costs in the ingredient cost reimbursement negotiated with those entities as part of negotiated prices on covered Part D drugs. However, it is unclear to us why dispensing fees should vary among non-profit and for-profit pharmacies based on differences in acquisition costs.

Comment: Several commenters emphasized the need to provide dispensing fees tailored to long term care pharmacies. They focused on the need to reimburse long-term care pharmacists for 24-hour care, the specialized packaging that is required, emergency preparation and delivery of medications, and the distinct type of medications typically prepared and delivered.

Response: The definition of dispensing fee in § 423.100 of our final rule encompasses some of the services—for example, specialized packaging, delivery, and preparation of medications (not including the actual administration of those medications)—typically provided by long-term care pharmacies. Additional long-term care pharmacy services could be reimbursed via medication therapy management programs established by Part D plans for institutionalized Part D enrollees.

Comment: Some commenters emphasized the need for the dispensing fee to cover all of the costs involved in providing a medication.

Response: As provided in section 1860D–11(i) of the Act, we cannot intervene in negotiations between pharmacies and Part D plans. Thus, the extent to which Part D plans reimburse pharmacies for their entire dispensing costs will depend on the outcome of those negotiations. Given Part D plans' need to secure a network of providers that meets our access standards, we believe that Part D plans will have every incentive to adequately reimburse pharmacies via dispensing fees for the costs involved with providing covered Part D drugs to Part D enrollees.

c. Long-Term Care Facility

We requested comments regarding the definition of the term long-term care facility in § 423.100 of our proposed rule, which we interpreted to mean a skilled nursing facility (as defined in section 1819(a) of the Act), or a nursing facility (as defined in section 1919(a) of the Act). We were particularly interested to explore whether we should include in the definition facilities other than skilled nursing and nursing facilities—particularly intermediate care facilities for the mentally retarded (ICFs/MR), described in § 440.150, and other types of facilities in which full-benefit dual eligible individuals may reside and which may exclusively contract with long-term care pharmacies in a manner similar to current practice in skilled nursing and nursing facilities.

Comment: We received a number of comments urging us to expand the definition of the term ''long-term care facility'' in the proposed rule. Some of the suggested additions include ICFs/MR; assisted living facilities; other facilities recognized by State law as eligible for payment under Sections 1915(c) (Home and Community Based waivers), 1616(e), and 1115 of the Act; group homes for the developmentally disabled; and other forms of congregate living arrangements regulated by the States. Some commenters suggested that many of these facilities operate under exclusive contracts with long-term care pharmacies. Other commenters urged us not to make the presence of exclusive contracts with long-term care pharmacies the only criterion for defining congregate living arrangements as long-term care facilities, as these beneficiaries could benefit significantly from subsidies for low-income institutionalized Part D enrollees.

Response: We have expanded the definition of the term ''long-term care facility'' in § 423.100 of our final rule to encompass not only skilled nursing facilities, as defined in section 1819(a) of the Act, but also any medical institution or nursing facility for which payment is made for institutionalized individuals under Medicaid, as defined in section 1902(q)(1)(B) of the Act. We note that we have eliminated the reference to nursing facilities as defined in section 1919(a) of the Act, as such facilities are captured as nursing facilities for which payment is made for institutionalized individuals under Medicaid. Such an expansion would include ICFs/MR and inpatient psychiatric hospitals along with skilled nursing and nursing facilities in the definition of a long-term care facility, provided those facilities meet the requirements of a medical institution that receives Medicaid payments for institutionalized individuals under section 1902(q)(1)(B) of the Act. We do not believe that the definition of term long-term care facility should be expanded to include other facilities recognized by State law but not by Medicare or Medicaid, regardless of whether some of these facilities contract on an exclusive basis with long-term care pharmacies. Furthermore, we do not believe that our definitions of terms associated with institutionalized Part D enrollees should conflict. Our revised definition of the term ''long-term care facility'' is consistent with the definition of ''institutionalized'' in subpart P of this rule and will allow for residents of a number of institutional settings to benefit from the special rules for access to covered Part D drugs established for residents of long-term care facilities. 2. Requirements Related to Qualified Prescription Drug Coverage (§ 423.104)

Under section 1860D–11(e)(2)(A) of the Act, we may approve as Part D sponsors only those entities proposing to offer qualified prescription drug

coverage in accordance with our requirements. As provided in section 1860D–2(a)(1) of the Act, qualified prescription drug coverage may consist of either standard prescription drug coverage or alternative prescription drug coverage.

a. Standard Prescription Drug Coverage

As provided under section 1860D–2(b) of the Act, ''standard prescription drug coverage'' consists of coverage of covered Part D drugs subject to an annual deductible; 25 percent coinsurance (or an actuarially equivalent structure) up to an initial coverage limit; and catastrophic coverage after an individual incurs out-of-pocket expenses above a certain threshold. In 2006, the annual deductible will be $250, the initial coverage limit will be $2,250, and the out-of-pocket threshold will be $3,600.

Once a Part D enrollee reached the annual out-of-pocket threshold, in 2006, his or her nominal cost-sharing will be equal to the greater of: (1) 5 percent coinsurance; or (2) a copayment of $2 for a generic drug or a preferred multiple source drug and $5 for any other drug, or an actuarially equivalent structure. (See Table C–1 for a summary version of standard prescription drug coverage benefits for 2006.)

Section 1860D–2(b) of the Act provides that, beginning in 2007, the annual deductible, initial coverage limit, out-of-pocket threshold, and beneficiary cost-sharing after the out-of-pocket threshold is met are to be adjusted annually. In accordance with section 1860D–2(b)(6) of the Act, these amounts will be increased over the previous year's amounts by the annual percentage increase in average per capita aggregate expenditures for Part D drugs for the 12-month period ending in July of the previous year. We requested comments regarding the methods and data sources we might use to determine the annual percentage increase in the first several years of the Part D program.

TABLE C–1
STANDARD PRESCRIPTION DRUG COVERAGE BENEFITS FOR 2006

	Cost-Sharing Percentage	Beneficiary Out-of-Pocket Costs	Plan Payment Percentage	Plan Payment
Annual Deductible ($0-$250 in spending on covered Part D drugs)	100 percent	$250	0 percent	$0
Initial Benefit ($250.01-$2,250 in spending on covered Part D drugs)	25 percent[1]	$500[2]	75 percent[1]	$1,500
No coverage of costs ($2,250.01-$5,100[3] in spending on covered Part D drugs)	100 percent	$2,850[3]	0 percent	$0
Catastrophic Coverage (after the enrollee has incurred out-of-pocket costs on covered Part D drugs greater than $3,600; this is generally equivalent to $5100[3] in covered Part D drug spending)	The greater of: (1) 5 percent; or (2) $2 for a generic or preferred multiple source drug/$5 for other drugs.[1]	—	95 percent	—

[1] Entities have the option of substituting a cost-sharing structure that is actuarially equivalent.
[2] $500 is the maximum out-of-pocket costs if coverage is based on 25 percent coinsurance. Under an actuarially equivalent cost-sharing structure, the maximum out-of-pocket costs and the maximum plan payment for any Part D enrollee could be higher or lower.
[3] This figure may, in fact, be higher to the extent that a Part D enrollee is reimbursed for out-of-pocket costs for covered Part D drugs covered under his or her plan by a group health plan, insurance or otherwise, or other third party arrangement.

In our proposed rule, we interpreted the provisions of section 1860D 2(b) of the Act to provide for two distinct types of standard prescription drug coverage-''defined standard coverage'' and ''actuarially equivalent standard coverage.'' Section 1860D–2(b)(2)(A)(ii) of the Act provides that Part D sponsors offering actuarially equivalent standard prescription drug coverage will be permitted to substitute cost-sharing requirements (including tiered structures tied to Part D plan formularies and particular pharmacies in a Part D plan's network) for costs above the annual deductible and up to the initial coverage limit, provided that those alternative cost-sharing requirements are actuarially equivalent to an average expected coinsurance of 25 percent for costs above the annual deductible and up to the initial coverage limit. Alternative cost-sharing arrangements under actuarially equivalent standard coverage could include reducing cost-sharing to $0 for generic or preferred covered Part D drugs, as provided under section 1860D–2(b)(5) of the Act, as long as the cost-sharing structure is actuarially equivalent to an average expected coinsurance of 25 percent for costs above the annual deductible and up to the initial coverage limit.

Based on our interpretation of section 1860D–2(b)(5) of the Act, we also proposed allowing Part D plans offering actuarially equivalent standard coverage to establish cost-sharing of an amount that is actuarially equivalent to the expected cost-sharing above the out-of-pocket threshold. We proposed requiring that any alternative cost-sharing structure for costs in the catastrophic range (whether under actuarially equivalent standard coverage or enhanced alternative coverage) be actuarially equivalent to standard prescription drug coverage's structure of the greater of 5 percent coinsurance or $2/$5 copayments. We noted that any such alternative cost-sharing arrangements would be reviewed, along with the rest of a Part D plan's benefit design, to ensure that they do not discourage enrollment by certain Part D eligible individuals.

Except as otherwise provided below, the final rule adopts the criteria for standard prescription drug coverage set

forth in § 423.104(e) of the proposed rule.

Comment: Several commenters felt that the benefit structure established in our proposed regulations was too complex and should be simplified to minimize beneficiary confusion.

Response: We do not have the statutory authority to simplify the benefit further, as suggested by this commenter. The MMA provides private plans with a great deal of flexibility to vary their benefit structures consistent with Congressional intent to ensure that Medicare beneficiaries have choices regarding outpatient prescription drug coverage under Part D that fit their particular needs and minimize beneficiary and Medicare costs.

Comment: One commenter asked how cross-licensed drugs will be classified as generics or as brands for the purpose of cost-sharing. The commenter also asks what the co-payments would be for multiple source drugs that are ordered ''dispensed as written.''

Response: The amount of cost-sharing, and any variations in cost-sharing based on brands, generics, or other classifications will be determined by Part D plans.

Comment: Two commenters suggested alternative data sources to use in determining the annual percentage increase in the first several years of the Part D program. The first commenter recommended two data sources to use for years 2007 and 2008—the annual estimates of prescription drug expenditures in the CMS National Health Accounts data (based on census data and sample surveys of private retail pharmacy sales) and employer retiree health plan data (released by Pharmacy Benefit Managers and benefit consulting firms). Either of these sources of data could be used as a starting point, but should be adjusted to account for any difference in trend for Medicare-eligible individuals compared to the overall prescription trend. In addition, the trend in Part D will likely differ from the overall prescription drug trend due to the large volume negotiating power which could control the trend or allow manufacturers leeway to raise drug prices. FEHBP experience may be useful in accounting for such large volume influences in Part D. This commenter also suggested using our Office of the Actuary (OACT) procedure in place for Medicare Advantage to make coverage limit adjustments the following year for over- or under-stated trends. The commenter also noted that the Medicare Current Beneficiary Survey (MCBS) and the Medicare 5 percent sample are not available in a timely enough fashion to be useful data sources.

Another commenter recommended that we use the OACT spending growth projections that will underlie the Fiscal Year (FY) 2007 President's Budget Medicare baseline that will be published in February 2006. We could use the March 2006 OACT Medicare baseline estimates as a reference check on the OACT projections. OACT and the Congressional Budget Office (CBO) are preferred because they use the latest available empirical data based on MCBS, these data are the basis for the Medicare Trustees' Reports, and the data are widely accepted. In addition, this commenter recommended that OACT use the Consumer Price Index for Prescription Drugs and Medical Supplies (CPI-PD), issued in a timely fashion by the Bureau of Labor Statistics (BLS), as the basis for projecting the price inflation component of per capita Part D spending growth. This commenter thought that utilization growth should be based primarily on the analysis of the latest available MCBS data.

Response: We appreciate the ideas suggested by the commenters and will take these recommendations into consideration as we develop our strategy for determining the annual percentage increase in the first several years of the Part D drug benefit program. We will provide further detail regarding the sources of data to be used and how the annual percentage increase will be determined via operational guidance to Part D sponsors prior to the deadline for bid submissions.

b. Incurred Costs/TrOOP Limit

According to section 1860D–2(b)(4)(C) of the Act, beneficiary costs for Part D drugs are only considered incurred (for purposes of applicability toward beneficiary spending against the annual out-of-pocket limit) if they are incurred—

(1) Against any annual deductible, any applicable cost-sharing for costs above the annual deductible and up to the initial coverage limit, and any applicable cost-sharing for costs above the initial coverage limit and up to the out-of-pocket threshold;

(2) By the Part D enrollee (or by another person on behalf of that individual); paid on behalf of a low-income individual under the Part D subsidy provisions described in § 423.782 of the proposed rule; or paid on behalf of the enrollee under a SPAP defined in § 423.454 of the proposed rule; and

(3) On covered Part D drugs (in other words, Part D drugs that are either included in a Part D plan's formulary or treated as being included in a Part D plan's formulary as a result of a coverage determination, redetermination, or appeal under § 423.566, § 423.580, § 423.600, § 423.610, § 423.620, and § 423.630 of our final rule).

We also proposed that beneficiary costs incurred under the following circumstances count as incurred costs (with Part D plans explicitly accounting for such price differentials in the actuarial valuation of their coinsurance in their bids): (1) any differential between a network retail pharmacy's negotiated price and a network mail-order pharmacy's negotiated price for an extended (for example, 90-day) supply of a covered Part D drug purchased at a retail pharmacy; and (2) any differential between an out-of-network pharmacy's usual and customary price for a covered Part D drug purchased in accordance with the out-of-network access rules and the plan allowance for that covered Part D drug. As further explained below, because we have clarified that the differential for a 90-day supply dispensed at a retail network pharmacy will generally be a differential in cost-sharing and not negotiated price (in other words, the difference in cost sharing for the 90-day supply between the retail and mail-order network pharmacies), we have modified the definition of incurred costs in § 423.100.

Section 1860D–2(b)(4)(C)(ii) of the Act provides that any costs for which a Part D individual is reimbursed by insurance or otherwise, a group health plan, or another third-party payment arrangement do not count toward incurred costs; only costs paid by a Part D enrollee, or on behalf of a Part D enrollee by another person, will count as incurred, or TrOOP costs. This provision thus creates a distinction between all enrollee out-of-pocket expenditures and those that are counted as TrOOP expenditures.

Except as otherwise provided below, the final rule adopts the rules applicable to incurred costs set forth in § 423.100 of our proposed rule.

Comment: Several commenters urged us to count all beneficiary spending on Part D drugs whether on a Part D plan's formulary or not toward TrOOP.

Response: Section 1860D–2(b)(4)(C)(i) of the Act specifically excludes from the definition of the term ''incurred costs'' those costs incurred for Part D drugs that are not included (or treated as being included on a formulary as a result of a coverage determination, redetermination, appeal, or exception) on a Part D plan's formulary. Therefore, we do not have the statutory authority to permit the payments to count toward a Part D enrollees' TrOOP limit.

Comment: Many commenters supported our proposal that beneficiary costs incurred as a result of any differential between a network retail pharmacy's negotiated price and a network mail-order pharmacy's negotiated price for an extended (for example, 90-day) supply of a covered Part D drug purchased at a retail pharmacy count as an incurred costs for the purposes of TrOOP. Only one commenter opposed allowing such differentials to count toward TrOOP.

Many commenters supported our proposal that beneficiary costs incurred as a result of any differential between an out-of-network pharmacy's usual and customary price for a covered Part D drug purchased in accordance with the out-of-network access rules and the plan allowance for that covered Part D drug count as an incurred costs for the purposes of TrOOP. Only one commenter specifically opposed our proposal, stating that if the differential were allowed to count toward TrOOP, the use of retail pharmacies would not be cost-neutral to Part D plans because individuals who use retail pharmacies would reach the out-of-pocket limit sooner.

Response: We agree with the majority of commenters that it is appropriate to allow beneficiary payment differentials to count toward TrOOP in cases in which a beneficiary accesses a covered Part D drug consistent with the out-of-network policy in § 423.124(a) of our final rule.

Section 423.120(a)(6) of our proposed rule provided that a Part D enrollee who obtained a 90-day supply of a covered Part D drug at a network pharmacy that is a retail pharmacy rather than a network mail-order pharmacy would be required to pay for any differential in the negotiated price for the covered Part D drug. However, consistent with section 1860D–4(b)(1)(D) of the Act, which requires that the Part D enrollee pay for ''any differential in charge'' when accessing a 90-day supply of a covered Part D drug at a network retail pharmacy instead of a network mail-order pharmacy, we have clarified in § 423.120(b)(10) of our final rule that the beneficiary is not responsible for the difference in negotiated price but, rather, for any higher cost-sharing associated with purchasing the drug at a retail pharmacy rather that a mail-order pharmacy. Any such difference in cost-sharing would therefore automatically count toward a beneficiary's TrOOP expenditures, since the covered Part D drug in question is being purchased at a network pharmacy.

Comment: Several commenters asked us to define the term ''person'' such that a family member can pay for enrollees' cost-sharing on their behalf.

Response: Section 1860D–2(B)(4)(C)(ii) of the Act specifically mentions a family member as an example of a person who may pay cost-sharing on behalf of a beneficiary. We clarify that our proposed rule defined the term ''person'' to include a ''natural person.'' Such a definition of the term ''person'' thus permits other individuals, such as family members, to pay for covered Part D drug cost-sharing on behalf of Part D enrollees. We have therefore retained this definition of the term ''person'' in § 423.100 of our final rule.

Comments: Several commenters supported our proposed definition of the term ''person,'' which would allow financial assistance for beneficiary cost-sharing rendered by ''bona fide'' charities to count toward enrollee's out-of-pocket threshold. Some commenters requested that we clarify what constitutes a ''bona fide'' charity. Another commenter objected to Part D plan member financial assistance programs being treated differently from third-party charities for purposes of TrOOP.

Response: Our broad definition of the term ''person'' captures not only ''bona fide'' charities, but other charitable organizations as well. We note that any arrangement in accordance to which a charitable organization pays a Medicare beneficiary's cost-sharing obligations must comply with all applicable fraud and abuse laws, including, where applicable, the anti-kickback statute at section 1128B(b) of the Act, as well as the civil monetary penalty provision prohibiting inducements to beneficiaries at section 1128A(a)(5) of the Act. Thus, even if a charity is not a bona fide charity for purposes of Federal fraud and abuse law, any drug payments it makes on behalf of Part D enrollees would count toward TrOOP unless otherwise excluded as payments by a group health plan, insurance or otherwise, or similar third party arrangement. Charities that are established, maintained, or otherwise controlled by an employer or union will likely fall under our definition of ''group health plan,'' and any benefits supplementing Part D benefits that they provide will therefore be excluded from TrOOP on this basis.

Comment: We noted in the proposed rule that we were considering whether assistance in paying enrollees' out-of-pocket cost-sharing obligations provided through prescription drug patient assistance programs sponsored by pharmaceutical manufacturers would be allowed under Federal fraud and abuse laws, including the anti-kickback statute, section 1128B(b) of the Act, as well as the civil monetary penalty provision at Section 1128A(a)(5) of the Act.

We received a number of comments requesting clarification regarding whether assistance in paying enrollees' out-of-pocket cost-sharing obligations provided through pharmaceutical manufacturer-sponsored patient assistance programs (PAPs) would be permissible under Federal fraud and abuse laws and request that we work with the OIG to develop guidelines. Some commenters believe that financial assistance and product donations provided by PAPs should be allowed to count toward beneficiaries' TrOOP expenditures. Some of these commenters recommended that product donations be counted as incurred costs and valued at the price beneficiaries would have paid at a network pharmacy (the negotiated price). One commenter recommended that we allow manufacturers to provide funds to Part D plans so that Part D plans can apply appropriate criteria and make payments on behalf of manufacturers. Another commenter cautions us that without a change in the current interpretation of Federal fraud and abuse laws preventing PAPs from providing cost-sharing assistance, many low-income beneficiaries may avoid filling scripts, resort to splitting pills, and interrupt critical drug therapy.

Response: Regardless of whether a manufacturer patient assistance program is a bona fide charity for the purpose of Federal fraud and abuse laws, any drug payments it makes on behalf of Part D enrollees would count toward TrOOP unless these organizations qualify as group health plans, insurance or otherwise, or similar third-party payment arrangements. However, any arrangements pursuant to which a charitable organization pays a Medicare beneficiary's cost-sharing obligations must comply with Federal fraud and abuse laws, where applicable, including the anti-kickback statute at section 1128(b) of the Act, as well as the civil monetary penalty provision prohibiting inducements to beneficiaries at section 1128A(a)(5) of the Act.

A related issue although it is not mentioned in the proposed rule is whether pharmacies can waive or reduce Part D cost-sharing obligations given Federal fraud and abuse laws and, if they can, whether such waived or reduced cost-sharing should count toward a beneficiary's TrOOP limit. Although we did not receive comments on this matter, we would like to clarify our policy. Under the new exception to

the anti-kickback statute added by section 101(e) of the MMA, pharmacies are permitted to waive or reduce cost-sharing amounts provided they do so in an unadvertised, non-routine manner after determining that the beneficiary is financially needy or after failing to collect the cost-sharing amount despite reasonable efforts, as set forth in section 1128A(i)(6)(a) of the Act. In addition, a pharmacy may waive or reduce a beneficiary's Part D cost-sharing without regard to these standards for beneficiaries enrolled in a Part D plan eligible for the low-income subsidy under section 1860D–14 of the Act, provided the pharmacy has not advertised that the waivers or reductions of cost-sharing are available. Depending on the circumstances, pharmacies that waive or reduce cost-sharing amounts for covered Part D drugs without following the requirements of the pharmacy waiver safe harbor could be subject to civil monetary penalties and exclusion from participating in Federal health care programs, as well as criminal fines and imprisonment under the anti-kickback statute.

We will allow waivers or reductions of Part D cost-sharing by pharmacies to count toward TrOOP. Not allowing such waived or reduced cost-sharing to count toward TrOOP would make it more burdensome for Part D plans given the need to track down whether cost-sharing was actually incurred by a beneficiary rather than a pharmacy. Moreover, we believe this option is consistent both with the definition of ''person'' in the proposed rule (making waiver or reduction of cost-sharing applicable toward an enrollee's incurred costs), and with Congressional intent in amending the anti-kickback statute to provide for a pharmacy waiver safe harbor.

Comment: Several commenters asked that coverage supplementing the benefits available under Part D coverage provided by various government programs be allowed to count as incurred costs for purposes of TrOOP. These government insurers and programs included Medicaid (using State-only funds), Medicaid Section 1115 ''Pharmacy Plus'' waiver programs, Federally qualified health centers (FQHCs), the Department of Veterans Affairs health care program, and local or State indigent drug programs.

In addition, a substantial number of commenters urged us to allow coverage that supplements the benefits available under Part D coverage that is provided by AIDS Drug Assistance Programs (ADAPs) funded under the Ryan White CARE Act to count as incurred costs. These commenters argued that ADAPs are an integral component of the safety net for HIV/AIDS patients because they fill coverage gaps in public and private insurance for critical HIV/AIDS drug treatments. They argue that if ADAP supplemental coverage payments do not count as incurred costs, ADAPs will have little incentive to coordinate coverage with Part D plans, particularly if Part D plans impose user fees on ADAPs. Many of these commenters also urged us to define ADAPs as SPAPs so that their supplemental coverage will be considered incurred costs for the purposes of TrOOP.

Several commenters also objected to the inclusion of IHS and Indian Tribes and Tribal organizations, and urban Indian organizations (collectively I/T/U) facilities in the definition of ''insurance or otherwise'' in § 423.100 of our proposed rule. Since IHS beneficiaries—by custom and regulation—may not be charged any cost-sharing, I/T/U facilities must provide supplemental coverage for all cost-sharing that would have been assessed by a Part D plan. For this reason, the commenters argue, our proposed regulations essentially ensure that most IHS beneficiaries will never incur costs above the out-of-pocket threshold and thus subject AI/AN enrollees and the I/T/U pharmacies that serve them to severe financial penalties in comparison to non-AI/ANs and non-I/T/U pharmacies. I/T/U facilities will have to continue to use their limited appropriated funds to pay the prescription drug costs of AI/AN beneficiaries. Commenters further argue that the proposed exclusion of financial assistance for cost-sharing provided by I/T/U facilities is not required by the statute and is simply an interpretation of the term ''insurance or otherwise.'' Given the Federal government's obligation to provide health services to AI-ANs based on the government-to-government relationship between the United States and Tribes, these commenters argue that IHS and tribal health programs are not ''insurance or otherwise,'' but instead ''persons'' given that I/T/U facilities are the functional equivalent of ''family members.'' We were also asked to clarify why supplemental coverage of deductible costs counts toward a beneficiary's deductible limit, but supplemental coverage of cost sharing above the deductible and initial coverage limit, does not count toward TrOOP.

Response: Section 1860D–24(a)(1) of the Act extends the coordination of benefits provisions required for SPAPs to entities providing other prescription drug coverage—including Medicaid programs, Section 1115 waiver demonstrations, group health plans, Federal Employee Health Benefits Program (FEHBP), military coverage (including TRICARE), and ''such other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of Part D eligible individuals as the Secretary may specify.'' Section 1860D–24(b) of the Act defines includes among these entities providing other prescription drug coverage some government payers, which when coupled with section 1860D–24(a)(2) of the Act, which specifically applies the TrOOP provisions at 1860D–2(b)(4)(D) of the Act to Rx plans suggests that the Congress intended for the term ''insurance or otherwise'' to include government benefit plans or programs that provide health care or pay the cost of covered Part D drugs. Although section 1860D–24(b) of the Act does not list all the government health care programs we consider to be ''insurance or otherwise,'' in the absence of a meaningful distinction between those entities specifically listed in section 1860D–24(b)—Medicaid, SPAPs, TRICARE, and FEHBP—and other government health care programs, allowing payments from such other programs to count toward TrOOP would be arbitrary. Further, in giving the Secretary the authority to identify other entities providing other prescription drug coverage under section 1860D–24(b)(5) of the Act, the Congress contemplated that its list of entities providing other prescription drug coverage was not exhaustive.

For additional clarification of this issue, we have split the definition of ''insurance or otherwise,'' in our proposed rule into two separate definitions—''insurance'' and ''or otherwise''—in our final rule. The term insurance (at § 423.100 of our final rule) refers to a health plan that provides, or pays the cost of covered Part D drugs, including, but not limited to health insurance coverage, a MA plan, and a PACE organization. We note that our definition of ''insurance'' does not modify the definition of ''health plan'' at 45 CFR 160.103 of the HIPAA Administrative Simplification Regulations, or any interpretation thereof issued by the Department of Health and Human Services.

We believe that the phrase ''or otherwise'' refers to government-funded health programs. We have defined the term ''government-funded health programs'' at § 423.100 of our final rule to mean any program established, maintained, or funded—in whole or in part—by the Federal government, the

governments of States or political subdivisions of States, or any agency or instrumentality of these governments which uses public funds in whole or in part to provide to, or pay on behalf of, an individual the cost of Part D drugs. Thus, insurance or otherwise encompasses not just traditional health insurance coverage that is not considered a group health plan, but also government programs and entities (including the Department of Veterans Affairs (VA), IHS, Federally Qualified Health Centers (FQHCs), Department of Labor (DOL) Federal Workers' Compensation Program), government insurers (including Medicaid, Medicaid 1115 demonstrations, and the State Children's Health Insurance Program (SCHIP)), and government-sponsored funds (including black lung benefits, Ryan White CARE Act funds, and State special funds that assist certain individuals with their medical costs, such as a special fund for AIDS patients).

We believe we have defined these terms consistent with the Congress's intent of reducing incentives for current employers, other insurers, and government programs to reduce their current levels of coverage. Because costs for covered Part D drugs paid by insurance or otherwise on behalf of a Part D enrollee do not, as previously discussed, count as incurred costs, any coverage that supplements the benefits available under Part D coverage that are provided to beneficiaries by Medicaid, Medicaid Section 1115 ''Pharmacy Plus'' waiver programs, the VA health care program, the IHS, ADAP programs, and local or State indigent drug programs would not count as an incurred cost for purposes of TrOOP. We note, however, that to the extent that a State provides assistance with covered Part D costs to Part D enrollees with State-only funds and meets the requirements of a State Pharmaceutical Assistance Program as specified in § 423.464(e)(1), such assistance does count as an incurred cost as provided by section 1860D–2(b)(4)(C)(ii) of the Act. However, if an entity providing for or paying the cost of drugs receives a government grant none of which is used to pay for drugs (for example, a low-income housing grant)—such an entity is not considered a government-funded program. On the other hand, if an entity pays for drugs using a mix of private and public funds, the entity is considered a government-funded health program, and all of its drug spending is excluded from TrOOP.

As mentioned above, Pharmacy Plus program costs, including State spending, cannot be counted towards TrOOP because Pharmacy Plus programs are funded under Medicaid and therefore do not qualify as SPAPs. For this reason, we believe that, generally, States will be better off and will realize savings if they restructure their prescription drug programs as SPAPs, rather than continuing their Pharmacy Plus programs. Their savings could be used in a variety of ways, such as directly paying for their enrollees' Part D premiums, wrapping around the Part D benefit by paying for the required cost-sharing, or paying Part D plans for supplemental benefits.

According to IHS estimates, we anticipate that a large proportion of AI/ANs will be eligible for low-income subsidies under Part D, which should significantly limit the financial impact on I/T/U facilities. For those AI/ANs not eligible for the low-income subsidies and enrolled in a Part D plan, the IHS will still obtain some benefit from Part D coverage because I/T/U facilities participating in Part D plan networks will be reimbursed for 75 percent of spending (on average) between the deductible and the initial coverage limit. Moreover, AI/AN enrollees will experience no difference in the way they obtain their prescription drugs to the extent that they use I/T/U pharmacies or IHS-contracted pharmacies.

ADAPs cannot be considered SPAPs because these programs receive Federal funding. As discussed in subpart J, we have interpreted section 1860D–23(b) of the Act, which requires SPAPs to be State programs that provide financial assistance for the purchase of provision of prescription drugs, to mean that an SPAP must provide such assistance with State funds. Therefore, the definition of the term SPAP excludes any program in which program funding is from Federal grants, awards, contracts, entitlement programs, or other Federal sources of funding (though we clarify that this does not exclude some Federal administrative funding or incidental Federal monies). Since ADAPs receive Federal funding, they cannot be defined as SPAPs under § 423.454 of our final rule. However, according to HRSA estimates, we anticipate that a substantial majority of ADAP enrollees will qualify for low-income subsidies. For those ADAP enrollees who do not receive a full or partial subsidy, we estimate that the Part D benefit would pay 75 percent, on average, of an enrollee's covered Part D drug expenditures between the deductible and initial coverage limit. To ensure coordination of benefits for the HIV/AIDS and population, as well as to eliminate any barriers to enrolling in Part D benefits, the ADAP program may wish to pay for their beneficiaries' premiums to eliminate any barriers to Part D benefits.

Per several commenters' request, we also wish to clarify that section 1860D–2(b)(4)(C) of the Act defines the term ''incurred costs'' only for the out-of-pocket threshold. Thus, the fact that coverage that supplements the benefits available under Part D coverage that is provided by certain entities is excluded from the definition of incurred costs for purposes of TrOOP has no bearing on counting that supplemental coverage against the deductible. In other words, ADAPs, IHS, and other programs providing coverage that supplements the benefits provided under Part D may subsidize costs incurred against a Part D enrollee's deductible for those patients unable to afford these costs. The provision of the supplemental coverage will not affect an enrollee's ability to satisfy the deductible and therefore qualify for reduced cost-sharing between the deductible and the initial coverage limit. In addition, these entities are not precluded from paying for a Part D enrollee's cost-sharing above the out-of-pocket threshold once a beneficiary has accumulated incurred costs in excess of the out-of-pocket threshold.

Comment: We requested comments regarding the treatment of health savings account (HSAs), flexible savings arrangements (FSAs), health reimbursement arrangements (HRAs), and medical savings accounts (MSAs) vis-à-vis our definitions of ''group health plan,'' ''insurance or otherwise,'' and ''third party payment arrangements.'' Many commenters suggested that HSAs, FSAs, MSAs, and HRAs be excluded from our proposed definition of ''group health plan'' such that any distributions used by Part D enrollees to pay out-of-pocket costs associated with cost-sharing for covered Part D drugs are allowed to count as incurred costs. These commenters agreed that these funds are analogous to beneficiaries' bank accounts. Some of these commenters asked that we specify that payment of out-of-pocket expenses via these accounts count toward TrOOP only when such accounts are bona fide arrangements set up in accordance with IRS rules and guidance, such funds are not limited to paying prescription drug expenses, and individuals have control over how the funds from these accounts are utilized. One commenter notes that any exemption of HSAs, FSAs, MSAs, and HRAs from our definition of ''group health plan'' should be written carefully to avoid circumvention of Medicare Secondary Payer (MSP) laws. Another

commenter noted that from Part D plans' perspective, it makes the most sense administratively and operationally to allow funds from these accounts to count toward incurred costs because it will be difficult for them to identify and differentiate between different sources of enrollee funds and carve out the payments from TrOOP calculations. One commenter noted that HRAs present a more difficult case, since they are by definition employer-funded only. However, this commenter noted that, from an administrative perspective, it may be difficult to distinguish between HRAs and other types of personal health savings vehicles.

In contrast, several commenters disagreed that HSAs and similar accounts should be exempted from our definition of ''group health plan.'' Some of these commenters believed that contributions from one type of employer-sponsored benefit should not receive differential treatment than other types, particularly when contributions from employer-sponsored group health coverage are not being counted as incurred costs. One commenter thought that we had no statutory authority to create a special rule to exempt HSAs from our definition of ''group health plan.'' This commenter was concerned about non-employer sponsored HSAs, that these funds are not like bank accounts given the tax breaks associated with them, that allowing these funds to count toward TrOOP discriminates against retirees with employer-sponsored drug coverage, and that we would create a substantial windfall and unjustified double taxpayer subsidy.

Response: We agree with the majority of the commenters that HSAs, FSAs, and MSAs are essentially analogous to a beneficiary's bank account, and that distributions from these personal health savings vehicles should count as incurred costs for the purposes of the out-of-pocket threshold. However, as one commenter noted, we believe that HRAs are fundamentally different from these personal health saving vehicles because they are required to be solely employer-funded. Although employers are permitted to contribute funds to HSAs, FSA, and MSAs and may administer the benefits associated with these accounts, employees are not foreclosed from contributing to these vehicles as they are under HRAs. Excluding FSAs, MSAs, and HSAs from the definitions of ''insurance'' and ''group health plan'' for purposes of calculation of TrOOP expenditures will further our objective of encouraging beneficiaries to set aside their own money for drug expenses by allowing those funds to count toward enrollees' TrOOP expenditures. In order to clarify that distributions from HSAs, FSAs, and MSAs can be counted toward a Part D enrollee's incurred costs, we have revised the definitions in § 423.100 of our final rule accordingly and added a definition of ''personal health savings vehicles'' that is limited to HSAs, FSAs, and Archer MSAs.

We note that the term ''group health plan'' is used in reference to TrOOP, creditable coverage, and the retiree subsidy in our final rule, but that we do not define the term uniformly in our final rule. Section 1860D–22(c) of the Act explicitly defines ''group health plan'' to include ERISA plans, which may include an FSA, MSA, and, in limited circumstances, an HSA. The reference to ''group health plan'' under the creditable coverage provisions in section 1860D–13(b)(4)(C) of the Act states that a group health plan includes a qualified retiree prescription drug plan as defined under section 1860D–22 of the Act, which is in turn based on the definition of ''group health plan'' under section 1860D–22(C) of the Act and thus may include an MSA or, in limited circumstances, an FSA or HSA. In contrast, the TrOOP provisions simply refer to a ''group health plan,'' without specifying what this term may include. Given that the statutory references to ''group health plan'' under the TrOOP and creditable coverage provisions use different language, and that the policies underlying these issues are different, we have adopted two different definitions of the term ''group health plan'': one with regard to the TrOOP provisions, and another with regard to the remaining provisions of Part D, including the creditable coverage and the retiree subsidy provisions. While the Congress specifically enumerated two types of coverage to be considered group health plans with regard to creditable coverage, the TrOOP provisions do not.

We also note that the definition of a ''group health plan'' used to implement the Part D drug benefit will differ from the definition of ''group health plan'' used by the Medicare Secondary Payer (MSP) program for recovery of Medicare payments. While both of our Part D definitions of ''group health plan'' are based on the ''ERISA'' definition set forth at 29 U.S.C. 1167(1), the MSP definition is taken from the Internal Revenue Service (IRS) definition of ''group health plan'' at 26 U.S.C. 5000(b)(1). Therefore, the definitions of ''group health plan'' in § 423.100 and § 423.4 of our final rule do not permit circumvention of the MSP laws since they will not apply in the MSP context.

b. Alternative Prescription Drug Coverage

Section 1860D–2(c) of the Act provides that a Part D sponsor may offer an alternative prescription drug benefit design, provided that the Part D sponsor applies for and receives our approval for the proposed alternative. In order to receive approval to offer an alternative prescription drug benefit design, a Part D sponsor will have to meet the requirements related to actuarial equivalence described in section 1860D–2(c)(1) of the Act, and must use defined standard coverage (and not actuarially equivalent standard coverage) as a fixed point of comparison.

- Basic Alternative Coverage

Beyond the required parameters for alternative coverage discussed above, we interpreted the provisions of section 1860D–2(c) of the Act, together with section 1860D–2(a)(1) of the Act, as providing for two forms of alternative coverage—either ''basic alternative coverage'' or ''enhanced alternative coverage.'' Basic alternative coverage refers to alternative coverage that is actuarially equivalent to defined standard prescription drug coverage. Enhanced alternative coverage refers to alternative coverage that exceeds defined standard coverage by offering supplemental benefits.

Within the parameters for alternative prescription drug coverage described above, a Part D sponsor with a basic alternative prescription drug benefit design can theoretically—by combining features such as a reduction in the deductible, changes in cost-sharing, and a modification of the initial coverage limit—still maintain an actuarial value of coverage equal to defined standard prescription drug coverage.

- Enhanced Alternative Coverage

Section 423.104(f) of our proposed rule permitted Part D sponsors to provide qualified prescription drug coverage that includes supplemental benefits. We referred to any Part D benefit package that includes supplemental benefits as ''enhanced alternative coverage.''

Enhanced alternative coverage includes basic prescription drug coverage and supplemental benefits. The requirements for the supplemental benefits that may be included in enhanced alternative coverage are found in section 1860D–2(a)(2) of the Act. These supplemental benefits will supplement basic prescription drug coverage, providing for a package of benefits that exceeds the actuarial value of defined standard coverage. Supplemental benefits can consist of:

+ Reductions in cost-sharing that increase the actuarial value of the coverage beyond that of defined standard coverage; or

+ Coverage of drugs that are specifically excluded from the definition of Part D drugs under section 1860D–2(e)(2)(A) of the Act and § 423.100 of our proposed rule.

Under section 1860D–2(a)(2)(B) of the Act, a PDP sponsor would not be permitted to offer a prescription drug plan that provided enhanced alternative coverage in a particular service area unless it also offers a prescription drug plan that provides only basic prescription drug coverage (which we defined as either standard prescription drug coverage or basic alternative coverage, with access to negotiated prices) in that same area.

Similarly, as provided under section 1860D–21(a)(1)(A) of the Act, beginning on January 1, 2006, an MA organization cannot offer an MA coordinated care plan in a service area unless that plan, or another MA plan offered by the same organization in the same service area, includes required prescription drug coverage. As defined in § 423.100 of our proposed rule, required prescription drug coverage, for the purposes of an MA organization offering an MA-PD plan, included either: (1) basic prescription drug coverage; or (2) enhanced alternative coverage, provided there is no MA monthly supplemental beneficiary premium applied under the MA-PD plan. The enhanced alternative coverage could be provided without a monthly supplemental beneficiary premium only if a MA-PD plan applied a credit against the otherwise applicable premium of rebate dollars available under section 1854(b)(1)(C) of the Act.

Rebate dollars represent the dollars available for supplemental (and other) benefits when an MA plan's risk-adjusted non-drug bid is under the risk-adjusted non-drug monthly benchmark amount. In other words, to the extent that an MA-PD plan chooses to provide enhanced alternative coverage for no additional premium through the application of rebate dollars, the enhanced alternative coverage would constitute required coverage for the purposes of meeting the requirement in section 1860D–21(a)(1)(A) of the Act.

As provided under section 1860D–21(a)(1)(B)(i) of the Act, an MA organization could not offer prescription drug coverage (other than that required under Parts A and B of Medicare) to enrollees of a medical savings account (MSA) plan. Under section 1860D–21(a)(1)(B)(ii) of the Act, an MA organization also could not offer prescription drug coverage (other than that required under Parts A and B of Medicare) under another type of MA plan—including a private fee-for-service plan—unless the drug coverage it provided under that MA plan consisted of qualified prescription drug coverage and met our requirements regarding required prescription drug coverage.

Given changes in § 417.440(b) of our final rule (described in subpart T), we clarify in our final rule the requirements associated with the offering of enhanced alternative coverage by cost plans. As provided in § 423.104(f)(4)(i) of our final rule, a cost plan that elects to offer qualified prescription drug coverage under Part D may offer enhanced alternative coverage only as an optional supplemental benefit (under § 417.440(b)(2)(ii)), and only if the cost plan also offers basic prescription drug coverage.

As provided in § 423.104(f)(4)(ii) of our final rule, a cost plan that elects to offer Part D coverage as an optional supplemental benefit (under § 417.440(b)(2)(ii)) may only do so if the coverage it offers consists of qualified prescription drug coverage. However, a cost plan that does not offer qualified prescription drug coverage may provide prescription drug coverage that is not qualified prescription drug coverage, and the requirements of Part D do not apply to the coverage.

Except as otherwise provided below, the final rule adopts the rules of alternative coverage set forth in § 423.104(f) and § 423.104(g) of our proposed rule.

Comment: One commenter recommended that we issue regulations encouraging basic alternative coverage including optional drugs because it will offer beneficiaries a more comprehensive benefit package.

Response: We do not have the statutory authority to allow basic alternative coverage to include drugs that are statutorily excluded from the definition of Part D drugs. Coverage of drugs otherwise excluded from the definition of Part D drug under section 1860D–2(e)(2)(A) of the Act is considered a supplemental benefit as provided under section 1860D–2(a)(2) of the Act. As specified in § 423.100 of our proposed and final rules, basic alternative coverage must be actuarially equivalent to defined standard coverage and cannot include any supplemental benefits. The only way that Part D plans may provide supplemental benefits, to include coverage of drugs excluded from the definition of Part D drugs under section 1860–D(2)(e)(2)(A) of the Act, is by providing enhanced alternative coverage.

Comment: One commenter sought clarification as to whether alternative coverage would be subject to the same kind of out-of-pocket cost limits and coverage thresholds instituted under standard prescription drug coverage.

Response: In accordance with section 1860D–2(b)(A)(i)(I) of the Act, Part D plans offering enhanced alternative coverage may only reduce certain cost-sharing specifically, a reduction in the deductible, a reduction in the coinsurance percentage or copayments applicable to covered Part D drugs obtained between the annual deductible, and the initial coverage limit, or an increase in the initial coverage limit. Section 1860D–2(A)(i) does not permit Part D plans to offer enhanced alternative drug coverage consisting of a reduction of the out-of-pocket threshold under § 423.104(d)(5)(iii) of our final rule. Section 1860D–2(c)(3) of the Act also requires that Part D plans offering alternative prescription drug coverage provide the same protection against high out-of-pocket expenditures as defined standard coverage. Thus, enhanced alternative coverage may fill in some of the coverage gaps in defined standard coverage, but it cannot affect the true out-of-pocket threshold described in § 423.104(d)(5)(B)(iii) of our final rule, which will be $3,600 in 2006. In other words, beneficiaries must still incur $3,600 (in 2006) in true out-of-pocket expenses before they can benefit from the Medicare catastrophic coverage cost-sharing amounts (the greater of 5 percent coinsurance or $2/$5 copayments), and before Part D plans are eligible to receive reinsurance subsidies from Medicare. As with actuarially equivalent standard coverage, Part D plans can provide an actuarially equivalent version of the coverage provided after the true out-of-pocket threshold is met. In addition, enhanced alternative coverage can improve this coverage.

Comment: Several commenters opposed the provisions of § 423.104(f) of our proposed rule and recommended that the final rule exclude provisions for enhanced alternative coverage. These commenters argue that this section exceeds the statutory authority supplied to the Secretary under the MMA and that allowing such Part D plans to be offered would make it impossible to make a valid comparison between Part D plans, thus making it more difficult for beneficiaries to choose a Part D plan.

Response: We disagree with these commenters. Section 1860D–2(a)(2) of the Act provides that qualified prescription drug coverage may include supplemental prescription drug

coverage consisting of: (1) reductions in cost-sharing (for example, a reduction in the deductible, a reduction in the coinsurance percentage or copayments applicable to covered Part D drugs obtained between the annual deductible and the initial coverage limit, or an increase in the initial coverage limit), provided these reductions in cost-sharing increase the actuarial value of the benefits provided above the actuarial value of basic prescription drug coverage; or (2) coverage of drugs that are specifically excluded as Part D drugs under section 1860D–2(e)(2)(A) of the Act. ''Enhanced alternative coverage'' is simply our term for qualified prescription drug coverage that includes these supplemental benefits specifically permitted by the statute. We understand commenters' concerns about beneficiaries' ability to compare Part D plan features given the benefit flexibility design accorded to Part D plans under the MMA and will work to ensure that our comparative information is as standardized and user friendly as possible.

c. Negotiated Prices

Section 1860D–2(d)(1) of the Act requires that a Part D sponsor provide beneficiaries with access to negotiated prices for covered Part D drugs. As required by section 1860D–2(d)(1)(B) of the Act, negotiated prices will have to take into account negotiated price concessions for covered Part D drugs such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, and would include any applicable dispensing fees. Access to negotiated prices will be provided even when no benefits would otherwise be payable on behalf of an enrollee due to the application of a deductible, the initial coverage limit, or other cost-sharing.

As required under section 1860D–2(d)(1)(C) of the Act, prices negotiated with manufacturers for covered Part D drugs by either (1) a Part D plan, or (2) a qualified retiree prescription drug plan for covered Part D drugs provided on behalf of Part D eligible individuals will not be taken into account in making best price determinations under the Medicaid program.

Section § 423.104(h)(3) of our proposed rule required that Part D sponsors disclose to us all aggregate negotiated price concessions including discounts, direct or indirect subsidies, and direct or indirect remunerations, they obtain from each pharmaceutical manufacturer that are passed through to the Medicare program in the form of lower subsidies or to beneficiaries in the form of: (1) lower monthly beneficiary premiums; or (2) lower covered Part D drug prices at the point of sale.

As provided under section 1860D–2(d)(2) of the Act, information on negotiated prices reported to us for the purposes of ascertaining the level of pass-through will be protected under the confidentiality provisions applicable to Medicaid pricing data under section 1927(b)(3)(D) of the Act. However, that these confidentiality protections did not preclude audit and evaluation of negotiated price concession information by the HHS OIG.

As provided under section 1860D–2(d)(3) of the Act and codified in § 423.104(h)(4) of our proposed rule, we are authorized to conduct periodic audits either directly or through contracts with other organizations of the financial statements and records of Part D sponsors pertaining to the Part D plans they offer. As required in section 1860D–2(d)(3) of the Act, this auditing will be performed with the ultimate goal of protecting the Medicare program against fraud and abuse, as well as ensuring proper disclosures and accounting under Part D.

Except as otherwise provided below, the final rule adopts the rules for negotiated prices set forth in § 423.104(h) of our proposed rule.

Comment: Some commenters believed that the phrase ''take into account'' in our definition of negotiated prices is not strong enough, and that we should establish minimum requirements for the proportion of total negotiated price concessions passed through to beneficiaries. Suggestions ranged from a majority (75 to 80 percent) to 100 percent of negotiated price concessions.

Response: Section 1860D–2(d)(1)(B) of the Act specifically requires that negotiated prices ''shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations.'' Had the Congress intended that all negotiated price concessions be passed through to beneficiaries, they would have used a phrase other than ''take into account'' in the definition of the term ''negotiated prices.''

In addition, section 1860D–2(d)(2) of the Act specifically requires that Part D plans disclose to us aggregate negotiated price concessions that are passed through to enrollees and to us through lower subsidies, lower monthly premiums, and lower prices through pharmacies and other dispensers. In requiring Part D plans to disclose to us the extent to which they pass through negotiated price concessions to enrollees and to us, section 1860D–2(d)(2) of the Act anticipates that Part D plans might not pass through all negotiated price concessions. Therefore, we interpret the definition of the term negotiated prices in section 1860D–2(d)(1)(B) of the Act as requiring Part D plans to pass on to enrollees some, but not necessarily all, of these price concessions and have clarified this interpretation in our definition of the term ''negotiated prices'' in § 423.100 of our final rule. We believe that market competition will encourage Part D plans to pass through to enrollees a high percentage of the negotiated price concessions they obtain in the form of negotiated prices at the point of sale. Establishing minimum threshold levels for the pass-through of negotiated price concessions would have the effect of undercutting market competition, as Part D plans might cluster their negotiated prices around that threshold.

Comment: Some commenters recommended that we clarify how price concessions will be passed through to the pharmacy and to the beneficiaries. Some of these commenters specifically asked us to ensure that Part D plans, not pharmacists, bear the costs of discounts.

Response: The Part D benefit was established by the MMA as a market-based model under which marketplace competition ensures that enrollees receive low prices for prescription drugs. Given this market-based approach envisioned by the Congress, we are wary of regulating negotiations between private parties particularly regarding the specifics of price negotiations so as to ensure that enrollees receive competitive prices on their covered Part D drugs. We note, as well, that pharmacies are not required to contract with Part D plans. To the extent that pharmacies believe that the discounts they are being asked to offer are too high, they can refuse to participate in Part D plan pharmacy networks. Given our pharmacy access standards at § 423.120(a)(1), we expect that pharmacies will have some leverage vis-à-vis the payment provisions in Part D plan contracts.

Comment: Two commenters stated that they considered our requirement that pharmacies pass through negotiated prices during coverage gaps and for non-covered formulary drugs to be price controls.

Response: Section 1860D–2(d)(1) of the Act requires, as implemented under § 423.104(g)(1) of our final rule, that a Part D sponsor provide enrollees with access to negotiated prices for covered Part D drugs even when no benefits would otherwise be payable on behalf of an enrollee due to the application of a deductible, the initial coverage limit, or other cost-sharing. We interpret the

reference to the lack of payable benefits due to the application of the initial coverage limit as referring to that portion of covered Part D drug expenditures between the initial coverage limit and the threshold for catastrophic coverage. In that expenditure range, a beneficiary enrolled in standard prescription drug coverage would be responsible for 100 percent cost-sharing. These are still covered Part D drugs, and enrollees should be able to benefit from negotiated prices during the coverage gap.

We clarify that negotiated prices do not have to be made available for non-covered Part D drugs. However, as we stated in the preamble to our proposed rule, we are interpreting the phrase ''or other cost-sharing'' as a reference to Part D plan designs that include, as part of their formulary design, access to negotiated prices on certain drugs but at a tier within their formulary in which the Part D plan would pay no benefits and the enrollee would be responsible for 100 percent cost-sharing (in other words, a negotiated price would be available and the drug would be on the Part D plan's formulary, but the beneficiary would always be responsible for 100 percent of the drug's negotiated price). These drugs would therefore be formulary drugs and would have to be offered at negotiated prices. As stated elsewhere in this preamble, however, we note that we will review formulary design as part of our benefit package review to ensure that Part D plans do not establish formulary structures (including tiered cost-sharing) that substantially discourage enrollment by certain beneficiaries. To the extent that Part D plans propose using certain cost-sharing tiers (including, but not limited to, 100 percent cost-sharing tiers) in a discriminatory fashion, they would not be allowed.

In addition, we clarify that we interpret the requirement that negotiated prices always be provided to mean that uniform negotiated prices must be available to beneficiaries for a particular drug when purchased from the same pharmacy. In other words, the negotiated price for a particular drug will be the same, at a particular pharmacy, regardless of whether a beneficiary's drug spending is between $0 and the deductible, between the deductible and initial coverage limit, between the initial coverage limit and the out-of-pocket threshold, or in excess of the out-of-pocket threshold. We believe that non-uniform negotiated prices would discourage enrollment by certain Part D eligible individuals in violation of section 1860D–11(e)(2)(D)(i) of the Act and, therefore, plans will not be able to apply differential negotiated prices to any drug purchased from a given pharmacy.

Comment: Other commenters recommended that the definition of the term ''negotiated price'' reflect the price to the Part D plan net of any rebates, discounts, or other price concessions paid to the Part D plan for a covered Part D drug prescription obtained from either a retail or mail-order pharmacy. Some commenters asked that price concessions not be allowed to artificially lower the cost of mail order prescriptions.

Response: Part D sponsors will negotiate prices with pharmacies and manufacturers, and we assume based on current market practices that negotiated prices will vary within a retail pharmacy network, as well as between retail and mail-order pharmacies. How a Part D sponsor nets out negotiated price concessions in its negotiated prices is at the discretion of the Part D sponsor, but we expect that competition will create incentives for Part D sponsors to offer reasonable negotiated prices. Ultimately, however, these pricing issues are between a Part D sponsor and the network pharmacies and manufacturers with whom the Part D plan negotiates price concessions.

Comment: Some commenters recommended that Part D plans be required to reimburse pharmacies to recover costs of purchasing, handling, and dispensing products to beneficiaries.

Response: As provided elsewhere in this preamble, negotiated prices will include any dispensing fees for covered Part D drugs related to the transfer of possession of the covered Part D drug from the pharmacy to the beneficiary, including charges associated with mixing drugs, delivery, and overhead. As provided in section 1860D–11(i) of the Act, we cannot intervene in negotiations between pharmacies and Part D plans. Thus, the extent to which Part D plans reimburse pharmacies for their entire dispensing costs will depend on the outcome of those negotiations.

Comment: Two commenters noted that our definition of the term ''negotiated prices'' appears to envision network model Part D plans, but that MA organizations and cost plans that own and operate their own pharmacies do not negotiate reimbursement rates with contract pharmacies. One commenter recommended that negotiated prices for such MA organizations and cost plans be defined as the prescription charge established by the organization, and that such charge include the acquisition cost of the drug, dispensing, operational, capital, overhead, and margin costs. The commenter suggested that, in determining whether Part D plans' negotiated prices meet the standard of section 1860D–2(d)(1)(B) of the Act, we could either compare an MA organization's negotiated prices to negotiated prices of network model Part D plans in the same market or, alternatively, require the MA organization to demonstrate how it takes price discounts it receives from manufacturers into account in its pricing methodology or formula. Another commenter suggested that we permit such MA organizations to establish a pricing methodology that reflects a good faith effort to reflect prices analogous to those that would be negotiated by an MA organization with third party pharmacy providers, and that we consult with affected MA organizations in establishing this policy.

Response: We clarify that our definition of the term ''negotiated prices'' in § 423.100 of the final rule requires that ''discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remunerations'' be taken into account in establishing covered Part D drug negotiated prices. Plans do not have to take into account pharmacy discounts to the extent that no such discounts exist. Moreover, we note that our definition of the term ''dispensing fees'' in § 423.100 of the final rule indicates that, in the case of pharmacies owned and operated by a health plan, dispensing fees are understood to be the equivalent of all reasonable pharmacy costs included in the definition (those related to the transfer of possession of a covered Part D drug to a Part D plan enrollee), including the salaries of pharmacists and other pharmacy workers as well of the costs associated with maintaining the pharmacy facility and equipment necessary to operate the pharmacy. For purposes of evaluating the validity of a Part D plan's bid, including its negotiated prices for covered Part D drugs, we will request and evaluate disaggregated negotiated price concession data only to the extent that such detail is necessary in order to justify actuarial assumptions or as part of an audit.

Comment: One commenter asked that we define the meaning of the terms ''direct or indirect subsidies'' and ''direct or indirect remunerations.'' Another commenter suggested that negotiated price concessions reported to us should include formulary placement incentives, market share movement incentives, administrative fees paid to

Part D plans, and direct and indirect forms of remuneration. One commenter asked that we provide clarification on how rebates will be calculated, reflected in negotiated prices, and reported to us.

Response: We note that Part D plans may fulfill the requirements of section 1860D–2(d)(2) of the Act through the data submission requirements discussed in further detail in subpart G. In other words, we should be able to determine the proportion of total aggregate price concessions passed through to either the Medicare program or to enrollees based on the cost data Part D plans will be required to submit to us. Although all negotiated price concessions be they direct or indirect subsidies, direct or indirect remunerations, rebates, or discounts must be reported to us, as provided in § 423.104(g)(3) of our final rule, we will require that Part D plans break out any fair market value administrative fees pharmaceutical manufacturers may pay Part D sponsors. The use of the term indirect with direct is meant to be all-inclusive. In other words, we clarify that this means any and all subsidies or remunerations. We will specify in operational guidance the format and frequency of these reports, as well as what constitutes direct or direct subsidies, direct or indirect remunerations, rebates, and discounts.

Comment: We received a number of comments regarding our aggregate negotiated price concession disclosure requirements. Several commenters asked us to clarify that only aggregate price concessions passed through to us and to enrollees will be reported to us, rather than the amount or proportion of total price concessions obtained by a Part D plan. Other commenters thought that Part D plans should be required to disclose all price concessions, not just the proportion passed through to Part D enrollees. A number of other commenters asked that we require the disclosure of negotiated price concession by drug.

Response: We clarify that, as provided under section 1860D–2(d)(2) of the Act, and specified in § 423.104(g)(3) of our final rule, we will require that all aggregate negotiated price concession data and not just the proportion passed through to beneficiaries be reported to us for purposes of Part D plan bids. However, as explained in subpart G, it may be necessary for us to receive disaggregated negotiated price concession data from Part D plans in order to ensure accurate payment to Part D plans. We will provide further information regarding negotiated price concession reporting in separate guidance.

Comment: Several commenters recommended that Part D plans share all negotiated price concession data reporting with SPAPs.

Response: Since nothing in the MMA addresses disclosure of negotiated price information to SPAPs, FOIA rules apply. FOIA applies to requests for data from States. FOIA Exemption 4 protects certain confidential commercial information that is submitted to a Federal agency. Determinations about the applicability of FOIA Exemption 4 to a Part D plan's pricing data would be made on a case-by-case basis depending on whether the submitter of the data could demonstrate that disclosure of this information would likely cause substantial competitive harm to the submitter's competitive position. If FOIA Exemption 4 is found to protect submitted price information, we cannot disclose this information to States because to do so would violate the Trade Secrets Act (18 U.S.C. 1905).

Comment: One commenter stated the ''best price'' provision undermined the original intent of section 1927 (c)(1)(C) of the Act and would have a negative financial impact on the Medicaid prescription drug program.

Response: We believe the Congress intended that there be no Federal barriers to Part D sponsors negotiating the lowest prices possible for their plan members. If negotiated prices counted towards ''best price,'' this could create a disincentive for manufacturers to offer discounts. Further, the purpose of ''best price'' exemptions in section 1927(c)(1)(C) of the Act is to ensure that manufacturers offer Medicaid programs strong rebates that are market-driven, without penalizing the manufacturers indirectly for the discounts they offer by law under other Federal drug programs. Exempting negotiated prices under the new Medicare prescription drug benefit is consistent with that purpose. The issue of effects on Medicaid best price is discussed in the impact analysis.

Comment: One commenter asked for further guidance regarding the ''best price'' exemption, stating that Part D providers should be able to negotiate simultaneously for commercial prices, which would count toward ''best price,'' and for Medicare/qualified retiree prices, which would not count toward ''Best Price.''

Response: Under section 1860D–11(i) of the Act, we have no authority to regulate price concessions between manufacturers and Part D plans. Consequently, we cannot prohibit or require Part D plans from negotiating simultaneously for commercial prices, which would be included in the calculation of the Medicaid drug rebate best price, and Medicare prices, which would not be included in the calculation of the Medicaid drug rebate best price. If Part D plans wish to simultaneously negotiate their commercial and Medicare prices, they are free to do so.

Comment: One commenter suggested that we recommend to the Congress alternatives to the existing ''best price'' rebate formula. The commenter recommended a flat rebate formula to generate savings for State Medicaid programs, while eliminating the negative impact of the ''best price'' formula on the prescription drug market generally.

Response: This regulation does not address the best price provisions of the Medicaid drug rebate statute as we do not have the statutory authority under Title I of the MMA to modify the Medicaid rebate program.

3. Establishment of Prescription Drug Plan Service Areas (§ 423.112)

Section 1860D–11(a)(2) of the Act provides us with the authority to establish PDP regions, and such PDP regions must be established in a manner that is consistent with the establishment of MA regions. Section 1860D–11(a)(2)(B) of the Act stipulates that PDP regions must be, to the extent practicable, consistent with MA regions as established under section 1858(a)(2) the Act. However, we may establish PDP regions that vary from MA regions if we determine that access to Part D benefits would be improved by establishing different regions. Section 1860D–11(a)(2)(C) of the Act stipulates that we designate a separate PDP region (or regions) for the U.S. territories.

Except as otherwise provided below, the final rule adopts the requirements related to the establishment of prescription drug plan service areas set forth in § 423.112 of the proposed rule.

Comment: We received a number of comments on the establishment of PDP regions both in response to the provisions of our proposed rule and as follow-up to a public meeting held in Chicago on July 21, 2004. The majority of commenters favored establishing 50 State-based regions or, more generally, a larger number of smaller regions—close to that of State-level regions. Issues identified in support of 50 State-based regions included the large assumption of risk associated with the establishment of larger regions; insufficient time for Part D plans to negotiate and develop networks, or to renegotiate providers' contracts and form partnerships; potential difficulties in meeting State licensure and solvency requirements; and greater ease in terms of

coordination between Part D plans and SPAPs in providing coverage that supplements the benefits available under Part D coverage. Several commenters recommended an intermediate number of regions between the 10 and 50 regions authorized by the MMA. One commenter cautioned us to develop an appropriate number of regions in order to ensure that beneficiaries particularly those in rural areas have meaningful access to Part D choices. Yet another commenter recommended that we align PDP and MA regions in order to preclude beneficiary confusion by MA enrollees as they try to understand their options during the initial enrollment period for Part D coverage.

Several other commenters specifically recommended that a standalone region be created for Puerto Rico separate from the 50 States and any of the other U.S. territories. These commenters believe it is necessary for Puerto Rico to be placed in its own PDP region because a multi-state PDP region for Puerto Rico would compromise the viability of Part D on the island. They argue that Puerto Rico-based plans have years of experience working with the local Medicare population and its distinct linguistic and cultural traditions and will be disadvantaged when competing with U.S. companies to build provider networks outside Puerto Rico. Some commenters also thought that combining Puerto Rico and another State or States (for example, Florida or New York) will drive up premiums for Puerto Rican enrollees. On the other hand, one commenter argued that a standalone region for Puerto Rico would isolate it, and preferred to stay in the New York region under the MA and PDP programs.

Response: We conducted a market survey and analysis, including an examination of current insurance markets as required in the MMA. Key factors in the survey and analysis included payment rates; eligible population size per region; PPO market penetration; current existence of PPOs, MA plans, or other commercial plans; and presence of PPO providers and primary care providers. Additional factors were also considered, including solvency and licensing requirements, as well as capacity issues. In response to the lack of specificity regarding the PDP regions in our proposed rule, we conducted extensive outreach in order to obtain public input prior to the publication of our final rule. On December 6, 2004, we announced the establishment of 26 MA regions and 34 PDP regions. For maps and fact sheets on the on the regions, please see *http://www.cms.hhs.gov/medicarereform/mmaregions/*.

4. Access to Covered Part D Drugs (§ 423.120)

a. Pharmacy Access Standards

As required by section 1860D–4(b)(1)(C) of the Act, Part D plans must secure the participation in their pharmacy networks of a sufficient number of pharmacies that dispense drugs directly to patients (other than by mail order) to ensure convenient access to covered Part D drugs by Part D plan enrollees. To achieve that goal, we are authorized to establish access rules that are no less favorable to enrollees than rules for convenient access established in the statement of work solicitation (#MDA906–03–R–0002) by the Department of Defense (DOD) on March 13, 2003, for purposes of the TRICARE Retail Pharmacy program. Consistent with the TRICARE standards, our proposed rule required that Part D plans establish pharmacy networks in which:

- In urban areas, at least 90 percent of Medicare beneficiaries in the Part D plan's service area, on average, live within 2 miles of a retail pharmacy participating in the plan's network;
- In suburban areas, at least 90 percent of Medicare beneficiaries in the Part D plan's service areas, on average, live within 5 miles of a retail pharmacy participating in the prescription drug plan's or MA-PD plan's network; and
- In rural areas, at least 70 percent of Medicare beneficiaries in the Part D plan's service area, on average, live within 15 miles of a retail pharmacy participating in the plan's network.

As provided under section 1860D–21(c)(3) of the Act and codified in § 423.120(a)(3)(i) of our proposed rule, we are authorized to waive the pharmacy access standards in § 423.120(a)(1) in the case of an MA-PD plan or cost plan that provides access (other than via mail order) to qualified prescription drug coverage through pharmacies owned and operated by the MA organization that offers the plan or the cost plan. However, in order for the pharmacy access standards to be waived, the MA-PD plan or cost plan in question is required to have a pharmacy network that, per our determination, provides comparable pharmacy access to its enrollees as provided under § 422.112.

Similarly, section 1860D 21(d)(2) of the Act provides that if a private fee-for-service MA plan offering qualified prescription drug coverage provides coverage for drugs, including covered Part D drugs, purchased from all pharmacies regardless of whether they are network pharmacies under contract with the MA plan, and provided that beneficiaries are not charged any cost-sharing above and beyond what they will be charged under standard prescription drug coverage—the pharmacy access requirements will also be waived.

As provided under section 1860D–4(b)(1)(A) of the Act, Part D sponsors will be required to permit the participation in their Part D plan networks of any pharmacy that was willing to accept the plan's terms and conditions. Based on section 1860D–4(b)(1)(B) of the Act, our proposed rule clarified that a Part D sponsor will have the option of reducing cost-sharing for its enrolled beneficiaries below the level that would otherwise apply for covered Part D drugs dispensed through network pharmacies. We interpreted this provision as permitting Part D sponsors from varying cost-sharing not only based on type of drug or formulary tier, but also on a particular pharmacy's status within the Part D plan's pharmacy network-in essence authorizing distinctions between ''preferred'' and ''non-preferred'' pharmacies.

As stipulated under section 1860D–4(b)(1)(E) of the Act and § 423.120(a)(4)(ii) of our proposed rule, pharmacies could not be required to accept insurance risk as a condition of participation in a Part D sponsor's pharmacy network. We defined ''insurance risk'' in relation to a network pharmacy as referring to risk of the type commonly assumed only by insurers licensed by a State, but not including payment variations designed to reflect performance-based measures of activities within the control of a pharmacy, such as formulary compliance and generic drug substitutions, or elements potentially in the control of the pharmacy (for example, labor costs, and productivity).

Section 1860D–4(b)(1)(D) of the Act requires Part D sponsors to allow their enrollees to receive benefits at a network retail pharmacy instead of a network mail-order pharmacy, if they so choose. Consistent with the statute, our proposed rule allowed Part D plan enrollees who choose to obtain an extended supply of a covered Part D drug through a network retail pharmacy to be responsible for any differential between the network retail pharmacy's and the network mail-order pharmacy's negotiated price for that covered Part D drug. We sought comments on our proposal that this price differential be counted as an incurred cost against the annual out-of-pocket threshold and note that, as discussed elsewhere in this preamble, we have modified the level

playing field provision at § 423.120(b)(10) of our final rule to clarify that an enrollee will be responsible for any higher cost-sharing (and not a differential in negotiated price) associated with purchasing a 90-day supply of a covered Part D drug at a network retail pharmacy, as well as our definition of incurred costs at § 423.100 of the final rule.

Except as otherwise provided below, the final rule adopts the access standards set forth in § 423.120(a) of the proposed rule.

Comment: In our proposed rule, we interpreted the TRICARE access standards such that a prescription drug plan or regional MA-PD plan would have been required to meet or exceed the access standards across each region in which it operates, and a local MA-PD plan would have to meet or exceed the access standards in its local service area.

Some commenters supported this application of the TRICARE access standards in our proposed rules (regional for prescription drug plans and MA-PD plans). A number of commenters expressed concerns about the adequacy of our proposed application of the access standards and urged us to apply the standards at the local (zip-code) level. A number of other commenters urged us to apply the TRICARE standards at the State level. Several other commenters recommended that Part D plans meet the access standards at the broadest geographic area served by the plan (for example, regional, multi-regional, or national).

Response: Although section 1860D–4(b)(1)(C)(ii) of the Act directs us to adopt access standards no less favorable to enrollees than those set forth in the March 13, 2003, statement of work solicitation (#MDA906–03–R–0002) of the Department of Defense under the TRICARE Retail Pharmacy Program, we note that the statement of work does not specify the geographic level at which to apply the TRICARE standard. We therefore believe that we have discretion to apply the TRICARE standards at the geographic level we believe to be most appropriate.

Although we considered applying the TRICARE standard at the local (zip code or county) level for Part D plans, we believe such application would make it impossible for Part D plans to meet the standards particularly the rural standard—in some parts of the country. On the other hand, we believe that application of the access standards at the broader, regional level would not adequately ensure convenient access for beneficiaries given the potential for Part D plans to ''average out'' the access standards across many urban, suburban, and rural areas in a region—thus meeting the access standards in the aggregate but potentially leaving certain parts of a region without convenient access to retail pharmacies.

We agree with commenters who proposed a State-level application of the TRICARE pharmacy access standards for regional MA-PD plans and prescription drug plans, and have made changes to § 423.120(a)(1) accordingly such that a prescription drug plan or regional MA-PD plan will have to meet or exceed the access standards across urban, suburban, and rural areas, respectively, in each State in which it operates, a local-MA-PD plan would have to meet or exceed the access standards across urban, suburban, and rural areas, respectively, in each service area (including multi-county service areas) in which it operates, and a cost plan would have to meet or exceed the access standards across urban, suburban, and rural areas, respectively, in each geographic area in which it operates. In other words, a prescription drug plan or regional MA-PD that operates in a multi-region or national service area could not meet the access standards proposed in § 423.120(a)(1) by applying them across the entire geographic area serviced by the plan; instead, it would have to meet the standards in each State of its multi-region or national service area. We believe that such an interpretation is a reasonable compromise between application at the local level and application at the regional or national level, and maximizes Part D plan flexibility while ensuring convenient access to network pharmacies for Part D enrollees.

Comment: Some commenters expressed concern that TRICARE's rural access standard was insufficient to provide convenient access to network pharmacies in rural areas and urged us to adopt a more adequate definition of rural. Others argued for an exceptions process for remote, isolated areas in which it is simply not feasible to establish pharmacy networks that comply with our requirements.

Response: We are aware of the difficulties faced by rural beneficiaries in accessing medical care. We believe that TRICARE's definition of ''rural'' is adequate and have not modified it in our final rule (though we will monitor the access standards over time to ensure they continue to provide convenient access to all beneficiaries). Furthermore, we believe access in rural areas will be improved given our revised interpretation of the access standards, whereby we will evaluate access at the State (and not the regional) level. However, we are aware—based on our experience implementing the Medicare Prescription Drug Discount Card and Transitional Assistance Program—that there are likely to be several States in which meeting the rural access standard will be impossible or impracticable given the lack of infrastructure. We expect to establish an exceptions process, which we will outline in operational guidance to Part D plans that will account for any problem areas and mitigate any disincentives plans may have to avoid doing business in parts of the country in which meeting the pharmacy access standards would be a challenge.

In addition, and as explained elsewhere in this preamble, and codified in § 423.120(a)(2) of our final rule, we will allow Part D plans to count certain non-retail pharmacies—specifically, I/T/U, Federally Qualified Health Center (FQHC), and Rural Health Center (RHC) pharmacies—toward the pharmacy access requirements in § 423.120(a)(1) of our final rule. We believe this policy will help ensure convenient access in rural areas.

Comment: Several commenters asked that we ensure that national Part D plans are created. These commenters thought that national Part D plans would be of benefit to beneficiaries who travel regularly or who reside in more than one State in a given year (for example, ''snowbirds''), and urged that the ramifications of choosing a local MA-PD plan or a regional Part D plan be made clear to beneficiaries who may not realize the implications of such limited geographic access when they select Part D plan coverage.

Response: Although a Part D sponsor may offer a Part D plan in more than one PDP or MA region, it is not required to do so. Therefore, we cannot require national Part D plans, though we certainly recognize the benefits of such plans for some beneficiaries given the limited applicability of our out-of-network access policy. We note that our pharmacy access standards would not in any way preclude Part D sponsors from contracting with pharmacies outside their Part D plans' service areas, provided that the plans meet the pharmacy access requirements within their service areas. Such a feature would be of particular use to beneficiaries who spend significant amounts of time outside their Part D plan's service area (for example, snowbirds) and could make a particular Part D plan that offered such benefits more attractive to beneficiaries who travel regularly. National Part D plans are also of interest to employers who have retirees living throughout the country, and the

employer group waiver authority discussed in subpart J could facilitate these employer-only national Part D plans. We also note that, as part of our information dissemination requirements in § 423.128(b) of the final rule, Part D plans will be required to inform beneficiaries about the plan's service area, as well as the locations of network pharmacies.

Comment: Several commenters asked us to make allowances for ''snowbirds,'' stating that our regulations should allow Part D sponsors to offer ''visitor/traveler'' benefits available under the MA program. One commenter specifically suggested the application of the MA requirements, which allow an organization to provide such benefits to an individual who is temporarily out of the area for up to 12 months. A few commenters stated that we should require prescription drug Part D plans to offer visitor/traveler benefits. One commenter suggested, however, that we allow exceptions for regional Part D plans and those with out-of-network services. One commenter suggested that we consider allowing Part D plans to offer ''travel'' networks without requiring them to contract in those regions, suggesting that this could be an interim approach pending evaluation of the cost/payment experience for both Part D plans and us.

Response: We appreciate the feedback provided by the commenters on applying a visitor/traveler benefit to prescription drug plans as has been provided to the MA program. We do not have the authority to establish a visitor/traveler benefit. However, as noted above, our pharmacy access standards would not in any way preclude Part D sponsors from contracting with pharmacies outside their plans' service areas, provided that plans meet the pharmacy access requirements within their service areas, and such access is not provided outside the United States.

Comment: We interpreted the access requirements in section 1860D–4(b)(1)(C) of the Act as requiring Part D plans to count only retail pharmacies as part of their networks for the purpose of meeting the access standards, and we proposed defining a retail pharmacy as any licensed pharmacy from which covered Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy. We also requested comment regarding whether we should allow Part D plans to count pharmacies that are operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (I/T/U pharmacies) toward their network access requirements when the pharmacies are under contract with the Part D plan, and it would be impossible or impracticable for the plan to meet the access standard in rural areas of its service area without the inclusion of some or all of these pharmacies. In addition, we solicited comments on permissible ways to ensure enrollee access to FQHC and rural pharmacies, since these pharmacies could potentially provide access to covered Part D drugs in remote, rural areas.

Several commenters support counting only retail pharmacies towards Part D plans' access requirements. Other commenters supported allowing I/T/U pharmacies to count toward Part D plans' pharmacy access requirements to the extent that we do not require Part D plans to offer I/T/U pharmacies a standard contract, at a minimum.

Response: We agree that, in most cases, only retail pharmacies, which we define in § 423.100 of our final rule as any licensed pharmacy from which covered Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy, should count toward our pharmacy access standards. Examples of non-retail pharmacies include I/T/U, FQHC, Rural Health Center (RHC), and hospital and other provider-based pharmacies, as well as Part D-owned and operated pharmacies that serve only plan members.

However, as explained elsewhere in this preamble, we are concerned about access to pharmacies in rural and underserved areas. As one way of addressing this concern, § 423.120(a)(2) of our final rule allows Part D plans to count certain non-retail pharmacies—specifically, I/T/U, FQHC, and RHC pharmacies toward the pharmacy access requirements in § 423.120(a)(1) of our final rule.

FQHCs and RHCs face many of the same barriers to inclusion in commercial plan networks as do I/T/U pharmacies, which we discuss in greater detail elsewhere in this preamble. Beneficiaries served by FQHCs and RHCs are often served in those settings because of their financial and geographic circumstances. We believe that allowing Part D plans to count these pharmacies toward their access requirements will incentivize plans to make an extra effort to solicit and include these pharmacies in their networks. As the number of these pharmacies is limited and, with the exception of I/T/U pharmacies, can generally offer services to a broad-based population, we do not believe that this exception will have a significant impact on convenient access to pharmacies in rural areas for the general population. However, we intend to review Part D plans' proposed pharmacy networks to ensure that their inclusion of I/T/U, FQHC, and RHC pharmacies does not substitute for the inclusion in Part D plan networks of retail pharmacies. We also note that this policy should not be interpreted as requiring broader access to I/T/U, FQHC, and RHC pharmacies than is currently permissible.

Comment: Several commenters expressed concern about the inclusion of rural and FQHC pharmacies in Part D plan networks, with some advocating for requiring plans to contract in some cases, under preferential contracting terms and conditions with these pharmacies. Other commenters opposed requiring Part D plans to contract with specific kinds of pharmacies, asserting that the any willing pharmacy and pharmacy network access requirements are sufficient to ensure an adequate pharmacy network for all beneficiaries. One commenter asked that, to the extent we require Part D plans to contract with certain pharmacies, plans would only be required to offer standard terms and conditions.

Response: With the exception of I/T/U pharmacies, we will not require Part D plans to contract with non-retail pharmacies including FQHC or rural pharmacies. We believe our access standards for rural areas and the Statewide application of access rules generally will ensure adequate access in rural areas. However, as discussed elsewhere in this preamble, we will allow Part D plans to count I/T/U, FQHC, and RHC pharmacies toward their access requirements as an incentive for Part D plans to contract with these pharmacies, which are critical providers in underserved areas.

Comment: One commenter believes we should mandate that Part D plans solicit inner city and rural pharmacies that meet the Small Business Administration's small business standard for participation in their pharmacy networks and should give them access to any terms that the Part D plan offers to a subset of pharmacies.

Response: We believe the pharmacy access standards, as well as their application at the State level, in § 423.120(a)(1) of our final rule, will ensure adequate access to covered Part D drugs for all Part D enrollees in urban, suburban, and rural areas. Given the standards, pharmacies' bargaining power will be strengthened in underserved areas. Ultimately, however, it is at Part D plans' discretion how they will establish pharmacy networks—

including the offering of contracting terms and conditions that are different than standard contracting terms and conditions and the establishment of preferred pharmacies provided they meet our pharmacy access standards, non-discrimination provisions, and other applicable requirements under Part D. We believe that the type of market intervention requested by the commenter is contrary to the Congress's intent that we not interfere in the private negotiations between Part D plans and pharmacies. We will therefore not mandate that Part D plans solicit inner city and rural retail pharmacies or that they automatically deem them preferred pharmacies within their networks.

Comment: We sought public comments regarding whether we should consider using the authority in section 1860D–4(b)(1)(C) of the Act to require that Part D plans contract with a sufficient number of home infusion pharmacies in their service area to provide reasonable access for Part D enrollees.

Several commenters supported requiring Part D plans to contract with a sufficient number of home infusion pharmacies in their service areas to ensure adequate access for beneficiaries. One commenter noted that this requirement would result in savings for the Medicare program by reducing expenditures under Parts A and B. In addition, these pharmacies allow beneficiaries to safely receive their medications at home by providing training and skilled support so beneficiaries can avoid the inconvenience of hospitals, clinics, and doctor visits. One commenter urged us to expand our proposed requirement to include all specialty pharmacies, not just home infusion pharmacies.

Other commenters recommended not mandating Part D plans to contract with these non-retail pharmacies but rather encourage participation because it would reduce negotiating leverage of plans with these pharmacies.

One commenter urged that home infusion pharmacies should not be counted toward network TRICARE standards.

Response: We agree with commenters who believe that we should use our authority under section 1860D–4(b)(1)(C) of the Act to require Part D plans to provide adequate access to home infusion pharmacies. Given coverage of home infusion drugs under Part D, we do not believe it is an option for Part D plans not to include at least some home infusion pharmacies in their networks in order to provide enrollees with meaningful access to those drugs. This is particularly a concern with regard to prescription drug plans which, unlike other Part D plans, do not benefit from reduced medical costs associated with home infusion and may therefore have little incentive to contract with home infusion pharmacies. Therefore, we have added a new provision to our final regulations at § 423.120(a)(4) which requires Part D plans to demonstrate to us that they provide adequate access to home infusion pharmacies consistent with CMS operational guidance to Part D plans. We expect that Part D plans will demonstrate adequate access based in part on the number of enrollees in their service areas and the geographic distribution and capacity of home infusion pharmacies in those service areas. We have not included specialty pharmacies that do not provide home infusion services in this requirement however, as it is unclear whether beneficiaries will need routine access to such pharmacies or would not be adequately served through our out-of-network access rules. We clarify, that we have made a distinction between specialty pharmacies and long-term care pharmacies. We note that home infusion pharmacies will not count toward Part D plans' pharmacy access requirements because they are not retail pharmacies.

Comment: We requested comments regarding the advantages and disadvantages of using the authority provided under section 1860D–4(b)(1)(C)(iv) of the Act to require Part D plans to approach some or all long-term care pharmacies in their service areas with at least the same terms available under their standard pharmacy contracts, or, alternatively, to not require (but strongly encourage) Part D sponsors to negotiate with and include long-term care pharmacies in their Part D plans' pharmacy networks. In addition, we requested comments regarding how to balance convenient access to long-term care pharmacies with appropriate payment to long-term care pharmacies under the provisions of the MMA.

Some commenters were adamant that the current one-to-one relationship between the long-term care pharmacies and nursing homes be preserved, as it is critical to ensuring safety and convenient access to drugs for Medicare beneficiaries residing in nursing homes. One commenter suggested that Part D plans should also provide standardized long-term care pharmacy contracts that recognize long-term care pharmacies' essential role.

Some commenters recommended that the final regulation require Part D plans to contract with any willing long-term care pharmacy. A number of commenters would prefer that we do not require Part D plans to contract with any particular non-retail pharmacies (including long-term care pharmacies) because both our access standards and the any willing pharmacy requirement adequately address our objective of ensuring access to Part D drugs for all enrollees. One commenter notes that Part D plans will need to include long-term care pharmacies in their networks to meet access standards, and that this will encourage Part D plans to contract with long-term care pharmacies. Another believes that we struck a balance with the option for long-term care pharmacies to provide benefits in- or out-of-network because it gives long-term care pharmacies and Part D plans the appropriate negotiating flexibility to reach mutually satisfactory arrangements for providing services to long-term care residents. Also, one commenter points out that some long-term care pharmacies would not be able to meet all the operational standards necessary to participate in Part D, and Part D plans would have to negotiate special reimbursement rates with these pharmacies. Some commenters believe that we should promote appropriate payment methodologies (for example, via dispensing fees or separate fee schedules to pay for specialized services) that would enable all long-term care pharmacies to join networks and provide a meaningful benefit. Another variation suggested was that a Part D plan should be required to include at least one long-term care pharmacy in its network and to contract with any long-term care pharmacy that agrees to the Part D plan's standard contract.

One commenter reasoned that there should be a balance in the contracting requirement; for example, long-term care pharmacies that service X percent of beneficiaries should also be required to contract with at least one Part D plan. But, without this balance, the commenter felt the Part D plans and long-term care pharmacies should be strongly encouraged to contract with each other. A few commenters believed that we should encourage, but not require, Part D plans to contract with long-term care pharmacies and that we should explicitly state in regulation that long-term care residents can access long-term care pharmacies as out-of-network providers when those pharmacies do not contract with particular Part D plans. Other commenters believe that it is sufficient to require that long-term care pharmacies be offered standard

contracting terms and conditions by Part D plans.

Response: Section 1860D–4(b)(1)(C)(iv) of the Act provides that, in establishing rules for convenient access to network pharmacies, we may include standards with respect to access to long-term care pharmacies for Part D enrollees who reside in long-term care facilities. For a variety of reasons, including the quality aspects of Federal nursing home regulations, it is generally the case that long-term care facilities have chosen to contract with a single long-term care pharmacy. Given this state of affairs, our proposed rule assumed that Part D enrollees residing in a long-term care facility could not reasonably be expected to access their Part D drugs at another pharmacy if their facility's long-term care pharmacy is not part of their Part D plan's network. In the proposed rule, we proposed that enrollees residing in long-term care facilities whose contracted long-term care pharmacies did not participate in their Part D plans' networks could continue to use those long-term care pharmacies consistent with our proposed out-of-network access policy. However, given the narrow statutory authority to establish out-of-network access rules provided by section 1860D–4(b)(1)(C)(iii) of the Act, we do not believe as discussed in greater detail elsewhere in this preamble that access to out-of-network pharmacies on a routine basis can be justified. Thus, beneficiaries residing in long-term care facilities that do not contract with a pharmacy included in their Part D plan network will not be able to access covered Part D drugs at the out-of-network long-term care pharmacy through the out-of-network access rules in § 423.124 of our final rule.

However, it is important to note that we will provide a SEP for prescription drug plan enrollment and disenrollment for beneficiaries entering in, living in, or leaving an institution. In addition, individuals enrolled in an MA-PD plan have an unlimited open enrollment period for institutionalized individuals (OEPI). While MA organizations may choose individually, at the plan level, whether or not to be open for enrollments during this period, they must always accept disenrollments.

Given the risk associated with institutionalized beneficiaries, relying on the market alone to ensure that Part D plans include a sufficient number of long-term care pharmacies in their networks may not be sufficient. We note that relying on the pharmacy access standards in § 423.120(a)(1) of our final rule will also not ensure sufficient access to long-term care pharmacies, since many of these pharmacies are not retail pharmacies and therefore would not count toward those requirements. Absent a contracting mandate, Part D plans may view contracting with long-term care pharmacies given the risk associated with institutionalized beneficiaries as too risky. To the extent that we require Part D plans to solicit long-term care pharmacies in their service areas to join their networks, plans may be forced to negotiate preferential contracting terms and conditions (relative to the terms they would offer any other pharmacy willing to participate in its network) for long-term care pharmacy-specific specialized packaging and services with a number of long-term care pharmacies in order to meet our requirement. In addition, although the statute includes an ''any willing pharmacy'' requirement, even if we require Part D plans to contract with any long-term care pharmacy in a service area, we cannot compel long-term care pharmacies to accept the plans' terms and conditions.

We believe it is essential to inject competition into the long-term care pharmacy market while preserving the relationships and levels of service that long-term care facilities now enjoy vis-à-vis their contracted long-term care pharmacies. To that end, we have used our authority under section 1860D–4(b)(1)(C)(iv) of the Act to require, in § 423.120(a)(5) of our final rule, that Part D plans offer standard contracting terms and conditions, including performance and service criteria for long-term care pharmacies that we will specify in operational guidance to all long-term care pharmacies in their service areas. In other words, we are establishing an ''any willing pharmacy'' requirement specifically for long-term care pharmacies, coupled with a requirement that Part D plans develop standard contracting terms and conditions for long-term care pharmacies, such that any pharmacy in a service area could become an eligible long-term care pharmacy by certifying that it meets certain performance and service criteria for providing pharmacy services to long-term care facilities. These criteria would be incorporated into a Part D plan's standard contracting terms and conditions for long-term care pharmacies. We will provide further detail regarding these criteria in operational guidance, but we expect that they will address access to urgent and emergency medications on a 24/7 basis, standardized prescribing systems, and the availability of one of several standard delivery packaging and delivery systems for routine medications. We expect to review the reasonableness of Part D plans' standard contracting terms and conditions for long-term care pharmacies. We note that entities other than current long-term care pharmacies (for example, retail pharmacies) could become an eligible long-term care pharmacy by meeting these standards of practice, so long as they also meet specific State law requirements, if any, for such entities. Plans in a region would be required to contract with any willing long-term care pharmacy in that region, provided those pharmacies were able to reach agreement with Part D plans on all standard contract terms and conditions including payment rates.

As provided in § 423.120(a)(5) of our final rule, we will require Part D plans to demonstrate that they have contracts with a sufficient number of long-term care pharmacies to ensure convenient access to prescription drugs for institutionalized beneficiaries within the service area. We will provide more detailed information in CMS guidance regarding what constitutes convenient access, but we expect that Part D plans will demonstrate convenient access based in part on the number of enrollees in their service areas and the geographic distribution, capacity, and contracting relationships with long-term care facilities of long-term care pharmacies in those service areas.

We expect that each long-term care facility will select one or more eligible network pharmacies to provide a Part D plan's long-term care drug benefits to all of its residents enrolled in a Part D plan. In order to minimize the number of pharmacy suppliers and maintain patient safety, long-term care facilities will likely select long-term care pharmacies that meet Part D standards and participate in the largest number of Part D plan long-term care networks. To maintain convenient access and minimize out-of-pocket expenses, Part D plan enrollees would obtain Part D benefits from the eligible long-term care pharmacy selected by the facility. The SEP and OEPI available to institutionalized beneficiaries, which will provide beneficiaries with the ability to change Part D plans to the extent that their current Part D plan does not include their facility's long-term care pharmacy in its network, will further incentivize long-term care pharmacies to participate in as many Part D plan long-term care networks as possible.

All long-term care pharmacies in a region will have to negotiate terms and conditions with as many Part D plans as possible or risk losing this business to

another more competitive long-term care pharmacy. This competition will preserve the one-to-one long-term care pharmacy long-term care facility relationship favored by so many commenters, but will require a negotiation between the long-term care pharmacy and the Part D plan to maintain that relationship. Given our rules for access to Part D drugs for institutionalized Part D enrollees, all Part D products and services would be removed from existing long-term care pharmacy contracts because payments for drugs for dual eligible individuals under Medicaid will become obsolete. This will likely necessitate the renegotiation of existing long-term care facility/long-term care pharmacy contracts. Separating the cost of the drug and dispensing fee from other long-term care pharmacy specialized services (for example, drug administration) may provide for more appropriate negotiation of these services and costs between long-term care facilities and pharmacies. We note that Part D plan payments under medication therapy management programs, described in further detail elsewhere in this preamble, may represent an additional revenue stream to long-term care pharmacy services for some of the special services provided by these pharmacies but not reimbursed through dispensing fees.

We believe that our long-term care pharmacy access rules will align incentives to accomplish several goals, including ensuring that long-term care pharmacies come to the table in good faith; negotiation of more competitive pricing than currently exists in the long-term care pharmacy market; and allowing for the one long-term care facility-one long-term care pharmacy relationship to remain intact, to the extent that long-term care facilities would like to keep it that way.

Comment: Two commenters favored the carve-out of beneficiaries in long-term care facilities through the establishment of a separate PDP region in which plans could bid, at risk, to serve this population.

Response: We understand that, given the institutionalized population's special needs, a carve-out of this population may seem logical. However, given the risk associated with institutionalized beneficiaries, we believe that carving out such a high-risk population would result in significant adverse selection and could result in unsustainable beneficiary premiums for the institutionalized population. In addition, our research related to risk adjustment is still in progress, and until that research is completed, we cannot be certain as to whether our risk adjustment model could adequately mitigate the risk inherent in this population under the highly unique circumstances of a plan serving only a carved-out institutionalized population. Consequently, particularly in the first few years after the implementation of the Part D program, we wonder whether potential Part D sponsors would be willing to serve a carved-out institutionalized population and therefore ensure access to Part D drugs for Part D enrollees residing in long-term care facilities. We are also concerned that beneficiaries entering and leaving long-term care facilities will be forced to change Part D plans to the extent that institutionalized beneficiaries are carved out into a separate PDP region. For these reasons, we will not create a separate PDP region for institutionalized beneficiaries and, as discussed above, will ensure convenient access to covered Part D drug in long-term care facilities as provided in § 423.120(a)(5) of our final rule.

Comment: We requested comments regarding whether we should use our authority under section 1860D–4(b)(1)(C)(iv) of the Act to require-or, instead, strongly encourage-that Part D sponsors approach any I/T/U pharmacies in their Part D plan service areas with at least the same terms available under the plan's standard pharmacy contracting terms and conditions.

Some commenters believe that we must use our authority under section 1860D–4(b)(1)(iv) of the Act to require Part D plans to contract with I/T/U pharmacies because, without this requirement, private plans will have little or no financial incentive to contract given the uniqueness of both the AI/AN population and I/T/U pharmacies. Simply encouraging contracts will not work because of the uniqueness and remoteness of I/T/U facilities and the perceived cost and time to contract with these pharmacies. These commenters urge us to require, in regulation, that Part D plans contract with I/T/U pharmacies using specific contract provisions. They urge us to consider one of several approaches to ensuring that I/T/U pharmacies experience no reduction in revenue as a result of the transition from Medicaid to Medicare Part D: supplemental payments from Part D plans or the Federal government to supplement the difference between the amount paid by the Part D plan and the amount the I/T/U pharmacy would have received under Medicaid, a carve-out of AI/AN enrollees for Part D plans willing to serve only those beneficiaries through I/T/U pharmacies, and an exemption of dual eligibles from Part D (with continued prescription drug coverage under Medicaid).

Response: There are currently 235 I/T/U pharmacies serving 107,000 senior and disabled AI/ANs in 27 States. In some areas, I/T/U pharmacies may be the only facilities capable of providing medication therapy management services to certain AI/AN beneficiaries due to language and cultural barriers. It is our understanding that I/T/U pharmacies are not currently well integrated in commercial pharmacy networks. We agree with the commenters who believe that—in the absence of a contracting requirement—Part D plans may make assumptions regarding the administrative costs (whether real or perceived) of contracting with I/T/U pharmacies and may not actively solicit the inclusion of these pharmacies in their networks. The lack of I/T/U pharmacies in Part D plan networks would render enrollment in Part D of little use to AI/AN beneficiaries who rely primarily on I/T/U facilities for their health care. For this reason, we have added a provision to our final regulations, at § 423.120(a)(6), requiring that Part D plans offer contracts to all I/T/U pharmacies in their service areas.

However, we recognize that contracting with I/T/U pharmacies is potentially more complex than contracting with retail pharmacies given that there are a number of provisions in the standard contracts of commercial health plans that would likely need to be modified or deleted given statutory or regulatory restrictions to which I/T/U pharmacies are subject, as well as the particular circumstances of I/T/U pharmacies (for example, I/T/U pharmacies purchase drugs off the Federal Supply Schedule (FSS) or through the 340B program; can only serve AI/ANs; may have less experience than retail pharmacies, or none at all, with point-of-sale technology; are not typically well integrated into commercial pharmacy networks; generally stock a more limited range of drugs than would be required under a Part D formulary; and always waive co-pays). Thus, standard contracting terms and conditions will not be sufficient for Part D plans to obtain the participation of I/T/U pharmacies in their networks. We are therefore requiring Part D plans to include a special addendum to their standard contracting terms and conditions in order to account for these differences. We will work with major stakeholders to develop a model special addendum that will take the special

circumstances of I/T/U pharmacies into account. As provided in § 423.120(a)(6) of our final rule, we will require Part D plans to demonstrate that they have contracts with a sufficient number of I/T/U pharmacies to ensure convenient access to prescription drugs for AI/AN enrollees within the service area. We expect to review the reasonableness of Part D plans' standard contracting terms and conditions for I/T/U pharmacies.

While we understand the Indian Health Service's concerns regarding reductions in revenue resulting from the transition of drug coverage from Medicaid to Medicare, we clarify that we do not have the statutory authority to require supplemental payments from Part D plans or the Federal government to supplement the difference between the amount paid by the Part D plan and the amount the I/T/U pharmacy would have received under Medicaid; a carve-out of AI/AN enrollees for Part D plans willing to serve only those beneficiaries through I/T/U pharmacies; or an exemption of dual eligibles from Part D (with continued prescription drug coverage under Medicaid). As we develop the model special addendum for I/T/U contracts, we will consider how, within our statutory authority, we might ensure that I/T/U pharmacies do not experience significant revenue losses as a result of the transitioning of drug coverage from Medicaid to Part D for dual eligible AI/ANs.

Comment: Several commenters noted that many small I/T/U pharmacies and dispensaries carry a limited stock of drugs, and that an exemption from formulary requirements (and the ability to use permissible substitutes) is necessary in order to accommodate the fact. In addition, these commenters note that another factor in whether I/T/U pharmacies will stock a particular drug is whether it is available from the Federal Supply Schedule or 340B program, which are the principal sources of drugs purchased by I/T/U pharmacies. Thus, a Part D plan may choose one particular cholesterol-lowering agent on its formulary because it is able to negotiate a greater discount for that particular Part D drug. However, I/T/U pharmacies may be able to access a different medication for a similar, or perhaps lower, price and therefore include that drug on its formulary.

Response: We are aware that most Tribes and Tribal Organizations (operating under health programs pursuant to contracts under the Indian Self-Determination Education and Assistance Act, Public Law 93–638) and all IHS facilities use the Department of Veterans Affairs Pharmaceutical Prime Vendor (PPV) for purchasing their pharmaceuticals. By ordering through the PPV, IHS and Tribes (but not Urban programs) are able to access FSS Contract, National Standardization Contract, and Blanket Purchasing Agreement pricing for pharmaceuticals. In addition to FSS pricing, Tribes and Urban programs that have been designated as Federally Qualified Health Centers (FQHCs) and have been approved by the Health Resources and Services Administration (HRSA) are eligible for HRSA 340B drug pricing. Since I/T/U facilities have access to different pricing than commercial health plans, their formulary selections reflect the drugs for which this pricing is available. As previously mentioned, we are requiring Part D plans to include a special addendum to their standard contracting terms and conditions in order to account for the differences between retail and I/T/U pharmacies and therefore facilitate contracting with these pharmacies. We will work with major stakeholders to develop a model special addendum that will take the special circumstances of I/T/U pharmacies into account, including the limited stocking of drugs at these facilities.

Comment: Several commenters said that the any willing pharmacy rule should apply to mail order as well as retail pharmacies, and that Part D plans should not be able to exclusively use a plan-owned mail order facility.

Response: We agree that the any willing pharmacy requirement at section 1860D–4(b)(1)(A) of the Act applies to all pharmacies—including non-retail pharmacies such as mail-order pharmacies—notwithstanding a Part D plan's ability to designate certain of its network pharmacies as preferred pharmacies with lower cost-sharing, or to negotiate terms better than those in its standard terms and conditions with certain pharmacies. We clarify that a Part D plan could have standard terms and conditions for retail pharmacies and a second, separate set of standard terms and conditions for mail order pharmacies in light of those pharmacies' different characteristics. For example, a plan's contracting terms and conditions for mail-order pharmacies could reflect the full cost of adding another mail-order vendor, as well as the differential costs of strong data controls involved with having multiple network mail-order pharmacies.

Comment: One commenter said it was not clear how the any willing pharmacy rule applies to facilities that are owned and operated by a Part D plan. The commenter said such plans should be permitted to maintain a limited network of contract pharmacies for purposes of meeting the access standard in order to maximize cost savings.

Response: We agree with this commenter that the any willing pharmacy requirement makes little sense in the context of Part D plans that own and operate their own pharmacies particularly since the pharmacy access rules in § 423.120(a)(1) of our final rule will be waived for MA-PD plans and cost plans that can demonstrate comparable pharmacy access under § 422.112. As provided in § 423.458(b) of our final rule, we may waive any Part D provision as applied to an MA-PD plan if it duplicates, or is in conflict with, provisions otherwise applicable to the MA organization or MA-PD plan under Part C of Medicare, or if waiver of a Part D provision is necessary in order to improve coordination of benefits under Part D with those offered under Part C. Similarly, § 423.458(d) provides that we may waive any Part D provision as applied to a cost plan if it duplicates, or is in conflict with, provisions otherwise applicable to the cost plan under section 1876 of the Act, or if waiver of a Part D provision is necessary in order to improve coordination of benefits under Part D with those offered by the cost plans. We will consider waiving this requirement for Part D plans that own and operate their own pharmacies to the extent that they request such waiver as provided in § 423.458(b)(2) and § 423.458(d) of our final rule.

Comment: We sought comment on whether, in order to guarantee that any pharmacy willing to meet a Part D sponsor's contracting terms and conditions could participate in a Part D plan's pharmacy network, we should require that a Part D sponsor make available to all pharmacies a standard contract for participation in their Part D plans' networks.

A number of commenters thought that Part D plans should be required to have a standard or model contract for use with all pharmacies. Other comments said that we should not require a standard contract. Alternatively, several commenters said that even with a standard contract, Part D plans should have maximum flexibility to vary their contracting terms and conditions in order to reflect local conditions. Some questioned whether we should try to evaluate whether pharmacy contract terms are ''reasonable and relevant,'' as proposed in subpart K of our proposed rule.

Response: We concur with the majority of commenters on this issue and will require, under § 423.505(b)(18) of our final rule that Part D plans offer pharmacies reasonable and relevant

standard terms and conditions for network participation. We do not intend to define ''reasonable and relevant'' in order to provide Part D plans with maximum flexibility to structure their standard terms and conditions.

However, it is unreasonable to assume—the any willing pharmacist requirement notwithstanding—that a Part D plan could establish a network using a uniform set of terms and conditions throughout a service area because it will likely need to modify contracting terms and conditions to ensure access to certain pharmacies (for example, rural and long-term care pharmacies). We clarify that standard terms and conditions particularly for payment terms may vary to accommodate geographic areas or types of pharmacies) and that this is acceptable, provided that all similarly situated pharmacies are offered the same standard terms and conditions. Thus, for example, provided Part D plans offer all mail-order pharmacies in a particular area with the same standard terms and conditions, they may offer separate standard terms and conditions to mail-order pharmacies. With standard terms and conditions as a ''floor'' of minimum requirements that all similarly situated pharmacies must abide by, Part D plans may modify some of their standard terms and conditions to encourage participation by particular pharmacies.

Comment: Many commenters disagreed with our interpretation of the ''any willing pharmacy'' provision, specifically with allowing Part D plans to construct networks of preferred and non-preferred pharmacies that have different requirements for beneficiary cost sharing. These commenters argued that allowing preferred networks undermines the any willing pharmacy rule and runs counter to Congressional intent. Many said that allowing Part D plans to steer beneficiaries to preferred pharmacies would impede pharmacy access and disrupt existing relationships between pharmacists and patients. Some argued that our interpretation would disadvantage small, independent, and rural pharmacies. Others said that a designation of ''non-preferred'' would carry a negative connotation about the pharmacy's quality of service.

Several other commenters concurred with the any willing pharmacy policy in our proposed rule. One commenter said that State any willing pharmacy laws should be expressly preempted, while another commenter said we should clarify that State any willing provider laws continue to apply to Part D plans' non-Medicare business. One commenter asked us to clarify the extent to which we will allow Part D plans to vary their cost sharing for preferred networks.

Response: We believe that we have correctly interpreted the two related provisions in sections 1860D–4(b)(1)(A) and (B) of the Act, which require Part D plans to allow any willing pharmacy to participate in their pharmacy networks, while also allowing Part D plans to reduce cost-sharing differentially for network pharmacies. General principles of statutory interpretation require us to reconcile two seemingly conflicting statutory provisions whenever possible, rather than allowing one provision to effectively nullify the other provision. Consequently, when a statutory provision may reasonably be interpreted in two ways, we have an obligation to adopt the interpretation that gives full effect to competing provisions of the statute. We believe that our policy of permitting cost-sharing discounts for preferred pharmacies, as codified in § 423.120(a)(9), strikes an appropriate balance between the need for broad pharmacy access and the need for Part D plans to have appropriate contracting tools to lower costs.

We note, however, that while these within network distinctions are allowed, the statute also requires that such tiered cost-sharing arrangements in no way increase our payments to Part D sponsors. Therefore, tiered cost-sharing arrangements based on within-network distinctions could be included in Part D plans' benefits subject to the same actuarial tests that apply to formulary-based tiered cost-sharing structures. Thus, a reduction in cost sharing for preferred pharmacies in a Part D plan network could be offered through higher cost sharing for non-preferred pharmacies (or as alternative prescription drug coverage). We also note that differential cost-sharing in the context of preferred and non-preferred pharmacies does not raise the cost-sharing obligation of low-income subsidy eligible enrollees above the levels specified in sections 1860D–14(a)(1) and (2) of the Act.

We recognize the possibility that Part D plans could effectively limit access in portions of their service areas by using the flexibility provided in § 423.120(a)(9) of our final rule to create a within-network subset of preferred pharmacies. In other words, in designing its network, a Part D plan could establish a differential between cost-sharing at preferred versus non-preferred pharmacies—while still meeting the access standards in § 423.120(a)(1) of our proposed rule—that is so significant as to discourage enrollees in certain areas (rural areas or inner cities, for example) from enrolling in that Part D plan. We emphasize that such a network design has the potential to substantially discourage enrollment by certain Part D enrollees, and that we have the authority under section 1860D–11(e)(2)(D) of the Act to disallow benefit designs that are discriminatory. We clarify that State any willing pharmacist laws would be preempted as applicable to plans' Part D business. This is consistent with section 1860D–12(g) of the Act, which extends the State preemption provisions under section 1856(b)(3) of the Act to Part D plans.

Comment: Several commenters thought that Part D plans should only be allowed to have differential cost sharing for preferred pharmacies if they exceed the TRICARE access standard.

Response: We see no statutory basis for such a rule. Moreover, it would be difficult to construct and operationalize such a policy.

Comment: Several commenters wrote that special needs enrollees should be exempted from higher cost sharing at non-preferred pharmacies.

Response: We see no statutory basis for such a rule, and we believe that Part D plans will provide sufficient access for all Part D enrollees under our access standards in § 423.120(a)(1). As noted in our proposed rule, we will use the authority provided under section 1860D–11(e)(2)(D) of the Act to review, as part of the bid negotiation process, how Part D plan networks make preferred and non-preferred distinctions among their network pharmacies and disallow them if such proposed network designs would substantially discourage enrollment by certain beneficiaries in any part of a Part D plan's service area. We believe that special needs enrollees will be sufficiently protected by this review. To the extent that special needs enrollees are also eligible for low-income subsidies, as indicated above, differential cost-sharing based on preferred pharmacy status does not raise the cost-sharing obligation of low-income subsidy eligible enrollees above the levels specified in the Act.

Comment: Several commenters suggested that the TRICARE access standards be applied to Part D plans' ''preferred'' networks rather than its general network. Several other commenters concurred with the regulation as drafted in the proposed rule.

Response: Section 1860D–4(b)(1)(B) of the Act clarifies that a Part D sponsor has the option of reducing cost-sharing for covered Part D drugs dispensed through network pharmacies below the level that would have otherwise applied. Because the statute provides

that such distinctions can be made within a network, we do not believe that only preferred pharmacies constitute a Part D plan's network for the purposes of meeting the access standards in § 423.120(a)(1) of our final rule. Rather, both preferred and non-preferred pharmacies form part of a Part D plan network, and plans may count both of these types of network pharmacies toward their access standards.

Comment: Several commenters recommended that beneficiaries be able to get an extended supply of drugs, greater than a 30-day supply, from network retail pharmacies and mail-order pharmacies.

Response: We clarify that section 1860D–4(b)(1)(D) of the Act, and § 423.120(a)(10) of our final rule, require Part D plans to permit enrollees to receive extended supplies (for example, 90-day supplies) of covered Part D drugs through a network retail pharmacy.

Comment: Some commenters noted that our proposed regulations would unfairly allow Part D plans to charge beneficiaries more when they obtain their prescriptions at a community pharmacy than when they use mail order. One commenter notes that seniors benefit from face-to-face interaction with a pharmacist more than other age groups, which would be precluded under mail order and would limit enrollees' ability to use the pharmacy and pharmacist of their choice.

Many commenters recommended that we specifically prohibit Part D plans from using economic incentives for beneficiaries to use mail order that could create significant differences in cost sharing for mail order versus retail pharmacy prescription, or that plans make such difference minimal. One commenter recommended that Part D plans use the same average wholesale price (AWP) basis to determine the reimbursement rate for mail order and retail pharmacies. Another commenter noted that there is substantial evidence that seniors, particularly low-income seniors, are victims of theft from their mailboxes, undermining the financial incentive of mail order. This commenter recommended that we allow beneficiaries to pay the mail order price at a retail pharmacy when they can demonstrate their mailbox is not secure.

Response: As provided in section 1860D–11(i) of the Act, we have no authority to interfere with the negotiations between Part D plans and pharmacies and therefore cannot mandate that Part D plans negotiate the same, or similar, reimbursement rates with all pharmacies. Provided Part D plans offer all pharmacies standard terms and conditions, they may modify their contracting terms—including payment provisions as necessary, as long as all similarly situated pharmacies are subject to the same minimum terms and conditions. Moreover, section 1860D–4(b)(1)(B) of the Act provides Part D plans with the authority to designate some network pharmacies, including mail-order pharmacies, as preferred pharmacies offering plan enrollees lower cost sharing.

Comment: One commenter noted that MA organizations that own and operate their own pharmacies usually have internal systems for providing prescription services by mail that are fully integrated with the overall pharmacy operation. As a result, it is difficult to provide an incentive to beneficiaries to use less costly mail services. The commenter said we should permit these organizations to establish differential benefit levels for mail delivery as opposed to in-facility pickup.

Response: As noted above, Part D plans have the flexibility to establish different cost-sharing requirements for the pharmacies in their networks consistent with section 1860D–4(b)(1)(B) of the Act. Accordingly, Part D plans have the flexibility to establish differential cost-sharing requirements for mail delivery and in-facility pickup.

Comment: One commenter recommended that we require Part D plans to contract with pharmacies that offer home delivery service, noting that same-day or next day need for medications makes mail-order an impracticable option.

Response: We do not believe there is a compelling rationale to require Part D plans to contract with pharmacies that offer home delivery service. As discussed elsewhere in this preamble, we have defined the term ''dispensing fees'' in § 423.100 of our final rule to include reasonable pharmacy costs, including delivery costs, associated with ensuring that possession of the appropriate covered Part D drug is transferred to a Part D enrollee. We clarify that reasonable delivery costs include only those costs appropriate for the typical beneficiary in a particular pharmacy setting. Thus, while it would be appropriate for Part D plans to reimburse long-term care, mail-order, and home infusion pharmacies for home delivery costs via the dispensing fee, this would not be the case for retail pharmacies (where the term ''delivery'' would be limited to the transfer of a covered Part D drug from the pharmacist to the patient at the point of sale) because the typical retail customer does not require home delivery. While retail pharmacies may offer home delivery services, Part D plans may not reimburse those pharmacies for these costs, and the delivery cost must be borne by the beneficiary.

Comment: Two commenters expressed their support for our interpretation of the term ''insurance risk'' and asked that we include in our regulations a statement that the prohibition against the assumption of risk by Part D plans' network pharmacies not preclude performance-based measures of activities within the control of a pharmacy (for example, formulary compliance and generic drug substitution).

Response: We clarify that our definition of the term ''insurance risk'' in § 423.4 of the final rule specifically excludes ''payment variations designed to reflect performance-based measures of activities within the control of a pharmacy, such as formulary compliance and generic drug substitutions.''

b. Formulary Requirements

1. P&T Committee Requirements

To the extent that a Part D sponsor uses a formulary to provide qualified prescription drug coverage to Part D enrollees, it will be required to meet the requirements of section 1860D–4(b)(3)(A) of the Act to use a pharmaceutical and therapeutic (P&T) committee to develop and review that formulary.

The majority of members comprising the P&T committee will be required to be practicing physicians or practicing pharmacists. In addition, at least one practicing pharmacist and one practicing physician member will have to be experts in the care of elderly and disabled individuals. Section § 423.120(b)(1)(ii) of the proposed rule also provided that at least one practicing pharmacist and one practicing physician members on a Part D plan's P&T committee be independent experts.

When developing and reviewing the formulary, the P&T committee will be required, in accordance with section 1860D–4(b)(3)(B) of the Act, to base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature. Section § 423.120(b)(1)(viii) of our proposed rule required that any decisions made by the P&T committee regarding development or revision of a Part D plan's formulary be documented in writing.

Except as otherwise provided below, the final rule adopts the requirements related to P&T committees set forth in § 423.120(b)(1) of our proposed rule.

Comment: Many commenters thought that P&T committee decisions regarding

a Part D plan's formulary should be binding on a plan. Other commenters thought that P&T committee recommendations should be advisory, and not binding. Several others believed that only clinical decisions should be binding on the Part D plan and that the ultimate responsibility for overall formulary design should reside with the plan and ultimately involved business leaders and technical experts. One commenter stated that it was not likely that a P&T committee comprised of non-employee clinicians would be able to make coverage determination in the Part D plan's and enrollees' best interests, particularly since many benefit design decisions have a financial, as well as a clinical, component.

Response: We agree with commenters who sought to draw a distinction between clinical and overall formulary design issues. We believe that the function of a P&T committee is to provide expertise on clinical issues, and not financial or benefit design issues. We interpret the requirement in section 1860D–4(b)(3)(A) of the Act and § 423.120(b)(1) of our final rule that Part D plan formularies be developed and reviewed by a P&T committee to mean that committee recommendations regarding which drugs are placed on a plan's formulary be binding on the Part D plan. Although § 423.120(b)(vi) and (b)(vii) of our final rule envision a role for the P&T committee in reviewing policies that guide exceptions and other utilization management processes including drug utilization review, generic substitution, quantity limits, and therapeutic interchange and in evaluating and analyzing treatment protocols and procedures related to the Part D plan's formulary at least annually, P&T committee recommendations in these areas should be considered advisory and not binding. We clarify, for example, that while the P&T committee may be involved in providing clinical recommendations regarding the placement of a particular Part D drug on a formulary cost-sharing tier, the ultimate decision on such formulary design issues is the Part D plan's, and that decision weighs both clinical and non-clinical factors. Thus, a P&T committee's role in formulary cost-sharing tiers, while important, would be advisory and not binding.

Comment: Many commenters recommended that we strengthen the statutory requirement in section 1860D–4(b)(3)(A)(ii) of the Act and require that more than just one practicing physician and one practicing pharmacist are independent and free of conflict. Suggestions for new requirements included that all, a majority, two-thirds, one-half, 40 percent, and at least four (at least two practicing physicians and two practicing pharmacists) members of a Part D plan's P&T committee be independent and free of conflict in order to ensure that formulary development is in line with beneficiary and not plan or pharmaceutical manufacturer interests. One commenter supported our current requirement requiring that at least one practicing physician and one practicing pharmacist on the committee be independent and free of conflict

Response: We appreciate commenters' suggestions and agree that maintaining the impartiality and objectivity of P&T committee members is an important goal. We have retained the proposed rule requirement that at least one practicing pharmacist and one practicing physician on the P&T committee be independent and free of conflict—in § 423.120(b)(1)(ii) of our final rule, though Part D plans should view this requirement as a floor which we encourage them to exceed. To balance concerns about conflicts of interest with regard to P&T committee members, and as proposed in the draft benefit design review criteria we recently issued for public comment, we would require all P&T committee members to sign a conflict of interest statement revealing economic or other relationships with entities that could influence pharmaceutical decisions, and to disclose such conflicts to other committee members. If P&T committee discussions center around a drug that presents a conflict of interest issue for a particular committee member, he or she would recuse himself or herself from any discussions or votes associated with that drug. We believe this requirement is necessary to ensure that the P&T committee's clinical decisions regarding development and review of the formulary are based on the strength of scientific evidence and standards of practice, safety and efficacy considerations, and other such appropriate information and considerations in accordance with section 1860D–4(b)(3)(B) of the Act. In addition, this requirement is consistent with best practices in pharmacy benefit management, and we expect that Part D plans will implement disclosure of conflicts and recusal procedures consistent with standard industry practice.

Comment: Many commenters requested clarification regarding our definition of the term ''independent and free of conflict'' with respect to a Part D sponsor and a Part D plan. Several commenters asked to clarify that our regulations regarding independence and freedom from conflict not preclude individuals from serving on a P&T committee simply because they are members of a Part D plan's provider network.

Response: In our proposed rule, we interpreted the language at section 1860D–4(b)(3)(A)(ii) of the Act requiring certain members of the P&T committee to be ''independent and free of conflict'' to mean that such P&T committee members could have no stake, financial or otherwise, in formulary determinations. We believe this interpretation is still appropriate, but clarify that we believe a P&T committee member not to be free of conflict of interest if he or she has any direct or indirect financial interest in any entity—including Part D plans and pharmaceutical manufacturers—that would benefit from decisions regarding plan formularies.

Thus, Part D plan network providers may be considered to be independent and free of conflict, provided they are not plan employees or contract workers and do not otherwise have any conflicts of interests that would compromise their independence. In cases of staff model HMOs, panel providers may be determined to be independent and free of conflict to the extent that any remuneration received from a Part D plan is limited to his or her clinical responsibilities for the care of plan enrollees.

Comment: In our proposed rule, we interpreted the language at section 1860D–4(b)(3)(A)(ii) of the Act requiring certain members of the P&T committee to be ''independent and free of conflict'' to mean that such P&T committee members would be required to be independent and free of conflict not only with respect to a Part D sponsor and its Part D plan, but also for pharmaceutical manufacturers. Some commenters supported such a requirement. A few commenters opposed such a requirement, however, claiming that our interpretation imposes a more stringent requirement than is permitted under the MMA. A number of other commenters cautioned us that our interpretation could exclude a significant number of individuals who are engaged in pharmaceutical and clinical research funded by pharmaceutical manufacturers.

Response: Section 1860D–4(b)(3)(A)(ii)(I) of the Act requires that at least one practicing physician and at least one practicing pharmacist on a Part D plan's P&T committee be independent and free of conflict only with respect to a Part D sponsor and its Part D plan. However, given the requirement in section 1860D–4(b)(3)(B) of the Act that

the P&T committee base clinical decisions on the strength of scientific evidence and standards of practice, and taking into account therapeutic advantages in terms of safety and efficacy, we believe it is necessary for those committee members who are ''independent and free of conflict'' to be so with respect to pharmaceutical manufacturers as well. We agree that P&T committee members could have certain non-employee relationships with pharmaceutical manufacturers (for example, consulting, advisory, or research relationships) and still be considered independent and free of conflict, provided those relationships do not constitute significant sources of their income and they do not otherwise have any conflicts of interests that would compromise their independence. As already mentioned, our draft benefit review criteria (recently issued for public comment) would require all P&T committee members to sign a conflict of interest statement revealing economic or other relationships with entities that could influence pharmaceutical decisions. This requirement is consistent with best practices in pharmacy benefit management, and we expect that it will be met consistent with industry standards for conflict of interest disclosures.

Comment: Several commenters supported requiring that a plurality of P&T committee members be experts in the care of elderly and disabled patients. Some commenters recommended that use of the certified geriatric pharmacist credential would be an appropriate way to ensure that at least one pharmacist on the P&T committee has expertise in care of the elderly. One commenter opposed requiring that at least one practicing physician and one practicing pharmacist be experts in the care of elderly and disabled patients. Another commenter thought that at least one member of Part D plans' P&T committees should be a State Medicaid representative.

Response: As provided in § 423.120(b)(1)(iii) of our final rule, we are retaining the requirement that at least one practicing physician and one practicing pharmacist on a P&T committee have expertise in the care of elderly or disabled persons, though plans should view this requirement as a floor which they can certainly exceed. As proposed in the draft benefit design review criteria we recently issued for public comment, we would require P&T committee members to represent various clinical specialties. This requirement is consistent with best practices in pharmacy benefit management and will ensure that appropriate expertise—including in the areas of care of disabled and elderly populations—is included on Part D plans' P&T committees and that their clinical decisions are based on the strength of scientific evidence and standards of practice, and safety and efficacy considerations. We expect that P&T committee members will represent a mix of clinical specialties in order to ensure that P&T committees have the breadth of expertise necessary to adequately evaluate scientific evidence, standards of practice, and other information.

Comment: A number of commenters suggested that we should require that P&T committees include experts in certain clinical specialties (for example, nephrology, oncology, rheumatology, dermatology, mental health, long-term care, and many others) or, at the very least, that such experts serve as consultants to P&T committees.

Response: We agree that P&T committee members should represent various clinical specialties in order to provide the depth of expertise needed to develop an adequate formulary and utilization management processes for the Medicare population. As proposed in the draft benefit design review criteria we recently issued for public comment, we would require P&T committee members to represent various clinical specialties. This requirement is consistent with best practices in pharmacy benefit management. In addition, we note that, since committee members must base clinical decisions on the strength of scientific evidence and standards of practice, it is not essential that every specialty be represented—either as a P&T committee member or as a consultant. For some issues, the use of peer-reviewed medical literature—including randomized clinical trials, pharmacoeconomic studies, outcomes research data, and other such information—may be sufficient.

Comment: We received a number of comments regarding our requirements for the basis of clinical decisions by Part D plan P&T committees. One commenter supported our characterization of the appropriate role of quality and cost considerations in Part D plan formulary development. Some commenters emphasized that cost considerations should be secondary to clinical issues in formulary development and review. One commenter suggested segregating cost and clinical reviews to preserve objectivity. Several commenters specifically suggested that we require Part D plan P&T committees to use classes of data that are included in the Academy of Managed Care Pharmacy (AMCP) format for Formulary Submissions—including clinical trials, health outcomes studies, and economic and budget impact models—as well as clinical guidelines issued by medical specialty societies. Several other commenters encouraged us to require Part D plans to consider data addressing total health care costs, if available, rather than pharmacy costs, in any cost considerations used for clinical decision-making.

Response: As required in section 1860D–4(b)(3)(B) of the Act, P&T committees will be required to base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature (for example, randomized clinical trials, pharmacoeconomic studies, outcomes research data, and other such information as the committee determines appropriate). In addition, a P&T committee must take into account whether including a particular Part D drug on the Part D plan's formulary (or on a particular formulary tier) has any therapeutic advantages in terms of safety and efficacy. Where applicable, therapeutic advantage should be considered in relation to the interaction of a drug therapy regimen and the use of other health care services.

We agree with commenters who urged that Part D plans consider data addressing total health care costs, if available, rather than pharmacy costs, in any cost considerations used for clinical decision-making. Since Part D sponsors have discretion with regard to the actual information their P&T committees use, we cannot mandate that all Part D plans use pharmacoeconomic studies, for example. However, in our subsequent guidance we intend to make clear that to the extent that the Part D plan considers costs in making its decision, it will take into account total health care costs rather than just drug costs. For example, to the extent that a particular drug has been shown to be more effective in preventing the need for hospital care or better at controlling acute flare-ups requiring the use of other services, we expect P&T committees to take these things into account in their determinations of drug efficacy. Given these requirements for evidence-based decision-making, it is our expectation that committee members will balance any relevant cost considerations with clinical considerations.

Comment: Some commenters supported a role for P&T committees in designing formulary tiers and any other clinical program implemented to encourage the use of preferred drugs. One commenter supported such a role,

provided that P&T committees are not required to be engaged in other benefit design issues.

However, several commenters believed that P&T committees should have no involvement in the development of utilization management programs including development of cost-containment tools, medication therapy management programs, and quality assurance programs, as well as more specific benefit design issues such as the development of cost-sharing tiers and should instead be limited to providing Part D plans with clinical recommendations on formularies. Other commenters thought that we should provide Part D plans with flexibility to determine how utilization management programs are designed and administered.

Response: We believe that the requirement in section 1860D–3(c)(1) of the Act that Part D sponsors establish an appropriate cost-effective drug utilization management program supports a role for P&T committees in the development of formulary management practices and policies—including prior authorization, step therapy, generic substitution, quantity limits, and other drug utilization management activities that affect access to covered Part D drugs. Furthermore, section 1860D–4(b)(3)(F) of the Act and § 423.120(b)(1)(vii) of our final rule require Part D plans to periodically evaluate and analyze treatment protocols and procedures. Clinical input is critical in the development of these policies in order to ensure that formulary management decisions balance economic and clinical factors to achieve appropriate, safe, and cost-effective policies. The review by P&T committees of Part D plan policies that guide exceptions and other utilization management processes is not only an important component in ensuring that plans adopt appropriate utilization management activities consistent with the statutory requirements, but also is consistent with best practices in pharmacy management policy. However, as previously stated, we believe that the primary function of a P&T committee is to provide clinical and not financial or benefit design—expertise.

Comment: Some commenters suggested that P&T committees review formularies regularly, with some suggesting a quarterly review and others an annual review

Response: As proposed in the draft benefit design review criteria we recently issued for public comment, we expect that P&T committees will meet on a regular basis, but not less frequently than on a quarterly basis. This standard is consistent with best practices in pharmacy management policy.

Comment: One commenter urged us to specify minimum timeframes for periodic evaluation of Part D plan treatment protocols and formulary-related procedures under § 423.120(b)(4) of our proposed rule. A number of commenters recommended that protocol reviews be conducted on an ongoing basis at least quarterly, whereas some specified that such reviews be conducted at least annually.

Response: As specified in § 423.120(b)(1)(vii) of our final rule, Part D plan P&T committees will be required to evaluate and analyze treatment protocols and procedures related to the plan's formulary at least annually.

Comment: A number of commenters also asked us to require that P&T committees have processes for making formulary revisions between regularly scheduled meetings when new clinical information becomes available or the FDA approves new medications.

Response: As proposed in the draft benefit design review criteria we recently issued for public comment, we expect that P&T committees will review new Part D drugs, or drugs for which new clinical information is made available by the Food and Drug Administration, within 90 days of the availability of new information. This will allow for appropriate formulary changes to be made with all due speed and ensure that a Part D plan's formulary is based on the most recently available scientific evidence, standards of practice, and drugs' relative therapeutic advantages in terms of safety and efficacy. However, we expect that drugs pulled from the market by the FDA or manufacturers will be removed from Part D plan formularies immediately.

Comment: Many commenters suggested additional requirements for ensuring P&T committee accountability, including requiring Part D plans to have a P&T committee regardless of whether they have a formulary or not; including a patient advocate on the committee to represent interests of patients; developing an oversight mechanism similar to local Medicare carrier advisory committees; requiring P&T committee meetings to be held publicly in order for consumers and stakeholders to have an opportunity to hear committee deliberations; requiring Part D plans to include a charge ensuring that the interests of beneficiaries are protected by their benefit design decisions; requiring thorough documentation of the rationale for P&T committee decisions; and requiring P&T committee decisions to be issued to the public upon request within a reasonable period of time.

Response: These requirements are not consistent with standard practice in pharmacy benefit management. We believe that our requirements in § 423.120(b)(1) of the final rule, as well as our formulary review which will consider the structure and utilization of an organizations P&T committee will sufficiently ensure that P&T committees function as a forum for evidence-based formulary review. As an added safeguard, and as provided in § 423.120(b)(1)(viii) of our final rule, we will require Part D plan P&T committees to document in writing the basis of their decisions regarding formulary development and revision and utilization management activities.

2. Plan Formularies

As provided under section 1860D–4(b)(3)(C)(ii) of the Act, we requested that the U.S. Pharmacopoeia (USP) develop a model set of guidelines that consists of a list of drug categories and classes that may be used by Part D sponsors to develop formularies for their qualified prescription drug coverage, including their therapeutic categories and classes. For more information about the USP model guidelines and the model guidelines themselves, please consult *http://www.usp.org/drugInformation/mmg/*.

Section 1860D–4(b)(3)(C) of the Act provides, and § 423.120(b)(2) of our proposed rule required, the inclusion of drugs in each therapeutic category and class of Part D drugs in a Part D plan's formulary, although not necessarily all drugs within such categories and classes. As discussed in the proposed rule, we interpreted this provision to require coverage of at least two Part D drugs within each therapeutic category and class of Part D drugs, unless only one Part D drug existed in a particular therapeutic category and class of Part D drugs.

We sought comments on ways to balance Part D plans' flexibility to use utilization management mechanisms to maximize covered Part D drug discounts and lower enrollee premiums with the needs of certain special populations of Part D enrollees, including Part D enrollees residing in long-term care facilities.

In accordance with section 1860D–4(b)(3)(C)(iii) of the Act, Part D sponsors cannot change therapeutic categories and classes in a formulary other than at the beginning of a Part D plan year, except as we would permit to take into account new therapeutic uses and

newly approved Part D drugs. Section 423.120(b)(4) of our proposed rule specified that, in accordance with section 1860D–4(b)(3)(F) of the Act, Part D sponsors will periodically be required to evaluate and analyze treatment protocols and procedures related to their formularies to ensure that their Part D plan members were receiving the best possible care for conditions related to their use of covered Part D drugs.

In addition, section 1860D–4(b)(3)(E) of the Act requires that Part D sponsors provide ''appropriate notice'' to us, affected enrollees, authorized prescribers, pharmacists, and pharmacies regarding any decision to either: (1) remove a drug from its formulary; or (2) make any change in the preferred or tiered cost-sharing status of a drug. Section 423.120(b)(5) of our proposed rule implemented this requirement by defining appropriate notice as at least 30 days prior to such change taking effect during a given contract year.

As provided under § 423.120(b)(6) of our proposed rule, we proposed that Part D sponsors be prohibited from removing a covered Part D drug or from changing the preferred or tiered cost-sharing status of a covered Part D drug between the beginning of the annual coordinated election period described in § 423.38(b) and 30 days subsequent to the beginning of the contract year associated with that annual coordinated election period.

Each Part D sponsor will also be required to establish policies and procedures to educate and inform health care providers and enrollees about its formulary, according to the provisions of section 1860D–4(b)(3)(D) of the Act. As required under section 1860D–4(b)(3) of the Act, the requirements regarding the development and application of formularies discussed in this preamble section may be met by a Part D sponsor directly, or through contracts or other arrangements between a Part D sponsor and another entity or entities.

Except as otherwise provided below, the final rule adopts the rules for Part D plan formularies set forth in § 423.120(b) of the proposed rule.

Comment: We received a significant number of comments that directly and indirectly relate to the USP draft model guidelines issued for public comment in August 2004. In general, the USP related comments can be grouped into two categories. On one side, many comments claim that the current draft model guidelines lack the necessary detail to ensure that beneficiaries will have access to a comprehensive drug benefit, often citing specific examples of medications that are necessary for the treatment of the most frail and vulnerable populations and could be excluded from Part D plan formularies that comply with the model guidelines.

On the other hand, many comments recommended that the USP model guidelines allow Part D plans the flexibility they need to develop clinically sound formularies that offer a prescription drug benefit at the lowest possible cost. Most of these commenters believe that the draft model guidelines, while in need of some specific modifications, are closer to reasonable than unreasonable. However, these commenters claim that the minimum ''drugs'' requirements for each category and class could significantly increase benefit costs if the categories and classes increase to a level of detail that interferes with Part D plans' ability to negotiate with manufacturers.

Response: We believe that the USP model guidelines identify a reasonable number of categories and classes that balance the need for a comprehensive Part D benefit with the need to allow Part D plans flexibility to develop their own formularies and manage costs. These model guidelines will provide us with a useful, standard format as a starting point for our review of Part D plan benefit packages, since we expect many plans will adopt the model guidelines as the basis for their formulary classifications and submissions.

The model guidelines, while important in creating a template for a formulary classification system, are not the only determinant of an adequate formulary. Plans will be required to include the types of drugs most commonly needed by Part D enrollees, as recognized in national treatment guidelines, in their formularies. Regardless of whether a Part D plan chooses to use the model guidelines or not, we will review the drugs chosen to populate plan formularies under our authority in section 1860D–11(e)(2)(D) of the Act to ensure that plan benefit design does not discourage enrollment by certain classes of Part D eligible individuals. However, formulary structure—including tiered cost-sharing structures -utilization management processes, P&T committee utilization and structure, and exceptions and appeals processes are just as important in ensuring a comprehensive benefit, and we intend to review these benefit design features as part of our comprehensive benefit package review. We discuss our benefit design review criteria in greater detail elsewhere in this preamble.

Comment: Several commenters disagreed with our interpretation of the statutory term ''drugs'' as requiring coverage of at least two Part D drugs within each therapeutic category and class of Part D drugs (unless only one Part D drug existed in a particular therapeutic category and class of Part D drugs), arguing that such an interpretation was too expansive, and requiring coverage of too many drugs in too many categories would diminish Part D plans' negotiating leverage. These commenters provided examples of drug categories for which a blanket requirement of two drugs is not appropriate, and an exception should be granted. One commenter recommended that we should allow an exception from this rule for categories and classes that only include two drugs, and allow enrollees to obtain the non-formulary drug in such categories via the exceptions process only.

In contrast, several commenters believed that requiring Part D plans to include two drugs in each therapeutic category and class of Part D drugs was not sufficient to ensure enrollee access to necessary medications. They were concerned that for some categories—including cancer treatments, rare diseases, mental illness, chronic pain, and other conditions—requiring only two drugs per drug category and class would be inadequate for Part D plans in terms of the statutory requirement that plan design not discourage enrollment.

Several commenters urged us to clarify that this minimum two-drug requirement must be met through drugs or biologicals offered on an unrestricted basis (for example, not subject to utilization management processes, such as prior authorization or step therapy, non-preferred cost-sharing tiers, or other such restrictions on access to necessary therapies), with some specifically urging us to impose restrictions on step therapy by Part D plans. Some asked us to specify that the two drugs must be distinct chemical entities. One commenter recommended that we do not allow any Part B-covered drugs to count toward the two-drug-per-category requirement.

Response: Section 1860D–4(b)(3)(C) of the Act requires that Part D plans' formularies include ''drugs within each therapeutic category and class of Part D drugs, although not necessarily all drugs within such categories and classes.'' We believe that our interpretation of ''drugs'' as ''at least two drugs'' is consistent with Congressional intent, and that it strikes an appropriate balance between providing Part D plans with the necessary leverage to negotiate with manufacturers for significant

discounts on covered Part D drugs and ensuring sufficient drug choice for beneficiaries. We have therefore retained the two-drug minimum requirement in § 423.120(b)(2)(i) of our final rule.

However, we recognize that Part D categories and classes may exist for which there are only two Part D drugs, and that including both of those drugs on a formulary may be problematic if the two drugs are vastly different in their clinical effectiveness. Given that section 1860D–4(b)(3)(C) of the Act requires that Part D plan formularies include ''drugs within each therapeutic category and class of Part D drugs, although not necessarily all drugs within such categories and classes,'' we will allow plans to request exceptions to the requirement in § 423.120(b)(2)(i) of our final rule to the extent they can demonstrate that there are only two Part D drugs available for a particular Part D drug category or class and that one of those drugs is clinically superior to the other. We have incorporated this provision at § 423.120(b)(2)(ii) of our final rule.

In response to comments that our proposed requirement is insufficient to provide adequate access to medically necessary treatments for Part D enrollees, we clarify that we will require Part D plans to adopt policies that ensure that beneficiaries have reasonable access to medically necessary drugs. Although Part D plans will not be required to include every Part D drug on their formularies, we will—as codified in § 423.120(b)(2)(iii) of our final rule—require that plans include adequate access to the types of drugs most commonly needed by Part D enrollees, as recognized in national treatment guidelines, on plan formularies. We are establishing this requirement consistent with section 1860D–11(d)(2)(B) of the Act, which provides us with authority similar to that provided to the Director of the Office of Personnel Management for setting ''reasonable minimum standards'' for health benefits plans. We are looking to existing national standards to inform our review at the drug level, and Part D plans will be expected to accommodate national guidelines and offer complete treatment options for a variety of medical conditions, including (but not limited to) asthma, diabetes, depression, lipid disorders, hypertension, and HIV. This is necessary in order to ensure that Part D plans do not substantially discourage enrollment by certain Part D eligible individuals based on exclusions of certain classes of drugs from their formularies. In addition to examining specific drugs on Part D plan formularies, and as discussed in greater detail elsewhere in this preamble, we will review other aspects of plan benefit designs—including tiered cost-sharing formulary structures, P&T committee structure and utilization, utilization management policies and processes, and exceptions and appeals processes—to ensure that Part D plans generally meet the requirements under Part D, including the provision of an adequate benefit.

We do not agree with comments asking that the two-drug requirement be met through drugs offered on an unrestricted basis. We recognize that Part D plans may establish utilization management processes in such a way as to substantially discourage enrollment by certain beneficiaries. On the other hand, utilization management restrictions may be entirely appropriate for specific drugs or categories of drugs. Furthermore, the statute specifically allows plans to utilize tiered cost-sharing structures provided they meet certain actuarial equivalence tests. As previously mentioned, part of our benefit design review will focus not only on the specific drugs included on a Part D plan's formulary, but also on a plan's utilization management policies and procedures, to ensure that plans do not discriminate against certain enrollees.

In addition, while drugs covered under Part B cannot be covered under Part D, as provided in section 1860D–2(e)(2)(B) of the Act, this exception to Part D coverage is limited to the drugs ''as so prescribed and administered'' under Part B. Thus, the fact that a beneficiary can have a particular drug covered under Part B ''incident to'' a physician service or as part of a hospital outpatient procedure does not mean that a prescription for the same drug should be denied by a Part D plan. We will provide more guidance on this issue, but we clarify that the number of drugs that may be denied coverage under Part D on the basis of the drug itself is limited. One category of drugs that can clearly never be covered under Part D is the list of oral cancer drugs covered under Part B. Such drugs and limited number of others may not be counted toward the two-drug minimum.

Finally, we clarify that our two-drug minimum requirement must be met through the provision of two chemically distinct drugs. In other words, Part D plans may not include two dosage forms or strengths of the same drug, or a brand-name drug and a generic equivalent, in a particular category or class and meet the requirement in § 423.120(b)(2)(i) of our final rule.

Comment: One commenter recommended that Part D plans' formularies include a wide variety of available dosage forms to the extent that was feasible. Another commenter asked us to clarify that we would not allow Part D plans to count different dosages of the same active ingredient as two separate drugs for the purposes of our two drug requirement. A third commenter asked us to clarify that it is acceptable for Part D plans to favor some dosages over others on their formularies.

Response: We stated in our proposed rule that it was our expectation that the drugs included in each therapeutic category or class would include a variety of strengths and dosage forms, and we stand by that expectation in our final rule. However, we clarify that Part D plans will not have to provide equal access to all strengths and dosage forms of a particular Part D drug, although beneficiaries will have the right to pursue coverage of additional strengths and dosage forms through the appeals process. We have clarified in § 423.120(b)(2)(i) of our final rule that Part D plans must include two chemically distinct Part D drugs in each therapeutic category and class of drugs, with different strengths and doses available for each of those drugs. Thus, Part D plans may not meet this requirement by only including two or more different dosages of the same Part D drug in a particular drug category or class.

Comment: Many commenters were concerned that our regulations will create barriers to physicians prescribing the best medication for their patients, including off-label uses of medications, which are common for many conditions and are the norm for some conditions. In actuality, off-label use is critically important and may be the mainstay of medical practice for successfully managing certain conditions, such as mental illnesses, chronic pain, chronic heart failure, arthritis, Parkinson's, HIV/AIDS and dementia. The FDA recognizes that ''off-label use of drugs by prescribers is often appropriate and may represent the standard of practice.'' A number of commenters opposed our position that the USP model guidelines should not be required to include classes of drugs if there is no FDA approved drug with an on-label indication for each class, even though there are FDA-approved drugs with commonly accepted off-label uses that would fall within a class. One commenter noted that any action taken by us regarding off-label use of medications would have a ripple effect on other public and private programs.

Some commenters requested that we clarify the formulary requirements in our final rule to require Part D plans to cover medically accepted off-label use of prescription drugs. They believe this is consistent with Congressional intent and past practice under the Medicare and Medicaid programs. In addition, one commenter is concerned that by assigning a drug to a specific class for formulary purposes, a Part D plan may not cover it for other medically accepted indications. One commenter suggested formularies should be required to include off-label uses for drugs for the prevention and treatment recommended in clinical guidelines issued by government agencies and medical societies, whether on-label or off-label. Another commenter said that off-label use must be accessible through a Part D plan's exceptions process for non-formulary drugs.

Response: We recognize the value of off label prescribing, particularly with regard to certain medical conditions. As mentioned in the proposed rule, we expect that the model categories and classes developed by USP will be defined so that each includes at least one drug that is approved by the FDA for the indication(s) in the category or class. That is, no category or class will be created for which there is no FDA approved drug and which would therefore have to include a drug based on its ''off label'' indication. We expect Part D plans using alternative drug classification systems to include at least one drug that is approved by the FDA for the indication(s) in each drug category or class. However, this would not preclude physicians and other prescribers from prescribing drugs for off label indications, provided the drug is prescribed for a ''medically accepted indication,'' as defined in section 1927(k)(6) of the Act. Further, we clarify that the USP model guidelines would not preclude Part D sponsors from assigning an FDA approved drug to a category or class based on an off label use for that drug, provided the FDA has not made a determination that the drug is unsafe for that use.

We do not have the authority to require that Part D plans cover the off-label use of certain Part D drugs. However, as discussed in greater detail elsewhere in this preamble, we will thoroughly evaluate plan benefit design to ensure that Part D plans provide an adequate benefit and do not discriminate against certain classes of Part D enrollees—including a review of plan utilization management policies and processes, formulary structure, and plan exceptions and appeals processes. We believe that these safeguards will ensure Part D enrollee access to Part D drugs dispensed for medically appropriate off label indications.

Comment: Multiple commenters were concerned that it is inappropriate for physicians to be given the new burden to ''document and justify'' off-label use in their Part D enrollees' clinical records due to the administrative burden and the interference with the practice of medicine by physicians. Many commenters mentioned that the FDA has recognized the right of physicians to use approved drugs and devices as they believe appropriate and never suggested there is a need to document such use. One commenter noted this documentation requirement is unprecedented and steps beyond well-established boundaries by inserting us into an individual physician's professional decision-making. If documentation is required, one commenter asked us to clarify what constitutes sufficient documentation.

One commenter, however, noted the need for documentation on prescriptions for off label use to enable pharmacists to conduct drug utilization review. Another commenter recommended regular reviews by us and by P&T committees through drug utilization and provider interviews as is customary in commercial plans.

Many commenters urged us to mandate that Part D plans give deference and flexibility to physicians when making coverage determinations since a patient's physician has clinical expertise and intimate knowledge of patients' medical needs. One commenter suggested that we specify that Part D plans may not prohibit providers from prescribing drugs for discretionary use if such use is supported by one or more standard reference compendia or by one or more scientific studies published in peer-reviewed medical journals or by generally accepted standards of clinical care. One commenter suggested that MMA regulations should restrict the ability of Part D plans to limit physician prescribing for off-label purposes unless there is objective medical evidence that such prescribing is inefficacious or harmful to the individual patient.

Commenters noted that onerous administrative hurdles associated with medically necessary off-label use could result in barriers to patient access to essential therapies. Without specific guidance, Part D plans could simply minimize financial risk through delay tactics disguised as Federal documentation requirements. One commenter recommended that at a minimum, we should clarify that there is nothing to prevent a Part D plan from covering an off-label use that does not meet the statutory definition of ''medically accepted indication'' if, based on expert advice, the plan determines that such use is appropriate. Multiple commenters suggested that the final rule guidance for Part D drugs should be at least as flexible as the current coverage policies for drugs covered under Medicare Part B. Under Part B, the definition of a ''medically accepted indication'' includes indications published in peer-reviewed literature; current Part B coverage policy regarding off-label drug use is also consistent with these norms.

Response: By stating in the proposed rule preamble that we strongly encouraged physicians and other prescribers to clearly document and justify off-label use in their Part D enrollees' clinical records, we did not intend to establish a new documentation requirement for prescribers. We agree with commenters that physicians must have sufficient latitude to prescribe drugs as necessary based on their patients' particular medical needs and consistent with medical standards of practice, and our statement should not be interpreted as imposing new and onerous reporting requirements on prescribers. As previously mentioned, we will thoroughly review plan benefit designs to ensure that Part D plans meet all applicable requirements under Part D including the provision of an adequate benefit. We expect that onerous documentation requirements for off-label prescribing could potentially be cause for finding that a Part D plan's proposed benefit structure does not meet Part D requirements.

We note that a drug is considered to be a Part D drug only if prescribed for a ''medically accepted indication'' as defined under section 1927(k)(6) of the Act. Drugs may not be covered under Part D even if they are not prescribed for a medically accepted indication. Coverage for other than a medically accepted indication is not permitted under the statute, since such drugs would not be considered Part D drugs. Plans have the flexibility to decide how to monitor whether a drug is prescribed for a medically accepted indication, as well as to determine whether the statutory definition of ''medically accepted indication'' is met with regard to the particular use of a drug.

Comment: We received numerous comments regarding our authority under section 1860D–11(e)(2)(D)(i) of the Act to review Part D plan benefit designs including any formulary or tiered formulary structure to ensure that plans do not discriminate against certain Part

D eligible individuals. Many commenters urged us to use this authority to thoroughly, comprehensively, and judiciously review Part D plan design and benefits including formulary structure to prevent discriminatory practices. Some of these commenters were adamant that such a review not be limited only to the particular drugs included on a formulary list, but also to tiered cost-sharing (including the use of 100 percent cost-sharing tiers), and utilization management requirements (for example, appeals, prior authorization, and step therapy requirements).

Several other comments cautioned us not to be overly prescriptive in our formulary review criteria and avoid unintentionally limiting the ability of Part D plans to manage the costs of the Part D benefit. One commenter suggested that our formulary review standards should provide substantial deference to P&T committees including on cost-sharing, step-therapy, and prior authorization processes, and that we should not establish our own requirements in these areas.

Other commenters asked that greater specificity regarding our criteria for formulary review, as well as practices that would be considered discriminatory, be provided either in regulation or in separate guidance, or both. Several commenters urged us to use defined performance metrics to make formulary discrimination assessments. Several commenters encouraged us to establish a flexible and readily accessible process for dialogue with a variety of stakeholders to create appropriate formulary review criteria, and one commenter urged us to actually involve States in the review process.

Several commenters thought our formulary review process should be performed annually and that contract renewal should be contingent upon passing our review. Others thought that Part D plan formularies should be reviewed more often given plans' ability to make formulary changes mid-year.

Response: We will comprehensively review Part D plans' proposed benefit structure to ensure that they generally comply with all applicable standards under Part D. We intend to conduct a reasonable review, providing guidelines that Part D plans can use in building formularies and structuring their bids. We recently shared with the public a first draft of our benefit package review criteria and, based on public comments received on that document, will finalize and make available publicly our final review criteria in early 2005.

Consistent with the authority provided under section 1860D–11(e)(2)(D)(i) of the Act, we will review Part D plan formularies to ensure that plans do not discriminate against certain classes of Part D eligible individuals by adopting a benefit design (including any formulary or tiered formulary structure) that would substantially discourage enrollment by certain beneficiaries. Nothing in the statute would foreclose us from concluding that a Part D plan's formulary substantially discourages enrollment even if the plan's classes and categories are considered non-discriminatory (for example, because the plan uses the USP model guidelines to structure its formulary). Although Part D plans will not be required to include every Part D drug on their formularies, we will require Part D plans to offer an adequate benefit. For example, we have the discretion to find that failure to include a specific drug would substantially discourage enrollment by beneficiaries with a condition that may only be treated by that drug. We are looking to existing national standards to inform our review at the drug level, and Part D plans will be expected to accommodate these national guidelines.

We believe that other aspects of Part D plan benefit design including formulary structure (including tiered cost-sharing structures), the structure and utilization of a plan's P&T committee, a plan's utilization management policies and procedures (for example, prior authorization, step therapy, and generic substitution), and a plan's exceptions and appeals processes are as important as a plan's formulary list of drugs in ensuring that beneficiaries are offered an adequate benefit that generally complies with all applicable standards under Part D. Therefore, we intend to review these plan features as part of our comprehensive review of Part D plan benefit designs.

We will review tiered cost-sharing arrangements to ascertain that the cost sharing associated with certain drugs or classes of drugs does not discourage enrollment by certain beneficiaries for example, those with certain diseases or medical conditions. We will also review a Part D plan's P&T committee structure and processes to ensure that plans comply with the requirements of section 1860D–4(b)(3)(B) of the Act, which creates standards designed to ensure impartial, clinically-based decision-making by P&T committees.

A Part D plan's utilization management policies and processes must ensure that beneficiaries have continuous, timely, and appropriate access to Part D drugs, and that such policies are structured on evidence-based criteria that are reviewed by a Part D plan's P&T committee. Section 1860D–4(c)(1)(A) of the Act requires Part D plans to establish cost-effective drug utilization management programs (including incentives to reduce costs when medically appropriate). Our review of plan utilization management policies and processes will ensure that those policies and processes are medically appropriate and do not discriminate against certain beneficiaries.

We clarify that a non-formulary drug is not necessarily a non-covered Part D drug. The MMA provides for an exceptions process whereby enrollees and prescribers can request Part D coverage at more favorable cost sharing than for non-preferred drugs, as well as access to non-formulary drugs at formulary cost-sharing levels. As discussed elsewhere in this preamble, we interpret section 1860D–4(h)(2) of the Act as requiring Part D plans to cover a non-formulary drug on appeal when, upon review, a physician determination of medical necessity is upheld. Thus, while Part D plans are not required to approve a non-formulary Part D drug in the first instance at the point of sale, plans are required to provide access to Part D drugs, both formulary and non-formulary, on appeal, where there is a legitimate medical need. We will review Part D plans' exceptions and appeals processes to ensure that evidence-based criteria are used to ensure medically appropriate access to all Part D drugs, including those drugs that are not favorably placed on a plan's formulary or not on the formulary at all.

Section 1860D–11(d)(2)(B) of the Act provides us with authority similar to that provided to the Director of the Office of Personnel Management with respect to health benefits plans; this includes setting ''reasonable minimum standards'' for plans. As we finalize our guidelines, we will look to existing national standards and guidelines, such as those established by the Utilization Review Accreditation Commission (URAC), the National Committee for Quality Assurance (NCQA), the American Society of Health Systems Pharmacists (ASHP), and the Academy of Managed Care Pharmacy (AMCP) to develop a framework for formulary management. The principles embodied in these standards and guidelines represent commercial best practice, and we believe Part D enrollees should be granted the same rights and protections under their Part D plan as generally

available to those enrolled in commercial plans.

Comment: Many commenters supported establishing rules for special treatment, to include alternative or open formularies and other special provisions and exemptions, for certain classes of enrollees. Commenters suggested a number of classes of beneficiaries that we may want to consider ''special populations'' for the purpose of offering such special rules, including dual eligibles, institutionalized beneficiaries, individuals with certain diseases or medical conditions, and minority populations. Other commenters opposed any requirement that special populations be subject to special rules. Instead, they argued that we should provide Part D plans the flexibility to manage and design benefits consistent with their enrollees' needs. They felt that prescriptive guidance was not necessary and that our review for discrimination should be sufficient to ensure adequate access to all medically necessary drugs.

Response: We share commenters' concerns about access to all medically necessary Part D drugs by vulnerable Part D enrollees. However, after much consideration, we disagree with commenters who advocated for specific requirements in regulation that would create special rules applicable only to certain classes of Part D enrollees. We believe commenters' concerns regarding access to Part D drugs for vulnerable populations will be addressed via our review of Part D plan benefit packages.

As discussed in great detail elsewhere in this preamble, we will comprehensively review Part D plans' proposed benefit structure to ensure that they generally comply with all applicable standards under Part D—including the provision of a benefit that provides for adequate coverage of the types of drugs most commonly needed by Part D enrollees, as recognized in national treatment guidelines. We intend to conduct a reasonable review, providing guidelines that Part D plans can use in building formularies and structuring their bids. We recently shared with the public a first draft of our benefit package review criteria and, based on public comments received on that document, will finalize and make available publicly our final review criteria in early 2005.

Comment: A number of commenters urged us to place strict limits on Part D plans' ability to remove drugs or increase the cost sharing associated with certain formulary drugs mid-year. One commenter suggested we allow for changes only at the beginning of a contract year so that changes are announced to current and prospective enrollees prior to the open enrollment period and Part D plans are able to market their new formulary for the upcoming plan year. Another commenter recommended that we allow formulary changes only from October 1st to November 14th of a given year.

Several commenters suggested that Part D plans be required to provide justification for any decision to remove a drug from the formulary. Another commenter stated that Part D plans should be required to document any decision to remove a drug from the formulary based on detailed scientific and clinical evidence. This commenter noted that reasons for discontinuing coverage could include new clinical evidence that a drug is unsafe, contraindicated for particular indications, or a manufacturer's withdrawal from the market. Other commenters noted that Part D plans should only be allowed to remove drugs from their formulary when new information about a drug's safety becomes available.

Response: The goal of the MMA was to encourage private sector organizations who meet the law's requirements to offer a range of Part D plan options for Medicare beneficiaries by providing flexibility in plan design and management. This flexibility is modeled after the way consumers in the private sector receive drug benefits. Although the statute requires us to limit changes in the therapeutic categories and classes of a Part D plan's formulary to the beginning of each plan year (except as we permit to take into account new therapeutic uses and newly approved Part D drugs), it does not give us similar authority to preclude mid-year changes to a Part D plan's formulary list. However, as provided in section 1860D–4(b)(3)(E) of the Act, codified in § 423.120(b)(5) of our final rule, and discussed in greater detail elsewhere in this preamble, Part D plans must provide appropriate notice to affected enrollees, among others, prior to removing a drug from their formulary or changing the preferred or tier status of a formulary drug. Such notice will provide beneficiaries with ample time to transition to a covered Part D drug that meets the enrollee's needs, or to request a coverage exception.

Comment: We received a number of comments urging us to consider requirements related to the ''grandfathering,'' on the same terms as previously available, of covered Part D drugs that are either removed from Part D plan formularies, or whose cost-sharing tier or preferred status changes, mid-year. One commenter stated that patients with chronic diseases who are stabilized by a plan-covered drug at the beginning of the year should not experience a higher copayment or be denied coverage of a drug based on a formulary change.

Other commenters thought the grandfathering should apply more broadly. Some commenters said that Part D plans should be required to grandfather a drug for anyone taking the medication prior to its removal from their formulary (unless removed due to FDA safety concerns). One commenter recommended that we require Part D plans to grandfather coverage of chronic medications until the next open enrollment period. Other commenters noted that, if we do not include rules placing strict limits on formulary changes during the year, Part D plans should be required to continue coverage of the discontinued drug for the remainder of year, at the same price, for all individuals taking the drug as part of an ongoing treatment regimen. One commenter suggested that Part D plans be required to provide patients with a 72-hour supply of a drug if it has been removed from the formulary. However, some commenters also clarified that such a requirement should not be meant to prohibit a Part D plan from asking physicians to voluntarily switch patients to less costly drugs through a therapeutic substitution initiative.

Response: Although the MMA does not preclude mid-year formulary changes by Part D plans, it does require that plans provide appropriate advance notice to affected enrollees of any removal of a covered Part D drug from a formulary, or any change in the preferred or tiered cost-sharing status of a covered Part D drug. As detailed elsewhere in this preamble, we have interpreted ''appropriate notice'' to mean at least 60 days prior to such change taking effect. We believe that 60 days, which is consistent with National Association of Insurance Commissioners (NAIC) model guidelines, provides affected enrollees with ample time to either switch to a therapeutically appropriate alternative medication, or obtain a redetermination by the Part D plan, reconsideration by the independent review entity, and request an administrative law judge hearing before the change becomes effective. To the extent that Part D plans do not provide such 60-day advance notice, they will be required to provide such notice and a 60-day supply of the drug at the same terms covered previously when affected enrollees request refills of their prescriptions. Once notice is provided, enrollees will have a 60-day window to either switch to a

therapeutically appropriate alternative medication, or obtain a redetermination by the Part D plan, reconsideration by the independent review entity, and request an administrative law judge hearing before the 60-day supply is exhausted.

Comment: A number of commenters voiced support for some kind of transition period for beneficiaries, particularly full-benefit dual eligibles, transitioning to Medicare Part D from other drug coverage. These commenters argue that, under Medicaid, many beneficiaries—especially those with certain conditions (HIV/AIDS and mental illness, for example, as well as those residing in long-term care facilities)—may experience relatively unfettered access to medically necessary drugs. This may not be the case when these enrollees transition their drug coverage from Medicaid to Part D, since different Part D plans will have different formularies, cost-sharing tiers, and utilization management requirements. Commenters are concerned that vulnerable beneficiaries may elect, or may be auto-enrolled in, a Part D plan that does not cover the drugs these beneficiaries need. More generally, several commenters noted that many beneficiaries—and not just those who are considered vulnerable or special populations—could face a significant loss of continuity of care if Part D plans' formularies are substantively different from each other or from commercial plans. They advocate for an additional coverage clause for patients transitioning into or changing Part D plans in order to avoid disruptions in care.

Response: We agree with commenters that Part D plans should have processes in place to transition current enrollees from their old coverage to their new Part D plan coverage, particularly in cases where new enrollees are currently taking Part D drugs that are not included on the Part D plan's formulary at the time of enrollment. However, we envision that the need for such a transition period will be limited for several reasons.

In reviewing a Part D plan's benefit package, we have the discretion to find that failure to include a specific drug on the formulary would substantially discourage enrollment by beneficiaries with a condition that may only be treated with that drug. For example, we expect that ensuring that beneficiaries with certain conditions, such as HIV/AIDS, are not as a group substantially discouraged from enrolling in a Part D plan will require that all or substantially all drugs in a particular therapeutic class be covered. In addition, in our review of plan benefit packages and our general oversight to ensure that Part D plans comply with all applicable requirements, we will examine not only the inclusion of particular drugs on a formulary, but also the structure and utilization of a plan's P&T committee, formulary structure (including tiered cost-sharing structures), a plan's utilization management policies and procedures (for example, prior authorization, step therapy, and generic substitution), and exceptions and appeals processes and how such processes guide access to both formulary and non-formulary drugs. Given such a review of the overall benefit package, we would expect that the majority of transition concerns vis-à-vis special populations will be obviated prior to beneficiary enrollment, as Part D plans will know our benefit package review criteria in advance of the bidding process. In addition, and as described in detail elsewhere in the section of this preamble discussing exceptions and appeals, we are adopting a substantive rule requiring coverage of non-formulary drugs on appeal provided that a medical necessity determination is upheld upon review.

To address the needs of new Part D plan enrollees who are transitioning to Part D from other prescription drug coverage, and whose current drug therapies may not be included in their Part D plan's formulary despite the safeguards noted above, we are requiring—in § 423.120(b)(3) of our final rule—that Part D plans establish an appropriate transition process for new enrollees which we would review as part of our benefit package review process. Section 1860D–11(d)(2)(B) of the Act provides us with authority similar to that provided to the Director of the Office of Personnel Management (OPM) with respect to health benefits plans; as provided in 5 U.S.C. 8902(e), this includes the authority to ''prescribe reasonable minimum standards for health benefits plans.'' It is our understanding that OPM, in its contract negotiations with FEHBP plans, requires a transition policy. Furthermore, many commercial plans include transition processes for new enrollees. Failure to appropriately transition certain beneficiaries could result in aggravation of certain medical conditions including, in some cases, hospitalization which could ultimately increase costs to Medicare under Parts A and B. Thus, requiring Part D plans to establish appropriate transition policies for new enrollees appears to be consistent with our authority to prescribe reasonable minimum standards for Part D plans.

We believe that a requirement for an appropriate transition process for new enrollees prescribed Part D drugs that are not on the Part D plan's formulary appropriately balances the protection of certain vulnerable populations with flexibility for Part D plans to develop a transition process that dovetails with plans' specific benefit designs. We will provide additional guidance regarding transition process requirements as part of our benefit package review criteria. However, we expect that a Part D plan's transition process would address procedures for medical review of non-formulary drug requests and, when appropriate, a process for switching new Part D plan enrollees to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination. Such a policy should also focus on particularly vulnerable populations, including dual eligibles and individuals with certain medical conditions (for example, enrollees with HIV/AIDS, mental illness, and those with other cognitive disorders).

Comment: Some commenters requested that we establish a standard process for making formulary changes that Part D plans are required to follow, including standard policies and procedures for communicating changes to beneficiaries, pharmacists, and physicians. Another commenter suggested that we develop a standard formulary change form.

Response: As provided in section 1860D–4(b)(3)(E) of the Act, and codified in § 423.120(b)(5)(i) of our final rule, we will require that Part D plans provide appropriate notice regarding any removal of a covered Part D drug from their formulary or any change in the preferred or tiered cost-sharing status of a drug to affected enrollees and other parties. We believe that Part D plans should have the flexibility to develop formulary change notices that meet their particular needs, provided they include the information elements we specify at § 423.120(b)(5)(ii) of our final rule and discussed in greater detail elsewhere in this preamble.

Comment: One commenter suggested that notice not be required when the enrollees' cost sharing is being reduced. This commenter also suggested that notice not be required when generic competitors have dropped out of the market, leaving only one supplier, and the generic drug as a result becomes effectively treated as a single-source ''brand name'' drug. Another commenter noted that the requirement for written notice should extend beyond changes in covered medication and should also be sent when the Part D plan changes procedures for accessing a

particular medicine. Some commenters suggested we define ''appropriate notice'' differently for the expansion of a formulary versus the removal of a drug from the formulary to be consistent with the private market.

Response: Section 1860D–4(b)(3)(E) of the Act requires Part D plans to provide notice before making ''any change in the preferred or tiered cost-sharing status of a drug.'' Plans must therefore provide notice regarding any cost-sharing changes be they increases or reductions, consistent with the requirements of § 423.120(b)(5) of our final rule. The previously cited statutory language limits the provision of notice of formulary changes to the removal of a drug from a formulary or any change in the preferred or tier status of a drug, meaning that Part D plans will not be required to provide notice regarding a change in utilization management processes associated with a particular drug. However, we encourage Part D plans to do so to the extent practicable. We agree with the commenter who asks that we make a distinction between drugs added to and removed from a formulary. As provided in § 423.120(b)(5)(i) of our final rule, Part D plans will only be required to provide advance notice of formulary changes to affected beneficiaries when drugs are removed from a formulary; at their option, Part D plans may also wish to notify enrollees of new additions to their formularies.

Comment: Some commenters support the 30-day notice provision in our proposed regulation. Other comments specifically noted that there should be exceptions to the 30-day requirement in cases where there has been an FDA directive to remove a drug from the market.

However, many commenters were concerned that the 30-day notice provision in the proposed regulation would not provide the adequate time frame for enrollees to make the necessary changes in their drug treatment and ensure continuity of care particularly for enrollees with chronic conditions. Many commenters suggested a 90-day notice requirement. Several commenters suggested that beneficiaries be notified directly in writing at least 60 days before any change, and one commenter noted that NAIC model regulations for drug benefit changes require a 60-day notice.

Response: We appreciate the feedback on our interpretation of ''appropriate notice'' in the proposed rule as consisting of advance notice of at least 30 days. To ensure that Part D enrollees are provided with sufficient time either to switch to a therapeutically appropriate alternative medication, or obtain a redetermination by the Part D plan, reconsideration by the independent review entity, and request an administrative law judge hearing, we have defined appropriate notice as at least 60 days in § 423.120(b)(5)(i)(A) of our final rule. In addition to affording enrollees more time to manage the consequences of mid-year formulary changes, a 60-day requirement is consistent with the NAIC model guidelines for drug benefit changes. As provided in § 423.120(b)(5)(i)(B) of our final rule, Part D plans also have the option to the extent that they are not able to provide a 60-day advance notice to provide the notice and provide 60 days' coverage of the Part D drug, under the same terms as previously available under the Part D plan, at the time the enrollee fills his or her prescription. Once notice is provided, enrollees will have a 60-day window to either switch to a therapeutically appropriate alternative medication, or obtain a redetermination by the Part D plan, reconsideration by the independent review entity, and request an administrative law judge hearing before the 60-day supply is exhausted.

We note that, in order for the requirement regarding plan changes during the beginning of a contract year in § 423.120(b)(6) of our final rule to be consistent with the 60-day advance notice requirement in § 423.120(b)(5)(i)(A) of the final rule, we have changed the requirement in the proposed rule such that a Part D sponsor may not remove a covered Part D drug from its Part D plan's formulary, or make any change in the preferred or tiered cost-sharing status of a covered Part D drug on its plan's formulary, between the beginning of the annual coordinated election period and 60 days after the beginning of the contract year associated with that AEP. As previously mentioned, we had proposed a period of 30 days in § 423.120(b)(6) of our proposed rule.

We note that, in cases in which the FDA requires the removal of a covered Part D drugs from the market or a manufacturer pulls the drug from the market for safety reasons, 60-day advance notice will not be required, as provided in § 423.120(b)(5)(iii) of our final rule. However, Part D plans will be required to provide notice to affected enrollees (as well as to SPAPs, entities providing other prescription drug coverage, authorized prescribers, network pharmacies, pharmacists, and us) about the removal of a such a covered Part D drug from their formularies as quickly as possible after the drug is actually removed from the formulary. This notification must comply with our notification requirements in § 423.120(b)(5)(ii)(A) through (b)(5)(ii)(D).

Comment: Some commenters asked for clarification on what is considered as ''appropriate notice''. Many commenters urged us to require Part D plans provide notice in writing and mail directly to each enrollee who is affected by the change. The commenters noted that without specifying that the notice must be provided in writing, Part D plans may believe they satisfy requirement by posting this information on their plan websites. Several commenters noted that website notification is inadequate. One commenter asked that Part D plans be allowed to give notice electronically if the enrollee opts for that communication method.

Another commenter asked that Part D plans, primarily MA plans, receive more flexibility in giving notice to enrollees. One commenter noted that Part D plans should be allowed to convey certain types of formulary changes through pre- and post-enrollment materials such as sales brochures, enrollment forms, evidence of coverage, or summaries of benefits.

Response: We agree that Part D plans must provide any formulary change notice in writing, and deliver it directly to affected enrollees. This requirement is reflected in § 423.120(b)(5)(i)(A) of our final rule. As provided in § 423.128(d)(2)(iii) of the final rule, Part D sponsors must also provide this notice to all current and prospective Part D enrollees via their plan websites. However, we agree with commenters who assert that website notification, on its own, is an inadequate means of providing specific information to the enrollees who most need it. Website notification will simply be an additional way in which Part D plans may provide notice of formulary changes to affected enrollees. We therefore require Part D plans to provide this notice directly to affected beneficiaries. As an alternative to providing this notice to affected beneficiaries via U.S. mail, to the extent that plan enrollees affirmatively elect to receive such notice electronically rather than in writing, via U.S. mail, Part D plans may provide notice electronically only.

We do not believe that the formulary change notice requirements should apply any differently to MA-PD plans (or to cost plans offering qualified prescription drug coverage) than they do to prescription drug plans. In order to ensure that enrollees receive and process information about formulary changes in a timely way, we believe that

a notice of formulary changes is the most efficient way to do so, and that other materials (including pre- and post-enrollment materials such as sales brochures, enrollment forms, evidence of coverage, or summaries of benefits) are not the most appropriate mechanisms to convey such information.

Comment: Many commenters recommended requiring Part D plans to include information about enrollees' rights to request an appeal or exception with their formulary change notification. One commenter urged that if the notice of the change in formulary involves the addition of a medication, the notice should also explain how the medication will be classed, if the Part D plan uses a tiered co-pay system or step therapy system. The notice should also indicate expected cost to the beneficiary. If a medication is being removed from the formulary, the notice should indicate what medication is available for individuals who were prescribed the medication being removed.

Response: In response to the helpful public comments received on what ''appropriate notice'' of formulary changes should comprise, § 423.120(b)(5)(ii) of our final rule requires that Part D plans include the following information on their formulary changes notices: (1) the name of the affected covered Part D drug; (2) whether the plan is removing such covered Part D drug from the formulary, or changing its preferred or tiered cost-sharing status; (3) the reason why the plan is removing such covered Part D drug from the formulary, or changing its preferred or tiered cost-sharing status; (4) alternative drugs in the same therapeutic category or class or cost-sharing tier and expected cost-sharing for those drugs; and (5) the means by which enrollees may obtain a coverage determination under § 423.566 or exception under § 423.578 of our final rule. These required information elements will provide enrollees with the information they need to request an independent review or to switch to an alternative formulary drug.

Comment: Several commenters noted that advance notice of formulary changes should only be required for enrollees currently using a particular drug, per our proposal in our notice of proposed rulemaking. One commenter asked that our interpretation of the term ''affected enrollee'' be further expanded to include an enrollee who has been dispensed a drug that has been removed, or whose status has changed, within the last 90 days. Other commenters urged us to require Part D plans to provide all enrollees (not just those taking the affected drug) with advance notice of formulary changes.

Response: We interpret the statutory term ''affected enrollee'' as referring to a Part D enrollee who is currently taking a covered Part D drug that is either being removed from a Part D plan's formulary, or whose preferred or tiered cost-sharing status is changing. In other words, Part D plans will not be required to notify all enrollees regarding formulary changes during a contract year only those directly affected by changes with respect to a particular covered Part D drug. This will minimize Part D plan administrative costs while getting information to those individuals who need it. We have incorporated this definition of the term ''affected enrollee'' in § 423.100 of our final rule.

Comment: Several commenters recommended that Part D plans notify prescribers, pharmacists and pharmacies through information posted on plans' websites or through routine communication to prescribers and pharmacists rather than contacting all prescribers and pharmacies directly. More than one commenter stated that sending a mailed notification to all beneficiaries, affected physicians, and pharmacists would be an enormous undertaking and expense. This commenter believes that it is appropriate to mail notifications to those taking the medication and provide it electronically to physicians, pharmacists, and other beneficiaries via the Part D plan website and upon request.

Response: We agree with commenters that we should provide greater flexibility in terms of the mechanism by which they provide notice to parties other than affected enrollees to whom they are required to provide advance notice of formulary changes (including authorized prescribers, pharmacists, pharmacies, and us). As provided in § 423.120(b)(5)(i) of our final rule, we do not specify that written notice is required to be provided to these parties. Thus, Part D plans can determine the most effective means by which to communicate formulary change information to these parties, including electronic means.

Comment: Several commenters suggested Part D plans also notify SPAPs, State retiree plans, and State Medicaid programs of formulary changes, and another commenter suggested State Medicaid offices as well.

Response: Section 1860D–4(b)(3)(E) of the Act requires that ''appropriate notice'' of formulary changes be made specifically to the Secretary, affected enrollees, physicians, pharmacies, and pharmacists. However, we expect Part D plans to coordinate with SPAPs and other plans providing benefits that supplement the benefits available under Part D coverage to Part D enrollees. Provision of formulary change information to these health plans and programs will be important in ensuring effective coordination. Given that section 1860D–24(a)(2)(F) of the Act provides us with flexibility to establish coordination of benefits requirements regarding other administrative processes not specified in section 1860D–24(a)(2) of the Act, we believe it is reasonable to require Part D plans to notify SPAPs and other health plans and programs (as defined in § 423.454(f)(1) of our final rule) regarding formulary deletions or changes to the tiered cost-sharing status of a drug. We have incorporated this requirement into § 423.120(b)(5) of our final rule.

Comment: One commenter recommended that Part D sponsors should include in their formulary notice to us a certification that they are still meeting the statutory formulary requirements.

Response: We note that, notwithstanding any formulary changes Part D plans make mid-year, plans will still be required to meet all the formulary requirements in § 423.120(b) of our final rule, and we will review all formulary changes to ensure that this is the case.

c. Use of Standardized Technology

In accordance with the requirements of section 1860D 4(b)(2)(A) of the Act, Part D sponsors must issue (and reissue, as appropriate) a card or other technology that enrollees could use to access negotiated prices for covered part D drugs. Section 1860D–4(b)(2)(B)(i) of the Act mandates that we develop, adopt, or recognize standards relating to a standardized format for a card or other technology for accessing negotiated prices to covered Part D drugs. Section 1860D 4(b)(2)(B)(ii) of the Act requires us to consult with the National Council for Prescription Drug Programs (NCPDP) and other standard setting organizations, as appropriate, to develop these standards.

Except as otherwise provided below, the final rule adopts the rules regarding use of standardized technology set forth in § 423.120(c) of the proposed rule.

Comment: A number of commenters support our using a standardized identification card using NCPDP standards. These commenters note that a standardized card using the NCPDP format will create increased efficiencies such as reduced waiting times for dispensing medications that will benefit pharmacy providers and beneficiaries. A

few commenters suggested that we provide MA organizations with the flexibility to integrate their drug card with their medical benefits card rather than issuing a separate card if the MA organization chooses to do so and others requested clarification that MA organizations could issue a single card for both their medical and drug benefits. One commenter expressed concern about using an identification number other than the beneficiaries' Medicare Identification Number because this number is familiar and known by the beneficiaries. In certain situations, if the card were lost or stolen, beneficiaries could easily remember their drug card number.

Response: As provided under section 1860D 4(b)(2)(B)(ii) of the Act, we will consult with the National Council for Prescription Drug Programs (NCPDP) and other standard setting organizations, as appropriate, to develop these standards. Given that NCPDP is recognized as the industry standard for current prescription drug programs, and we relied on its standards in developing requirements for discount card sponsors' cards under the Medicare Prescription Drug Discount Card and Transitional Assistance Program, we expect to base our card standards on NCPDP's ''Pharmacy ID Card Standard.'' This standard is based on the American National Standards Institute ANSI INCITS 284–1997 standard titled *Identification Card—Health Care Identification Cards*, which may be ordered through the Internet at *http://www.ansi.org*. We will provide further operational guidance regarding our standards for a card (or other technology) to entities wishing to become Part D sponsors in time for these entities to use the standards (and have their cards approved for use by us) beginning January 1, 2006. We understand that Part D sponsors would like flexibility to integrate their medical and drug benefit cards and will provide Part D sponsors with that flexibility consistent with our approach under the Medicare Prescription Drug Discount Card and Transitional Assistance Program. It is our intent, however, that these standards require that Part D plans use something other than an enrollee's social security number (SSN) as an identifier on their cards given rising concern over the increasing number of cases regarding identity fraud using an individual SSNs and privacy concerns. We understand that this number is the most familiar and known to the beneficiaries but we will work to make the drug card identification number and process easy and convenient for beneficiaries.

5. Special Rules for Out-of-Network Access to Covered Part D Drugs at Pharmacies (§ 423.124)

Section 1860D–4(b)(1)(C)(iii) of the Act requires us to establish pharmacy access standards that include rules for adequate emergency access to covered Part D drugs by Part D enrollees. Given the inherent difficulties in establishing emergency access standards for covered Part D drugs, we proposed to meet the requirements of section 1860D 4(b)(1)(C)(iii) of the Act by establishing a broader out-of-network access requirement. We proposed requiring that Part D sponsors ensure that their enrollees had adequate access to drugs dispensed at out-of-network pharmacies when they could not reasonably be expected to obtain covered Part D drugs at a network pharmacy. In the proposed rule, we stated that we expected out-of-network access to be guaranteed under at least the following four scenarios:

- In cases in which a Part D enrollee meets all of the following: is traveling outside his or her Part D plan's service area; runs out of or loses his or her covered Part D drug(s) or becomes ill and needs a covered Part D drug; and cannot access a network pharmacy;
- In cases in which a Part D enrollee cannot obtain a covered Part D drug in a timely manner within his or her service area because, for example, there is no network pharmacy within a reasonable driving distance that provides 24-hour-a-day/7-day-per-week service;
- In cases in which a Part D enrollee resides in a long-term care facility and the contracted long-term care pharmacy does not participate in his or her Part D plan's pharmacy network; and
- In cases in which a Part D enrollee must fill a prescription for a covered Part D drug, and that particular covered Part D drug (for example, an orphan drug or other specialty pharmaceutical typically shipped directly from manufacturers or special vendors) is not regularly stocked at accessible network retail or mail-order pharmacies. Both the enrollee and his or her Part D plan would have been financially responsible for covered Part D drugs obtained at an out-of-network pharmacy as described. In the proposed rule, we specified that such cost-sharing would have been applied relative to the plan allowance for that covered Part D drug. We requested comments on how to further define the term ''plan allowance.''

In addition to this cost-sharing, and as provided under proposed § 423.124(b)(2), the enrollee would have been responsible for any difference in price between the out-of-network pharmacy's usual and customary (U&C) price and the plan allowance for that covered Part D drug. We requested public comments regarding our definition of usual and customary price. We also sought comments regarding our proposal that the price differential between out-of-network pharmacies' U&C costs and the plan allowance be counted as an incurred cost against the out-of-pocket threshold consistent with the definition of ''incurred cost'' in § 423.100 of the proposed rule. Finally, we requested general comments regarding our proposed payment rules for covered Part D drugs obtained at out-of-network pharmacies when enrollees cannot reasonably obtain those drugs at a network pharmacy.

Except as otherwise provided below, the final rule adopts the out-of-network access rules set forth in § 423.124 of the proposed rule.

Comment: Many commenters generally supported our proposed out-of-network pharmacy proposal and said beneficiaries—particularly those in rural areas—should not be penalized for going out-of-network when necessary. However, some commenters felt the proposal's list of situations in which access to out-of-network pharmacies would be allowed was overly broad and recommended limiting such access to emergency situations only. Some commenters expressed support for plans having the discretion to establish out-of-network access requirements, but not being given a specific list of requirements. Some expressed concern that the message to beneficiaries might be that they can go to out-of-network pharmacies at will, resulting in increased costs.

A number of commenters stated that as proposed, allowing access to out-of-network pharmacies is impractical because these pharmacies cannot determine if beneficiaries have met their deductibles, are in the coverage gap, or the amount their Part D plan would pay had they gone to a participating pharmacy. Out-of-network pharmacies do not have access to data needed to calculate payment rates other than their own usual and customary price. These commenters asked that we clarify that out-of-network pharmacies may charge beneficiaries their usual and customary price that beneficiaries must be responsible for submitting claims for out-of-network medications they purchase to their Part D plans, and that plans must accept claims submitted to them by beneficiaries once such a purchase is made. One commenter recommended Part D plans be given

time to retroactively modify claims databases to accommodate paper claims tracking, suggesting that we minimize these requirements and be specific in the timeline under which these modifications are required (for example, 60 days).

Some commenters stated that the proposal is inadequate for emergency situations and should require Part D plans to cover a temporary supply of drugs. One commenter recommended that we require Part D plans to establish a mechanism to guarantee payment for at least a 72-hour supply of any medically necessary, covered Part D drug obtained out-of-network. One commenter disagreed with the proposal entirely, stating that if the TRICARE access standards were met by a Part D plan, this should be a sufficient guarantee of adequate network access.

Response: We expect that, given our pharmacy access standards, Part D enrollees will have adequate access to network pharmacies. However, section 1860D–4(b)(1)(C)(iii) of the Act requires us to establish pharmacy access standards that include rules for adequate emergency access to covered Part D drugs by Part D enrollees. Given the inherent difficulties in establishing what constitutes an ''emergency,'' we believe it is most appropriate to establish a broader out-of-network access requirement. Section 423.124(a)(1) of our final rule clarifies that Part D plans are required to ensure that their enrollees have adequate access to drugs dispensed at out-of-network pharmacies when they cannot reasonably be expected to obtain covered Part D drugs at a network pharmacy. Provided that such access to out-of-network pharmacies is not routine, we expect that Part D plans would guarantee out-of-network access in cases in which an enrollee: (1) is traveling outside his or her plan's service area, runs out of or loses his or her covered Part D drugs or becomes ill and needs a covered Part D drug, and cannot access a network pharmacy; (2) cannot obtain a covered Part D drug in a timely manner within his or her service area because, for example, there is no network pharmacy within a reasonable driving distance that provides 24/7 service; (3) must fill a prescription for a covered Part D drug, and that particular drug (for example, an orphan drug or other specialty pharmaceutical) is not regularly stocked at accessible network retail or mail-order pharmacies;; and (4) is provided covered Part D drugs dispensed by an out-of-network institution-based pharmacy while a patient is in an emergency department, provider-based clinic, outpatient surgery, or other outpatient setting. We are not incorporating these scenarios into our final regulations but will closely monitor out-of-network access to ensure that Part D plans are adequately meeting beneficiaries' out-of-network access needs. In addition, plans must provide coverage of drugs in physician's offices in cases in which a beneficiary is administered a vaccine covered by Part D (or another covered Part D drug that is appropriately dispensed and administered in a physician's office).

We understand commenters' concerns that routine access to out-of-network pharmacies could undermine a Part D plan's ability to achieve cost-savings for both beneficiaries and the Medicare program. For this reason, we would like to clarify that § 423.124(c) of our final rules requires Part D plans to establish reasonable rules to ensure that enrollees use out-of-network pharmacies in an appropriate manner—provided they ensure adequate access to out-of-network pharmacies on a non-routine basis when enrollees cannot reasonably access network pharmacies. For example, Part D plans may wish to limit the amount of covered Part D drugs dispensed at an out-of-network pharmacy, require that a beneficiary purchase maintenance medications via mail-order for extended out-of-area travel, or require a plan notification or authorization process for individuals who fill their prescriptions at out-of-network pharmacies. Plans will be required to disseminate information to enrollees about their out-of-network access policies as provided in § 423.128(b)(6) of our final rule.

We wish to clarify that enrollees obtaining covered Part D drugs at out-of-network pharmacies, which by virtue of not being under contract with an enrollee's Part D plan will not have access to the data needed to calculate Part D plan payment rates, will have to pay the pharmacy's U&C price at the point-of-sale, submit a paper claim to their Part D plan, and wait for reimbursement from the plan. Out-of-network pharmacies will therefore be made whole, relative to their U&C price for a covered Part D drug, at the point of sale.

Comment: One commenter stated that patients in emergency departments, provider-based clinics, outpatient surgery, or under observation are often administered drugs (self-administered drugs or insulin, for example) under physician order for medically necessary conditions. These drugs are not covered under Part A or Part B and are billed to patients as a patient liability. For safety and quality of care reasons, patients often cannot bring their own medications into hospitals or outpatient settings when they are being treated for other conditions. This commenter asked for clarification regarding whether Part D plans will cover self-administered prescription drugs dispensed by hospital pharmacies; if so, how beneficiaries will avail themselves of their Part D benefits; and, if not, whether hospitals will have to provide drug coding and other detail on billing statements for beneficiaries so they can submit those statements to their Part D plans for reimbursement.

Response: As provided elsewhere in this preamble, Part D plans may include institutional pharmacies, including hospital-based pharmacies, in their networks, although these pharmacies will not count toward the access requirements Part D plans must meet under § 423.120(a)(1) of our final rule. To the extent hospital pharmacies are included in Part D plan networks, Part D enrollees who are furnished covered Part D drugs by those pharmacies, the situations noted by the commenter will not be an issue. However, we recognize that enrollees who are provided covered Part D drugs by hospital and other institution—based pharmacies under the circumstances described by this commenter cannot reasonably be expected to obtain needed covered Part D drugs at a network pharmacy. We therefore clarify that we expect that Part D plans guarantee out-of-network access to covered Part D drugs in cases in which an enrollee is provided covered Part D drugs dispensed by an out-of-network institution-based pharmacy while a patient in an emergency department, provider-based clinic, outpatient surgery, or other outpatient setting.

Comment: Two commenters recommended that Part D plan enrollees who live in different States during the year should be allowed access to out-of-network pharmacies, as with the other four instances we proposed. One commenter further argued that restricting pharmacy access to mail order during long absences from or trips out of a Part D plan's service area violates the prohibition on exclusive use of mail order pharmacies.

Response: The statutory authority for our proposed out-of-network access policy derives from the requirement, in section 1860D–4(b)(1)(C)(iii) of the Act, that our network access rules include provisions for adequate emergency access for Part D enrollees. Given that narrow statutory authority, we do not believe that access to out-of-network pharmacies on a routine basis can be justified under our out-of-network

access rules. Through our educational efforts, we will encourage enrollees who live in different States during a year (snowbirds, for example) to enroll in national or regional Part D plans that will provide coverage in multiple areas, or in Part D plans that include out-of-area pharmacies in their networks. However, to the extent that a beneficiary is enrolled in a Part D plan that does not provide such access, plans may not allow routine out-of-network access consistent with § 423.124(a)(2) of our final rule.

Comment: Two commenters emphasized the need to allow out-of-network access for specialty medications, such as orphan drugs, that are not typically stocked in a retail pharmacy. Their argument was echoed by commenters who emphasized the need to allow for out-of-network access to home infusion therapy.

Response: We expect that Part D plans will provide out-of-network access to specialty pharmacies in cases in which specialty medications, such as orphan drugs, are not available at a network pharmacy, as this is a case in which enrollees could not reasonably be expected to access their medications at a network pharmacy. However, given that out-of-network access to covered Part D drugs may not be provided routinely, consistent with § 423.124(a)(2) of our final rule, Part D cannot not provide access to out-of-network access to a specialty pharmacy on an ongoing basis. As discussed elsewhere in this preamble, our final rule requires that Part D plans provide adequate access to home infusion pharmacies. We established this access requirement to mitigate the need for routine out-of-network access to home infusion drugs. However, in cases in which an enrollee cannot reasonably access a home infusion pharmacy in his or her Part D plan's network, we expect that plans will provide access to an out-of-network home infusion pharmacy consistent with § 423.124(a) of our final rule.

Comment: Some commenters stated that the final rule should clarify that beneficiaries residing in a long-term care facility should be allowed access to long term care pharmacies as out-of-network pharmacies, should the pharmacy contracting with the long-term care facility in which they reside not participate with their chosen Part D plan. Another commenter thought that our proposed policy vis-à-vis beneficiaries residing in long-term care facilities is inappropriate given that our authority for establishing such requirements is based on emergency access only.

Response: As noted previously, we agree with the commenter who questioned our authority for allowing access to out-of-network long-term care pharmacies on a routine basis. The statutory authority for our proposed out-of-network access policy derives from the requirement, in section 1860D–4(b)(1)(C)(iii) of the Act, that our network access rules include provisions for adequate emergency access for Part D enrollees. Given that narrow statutory authority, we do not believe that access to out-of-network pharmacies on a routine basis including in cases where a beneficiary resides in a long-term care facility whose contracted long-term care pharmacy is not in his or her Part D plan's network can be justified under our out-of-network access rules.

Comment: One commenter said that physician offices should be considered out-of-network pharmacies insofar as they supply covered Part D drugs.

Response: We note that vaccines (and other covered Part D drugs that are appropriately dispensed and administered in a physician's office) administered in a physician's office will be covered under our out-of-network access rules at § 423.124(a)(2) of our final rule, since Part D plan networks are defined as pharmacy networks only. A scenario under which a Part D enrollee must obtain a Part D-covered vaccine in a physician's office constitutes a situation in which out-of-network access would be permitted because a beneficiary could not reasonably be expected to obtain that vaccine at a network pharmacy. We expect that the application of this requirement will be limited to vaccines and a handful of drugs (for example, some injectable long-acting anti-psychotics) that are appropriately dispensed and administered in a physician's office and are not covered under Part B, and that plans may establish utilization management policies and procedures to ensure that out-of-network coverage is limited to such covered Part D drugs. Enrollees will be required to self-pay the physician for the cost of the vaccine (or other covered Part D drug appropriately dispensed and administered in a physician's office) and submit a paper claim for reimbursement by their Part D plan.

Comment: Commenters generally recommended the beneficiary pay the difference between the network price applicable to that beneficiary and the maximum price charged to any Part D plan with which the pharmacy participates. However, they argue, determining that amount would be difficult because out-of-network pharmacies do not have access to the data necessary to calculate that amount. Some commenters specified that beneficiaries purchasing drugs from an out-of-network pharmacy in an emergency situation should not be charged anything more than the network amount. Several commenters urged us to exempt low-income beneficiaries from any differential costs incurred for visiting an out-of-network pharmacy. One noted that we should monitor usage of out-of-network pharmacies by low-income beneficiaries.

Response: As provided in § 423.124(b) of our final rule, if a Part D plan offers coverage other than defined standard coverage, it may require enrollees to not only be responsible for any cost-sharing, including a deductible, that would have otherwise applied had the covered Part D drug been purchased at a network pharmacy, but also any differential between the out-of-network pharmacy's (or provider's) usual and customary (U&C) price and the enrollee's cost-sharing. However, given the cost-sharing requirements for defined standard coverage in § 423.104(d)(2)(A) of our final rule, under which the cost-sharing between the deductible and initial coverage limit must be 25 percent of the actual cost of a drug at the point of sale, Part D plans offering defined standard coverage may not offer such an out-of-network differential. Instead, a Part D plan offering defined standard coverage must simply require its enrollees to pay any deductible or cost-sharing, relative to the out-of-network pharmacy's (or provider's) usual and customary price. The Part D plan will pay the difference between the out-of-network pharmacy's (or provider's) U&C price and the enrollee's cost-sharing.

In either case, enrollees will likely be required to pay more for a covered Part D drug purchased out-of-network than one purchased at a network pharmacy, though, as explained below, any such differential will count toward an enrollee's TrOOP limit. In order to curb unnecessary out-of-network use and preserve Part D plans' ability to achieve cost-savings based on network pharmacy use, we believe it is appropriate that beneficiaries pay more for out-of-network access to covered Part D drugs.

As explained below, we will pay any out-of-network differential for appropriate non-routine use of out-of-network pharmacies (or providers) for full and other subsidy-eligible individuals as part of our low-income subsidy under subpart P of the final rule.

Comment: Some commenters asked us to clarify whether subsidy eligible

individuals who reside in long-term care facilities will have to pay any out-of-network differentials when obtaining drugs from an out-of-network long-term care pharmacy. Many recommended that we pay the out-of-network differential for institutionalized enrollees who are subsidy eligible.

Response: We agree that for full and other subsidy-eligible individuals—whether they are institutionalized or not—we should pay any out-of-network differential for appropriate non-routine use of out-of-network pharmacies. As provided in § 423.104(d)(2) of our final rule, we define enrollee cost sharing in relation to the total cost of the drug to the Part D plan and the beneficiary (actual costs). Therefore, in cases where the total payment is not limited by the plan allowable because a drug is obtained out-of-network, the cost sharing can be defined as the total paid by beneficiary, or in the case of a subsidy eligible individual, as the total cost sharing paid by both the beneficiary and by us. This approach reconciles the need to charge the OON differential and to hold the subsidy eligible individual liable for only the statutorily allowed copayment amounts ($1/$3, $2/$5, or $0 in the case of institutionalized full subsidy individuals who are full-benefit dual eligible individuals).

Comment: A few commenters argued that enrollees accessing covered Part D drugs at out-of-network FQHC, rural and I/T/U pharmacies should also be exempt from any out-of-network differentials.

Response: We do not believe there exists a compelling rationale to exempt beneficiaries who access their drugs at FQHC, rural, or I/T/U pharmacies. However, to the extent such individuals qualify as full or partial subsidy eligible individuals, they will be responsible only for the cost-sharing amounts required in subpart P.

Comment: Comments on the definition of ''U&C price'' fell into three groups. Some commenters felt that the U&C price should be defined as that amount charged to cash paying customers, excluding sales tax. Others argued that the U&C price should be the amount typically charged to senior groups or other cash customers who are directly given some sort of discount as an inducement to make a purchase from a given supplier. A third group of commenters felt that the U&C price should be the maximum the pharmacy charges any customer covered by a Part D plan. Several commenters noted that we should not allow pharmacies to manipulate their U&C prices and should check them periodically to be sure they were less than or equal to the average wholesale price.

Response: We appreciate commenters' suggestions. We believe our proposed definition of the term ''usual and customary price'' the price that a pharmacy (or provider) charges a customer who does not have any form of prescription drug coverage is adequate and are retaining it in § 423.100 of our final rule. We note, in response to several commenters' suggestions, that we do not have the authority to require out-of-network pharmacies to accept a particular price (for example, the maximum price a pharmacy charges any of its customers enrolled in Part D plans) as their U&C price. We believe that Part D plans, not CMS, should be responsible for monitoring of U&C prices for covered Part D drugs at out-of-network pharmacies, since, given that any price differential paid by a beneficiary would count toward the TrOOP threshold, they ultimately have a vested interest in limiting the costs associated with out-of-network use.

Comment: With regard to the definition of ''plan allowance,'' several commenters recommended that it be defined as ''the lowest of contractual discounts offered in a standard contract or U&C price.'' One commenter recommended defining the term in CMS guidance to permit consultation with affected parties. One commenter pressed for Part D plan flexibility so that they could ensure the lowest prices for their members.

Response: We have retained our proposed definition of ''plan allowance'' in § 423.100 of our final rule in order to provide Part D plans with maximum flexibility to establish the most appropriate plan allowance for drugs obtained out-of-network.

Comment: One commenter asked for clarification of the appeals process relating to adverse coverage decisions for out-of-network drugs.

Response: As provided under § 423.566(b)(1) of our final rule, a Part D plan's failure to pay for a covered Part D drug furnished by an out-of-network pharmacy is an action that is a coverage determination.

Comment: Another commenter wanted to be sure that out-of-network pharmacies did not advertise their services as Medicare covered so that beneficiaries would not be confused.

Response: We believe that beneficiaries should always receive accurate and clear information about their pharmacy benefits, and we believe pharmacies must ensure that out-of-network beneficiaries are not misled. However, we have no authority under the MMA to regulate pharmacies' marketing activities. Marketing activities of pharmacies may implicate other Federal or State laws, however, including, but not limited to, consumer protection laws. Pharmacies may also be subject to sanction under section 1140 of the Social Security Act if they misrepresent an affiliation with, or endorsement by the Medicare program.

6. Dissemination of Plan Information (§ 423.128)

Our proposed rule established beneficiary protection requirements concerning the dissemination of Part D information by Part D sponsors to enrollees in, and individuals eligible to enroll in, a Part D plan. Part D information disseminated by Part D sponsors to current or prospective Part D enrollees will constitute marketing materials and must be approved by us.

With the exception of the drug-specific information dissemination requirements, many of the proposed requirements duplicated information dissemination requirements contained in § 422.111 of our proposed MA rule that are applicable to all MA plans, including MA-PD plans. We proposed applying the requirements of section 1860D–4(a) of the Act to other Part D plans to ensure that all Part D eligible enrollees have access to comparable drug-specific information about Part D plans.

a. Content of Plan Description

Proposed § 423.128(a) and (b) complied with the stipulation in section 1860D–4(a)(1) of the Act that requirements for the dissemination of Part D information be similar to the information dissemination requirements for MA organizations under section 1852(c)(1) of the Act and as interpreted in § 422.111(b).

In order to ensure that individuals who are either eligible for, or enrolled in, a Part D plan receive the information they need to make informed choices about their Part D coverage options, Part D sponsors would be required to disclose, to each enrollee in a Part D plan offering qualified prescription drug coverage, a detailed description of that plan. This description must be provided in a clear, accurate, and standardized form at the time of enrollment and annually, at a minimum, after enrollment. The information provided will be similar to the information MA plans must disclose to their enrollees.

Except as otherwise provided below, the final rule adopts the requirements pertaining to plan content description set forth in § 423.128(b) of the proposed rule.

Comment: One commenter sought clarification regarding what we mean by ''standardized'' in our requirement that

Part D plans provide information to enrollees in a ''clear, accurate, and standardized form.''

Response: We expect Part D plans to provide information about their benefit packages in a manner that is consistent with marketing guidelines that we will make available to plans.

Comment: Several commenters requested that we allow Part D plans the flexibility to make plan information available through the Internet. For the convenience of beneficiaries as well as to control costs, these commenters recommend that we encourage the use of more efficient information distribution channels (for example, Internet and email) to disseminate detailed Part D plan information and thus limit the distribution of paper materials to situations in which that makes sense. Another commenter recommended that we clarify that, with the express consent of the enrollee, Part D plans may waive enrollees' right to request and receive any required information in writing and allow for the enrollee to obtain that information via a plan website or email.

Response: We agree that some beneficiaries may prefer to receive Part D plan information electronically and that the provision of plan information through electronic means has the potential to significantly reduce Part D plans' costs. However, a number of Medicare beneficiaries still do not have access to the Internet or prefer to receive their information in written formats. We have modified § 423.128(a) of our final rule to note that we may specify the manner in which plan information must be disseminated to beneficiaries. We clarify that information disseminated by Part D plans as part of a plan description under § 423.128(b), as well as information disclosed upon enrollee request under § 423.128(c), must be provided in a written format and delivered to beneficiaries via U.S. mail unless a beneficiary explicitly consents—by actively opting in—to receive information electronically or via telephone rather than by mail. The electronic provision of Part D plan information should simply be one additional mechanism for Part D plans to communicate with enrollees and potential enrollees.

Comment: One commenter recommended that Part D plans provide information regarding any prior authorization processes required for certain drugs as part of their information dissemination efforts regarding formularies.

Response: We agree with this commenter and have modified that language at § 423.128(b)(4) to clarify that Part D plans must disclose information about any utilization management procedures they may use as part of the formulary information they must disseminate to beneficiaries.

Comment: One commenter recommended that Part D plans be required to provide a list of pharmacies in their networks since the proposed rule requires information only about the types of pharmacies in plans' networks.

Response: We believe the commenter misinterpreted the provision at § 423.128(b)(5) of our proposed rule. This provision, which we have retained in our final rule, requires Part D sponsors to disseminate information about ''the number, mix, and distribution (addresses) of network pharmacies.'' We believe that requiring Part D plans to disseminate information about the addresses of network pharmacy at which an enrollee may reasonably be expected to obtain covered Part D drugs is, in fact, tantamount to requiring plans to provide a list of network pharmacies serving enrollees' service areas. We therefore clarify that Part D plans will be expected to provide enrollees with a list of network pharmacies, including addresses, as well as information about the number and mix of network pharmacies available.

Comment: One commenter requested greater detail regarding the contents of the description of quality assurance policies and procedures that Part D plans must provide under § 423.128(b)(8) of our proposed rule. Another commenter states that, as written, the provision requiring Part D plans to describe their quality assurance policies and procedures did not indicate a clear CMS-directed oversight and enforcement structure. This commenter argues that compliance monitoring and enforcement would at best be indirect, leaving us reliant on the results of deemed status arrangements as set forth in our proposed § 423.165.

Response: We expect plans to provide descriptions of their policies and procedures for concurrent drug utilization review, retrospective drug utilization review, and internal medication error identification and reduction systems. We also expect plans to provide descriptions of their medication therapy management programs, including information describing which enrollees are eligible for such services. With respect to CMS-directed oversight and enforcement, we have added reporting requirements to § 423.153(c) and § 423.153(d) of our final rule, and we will specify the details of these reporting requirements in separate guidance.

Comment: One commenter was concerned that the transition of full-benefit dual eligible individuals from Medicaid to Medicare Part D on January 1, 2006 will likely lead full-benefit dual eligible individuals to contact Medicaid agencies for more information regarding their new pharmacy benefits. This commenter recommended that we require Part D plans to include information in their enrollee materials that clarifies that State Medicaid agencies are no longer the primary providers of pharmacy benefits and cannot answer questions about the Medicare benefit, except as pertains to limited supplemental coverage that Medicaid may provide.

Response: Our education and outreach efforts will ensure that beneficiaries receive detailed information regarding their transition from Medicaid to Medicare for prescription drug coverage. Therefore, we do not believe it is necessary to require Part D plans to include this information in their materials.

b. Disclosure of Information upon Request

In addition, in accordance with section 1860D–4(a)(2) of the Act, the proposed rule at § 423.128(c) provided that a beneficiary who is eligible to enroll in a Part D sponsor's Part D plan will have the right to obtain, upon request, more detailed plan information. Except as otherwise provided below, the final rule adopts the standards set forth in § 423.128(c) of the proposed rule.

Comment: A number of commenters are supportive of the provision in the proposed rule that required Part D plans to make available information about how to obtain information about the formulary, but thought that this requirement was insufficient given that beneficiaries will need precise and detailed formulary information to make informed choices about enrollment. These commenters recommend requiring Part D plan descriptions to include a detailed formulary listing not only the drugs on the formulary, but also any formulary tiers and corresponding copayment amounts.

Response: We agree that it will be critically important for Part D enrollees and prospective enrollees to have access to complete formulary information in order to make the best possible Part D plan selection for their particular medical and prescription drug needs. For this reason, we have modified the formulary information requirements under § 423.128(b)(4) such that Part D plans will be required to include not only information about the manner in which the formulary functions (including tiering structures and any

utilization management procedures used), a process for obtaining an exception to a Part D plan's tiered cost-sharing structure or formulary, and a description of how an enrollee may obtain additional information on the formulary, but also an actual list of drugs included on the Part D plan's formulary. For each drug, this list must indicate any cost-sharing tier information applicable to that drug and whether utilization management programs apply.

Comment: Several commenters urged us to expand the requirement that Part D plans disclose, upon request, information about the number of disputes and their disposition in the aggregate to include exceptions. Another commenter noted that we appeared to have made a mistake in terms of our references to the provisions on grievances and reconsiderations in § 423.128(c)(3) of our proposed rule.

Response: We agree with these commenters. We have corrected the reference errors in § 423.128(c)(3) of our final rule and have expanded this requirement such that Part D plans must disclose, upon request, information about the number of exceptions and their disposition in the aggregate. We did not originally include a reference to exceptions in our proposed because section 1852(C)(2) of the Act, on which the requirements in our proposed § 423.128 were based, did not envision an exceptions process for the MA program.

Comment: Several commenters noted that § 423.128(c)(1)(iii) of our proposed rule required Part D plans to inform enrollees about the potential for contract termination, but only upon request. However, these commenters felt strongly that this information needed to be included in all plan descriptions and marketing materials, and not just if requested by an enrollee or prospective enrollee, particularly in light of previous experience with volatility in the Medicare+Choice market.

Response: We agree with these commenters and have moved the requirement that Part D plans disclose information about the potential for contract termination upon request only, to § 423.128(b)(10), under which plans will be required to disclose this information as part of the plan description provided at the time of enrollment and at least annually thereafter.

c. Provision of Specific Information

As required under section 1860D–4(a)(3) of the Act and proposed at § 423.128(d) of our proposed rule, Part D sponsors will be required to have in place a mechanism for providing, on a timely basis, specific information to current and prospective enrollees upon request. Such mechanisms will include:

- A toll-free customer call center;
- An Internet website; and
- Responses in writing upon beneficiary request.

As proposed at § 423.128(d)(1)(i) and (d)(1)(ii), Part D plans' customer call centers will be required to be open during usual business hours and provide customer telephone service, including to pharmacists, in accordance with standard business practices. We strongly recommended, however, that Part D plans provide some sort of 24-hour-a-day/7 day-a-week access to their toll-free customer call centers in order to provide timely responses to time-sensitive questions. In addition, we proposed requiring that Part D plans maintain websites as one means of disseminating information to current and prospective Part D enrollees that would include the detailed plan description information described in § 423.128(b) of our proposed rule. Finally, Part D plans would be required to respond to beneficiary requests for specific information in writing, upon request. This requirement was codified in § 423.128(d)(3) of our proposed rule.

Except as otherwise provided below, the final rule adopts the specific information disclosure standards set forth in § 423.128(d) of the proposed rule.

Comment: Several commenters recommended against requiring a 24-hour/7-day-a-week call center because of the high costs associated with operating a call center during off-hours. These commenters support operating a call center during normal business hours as required in the proposed regulations. One commenter suggested Part D plans consider developing a website and IVR system that allows beneficiaries to access their accounts to determine their TrOOP balance.

Other commenters recommended requiring Part D plans to operate 24/7 call centers, stating that the need for prescription drugs may arise outside of normal business hours and would necessitate timely assistance and resolution of coverage issues. These commenters noted that the implications of delayed access are potentially very serious. One commenter stated that advice hotlines should be available 24-hour/7-days a week to assist enrollees and pharmacies in understanding Part D plan formularies. Another commenter urged requiring extended service hours especially during the initial enrollment period and also ensuring that language specialists are available.

Response: We have retained our proposed requirement (in § 423.128(d)(1) of our final rule) that Part D plans maintain a toll-free customer call center that is open during usual business hours and provides customer telephone service, including to pharmacists, in accordance with standard business practices. However, Part D plans should view this requirement as a floor which they can exceed—particularly at times such as annual open enrollment periods. Access to bilingual customer service representatives may also be appropriate in certain parts of the country. Given the need for Part D plans to provide timely information on certain time-sensitive issues, however, we strongly recommend that Part D plans also provide access to 24/7 clinical advice hotlines as is customary for many health plans.

Comment: One commenter recommended that we require formulary updates to plans' websites only when actual changes are made, but no more than once per month.

Response: We agree with this commenter. We recognize the need for formulary information to be kept as current as possible to allow enrollees and prospective enrollees to make the best possible decisions regarding coverage of their particular Part D drugs. However, P&T committees typically meet quarterly, and we expect that most formulary changes recommended by a P&T committee will be implemented following regular committee meetings. We have therefore changed the requirement in § 423.128(d)(2)(ii) of our proposed rule, which required weekly updates of formulary information on Part D plan websites, to require monthly updates instead. This requirement is codified at § 423.128(d)(2)(ii) of our final rule.

Comment: One commenter asked us to clarify that formulary information will be made available through means other than plan websites.

Response: As previously stated, enrollees and prospective enrollees will be able to obtain specific Part D plan information, including formulary information, upon request via telephone and in writing. In addition, we have revised our final rule at § 423.128(b)(4) to require Part D plans to provide enrollees with an actual list of drugs included on the plan's formulary.

Comment: One commenter requested clarification that our requirement that formulary information be posted on a Part D plan website be limited to including only a list of formulary drugs and not the full range of clinical information associated with those drugs.

Response: Plans will only be required to include a list of drugs included on their formularies—and not the clinical information associated with those drugs—under our information dissemination requirements.

d. Claims Information

In accordance with the requirements of section 1860D-(4)(a)(4) of the Act, § 423.128(e) of the proposed rule required Part D sponsors to furnish to enrollees who receive covered Part D drugs an explanation of benefits (EOB). EOBs will be required to be written in a form easily understandable to beneficiaries. In § 423.128(e)(6) of our proposed rule, we proposed that an EOB be provided at least monthly for those utilizing their prescription drug benefits in a given month.

We also proposed in § 423.128(e)(1)-(5) that Part D plans' EOBs include:

- A listing of the item or service for which payment was made, as well as the amount of such payment for each item or service;
- A notice of the individual's right to request an itemized statement;
- Information regarding the cumulative, year-to-date amount of benefits provided relative to the deductible, the initial coverage limit, and the annual out-of-pocket threshold for that year;
- A beneficiary's cumulative, year-to-date total of incurred costs (to the extent practicable); and
- Information about any applicable formulary changes.

Except as otherwise provided below, the final rule adopts the EOB standards set forth in § 423.128(e) of the proposed rule.

Comment: Some commenters supported the requirement to mail enrollees an EOB each month that the drug benefits are provided, as stated in the proposed regulations. Some commenters recommended dissemination of the EOBs quarterly and upon request of the enrollees rather than monthly when prescription drug benefits are provided.

Several commenters urged us to allow Part D plans the flexibility to provide an EOB to enrollees through means other than mail, such via a plan website, electronically through email, or by telephone inquiry. One commenter noted that it is not current practice for health plans to mail enrollees an EOB monthly and that this would raise administrative costs. Some commenters expressed their objection to providing an EOB at pharmacies, stating this would be far beyond pharmacies' technological capabilities, and that provision of the EOB via mail or electronically should be plans' responsibility.

Some commenters expressed that the EOBs should also include information about appeals right and processes, information about formulary information and plan terminations, and information regarding whether the deductible and out-of-pocket thresholds have been met. Another commenter stated that the EOB should be modified to be applicable to beneficiaries who are subsidy eligible individuals due to the differences in the deductibles and cumulative spending limits for these individuals.

Response: We appreciate commenters' feedback regarding our proposed EOB requirements. As provided in § 423.128(e)(6) of our final rule, we are retaining our proposed requirement that an EOB be provided at least monthly for those enrollees utilizing their prescription drug benefits in a given month. This requirement is consistent with our policy regarding the Medicare Summary Notice, which is provided monthly for beneficiaries with Part A or Part B utilization.

We believe it is most appropriate for enrollees to receive a written EOB, via U.S. mail, and have provided for this under § 423.128(e) of our final rule. Plans may offer additional mechanisms for the provision of such information—for example, via a website or call center. Plans may provide the EOB through alternative means electronically via email, for example only to the extent that enrollees affirmatively elect to receive their EOBs in such a manner. In the preamble, we suggested that Part D plans might explore provision of EOBs at the point-of-sale, but that statement was in no way intended to impose a requirement on pharmacies to provide Part D plan information in the absence of the technological capacity to do so.

We do not believe that the EOB is the most appropriate mechanism for provision of information about appeals rights and processes or information about plan terminations; this information will be provided through other mechanisms. We clarify, however, that EOBs will be required to include information regarding the cumulative, year-to-date amount of benefits provided relative to the deductible, the initial coverage limit, and the annual out-of-pocket threshold for that year, as well as information about any upcoming formulary changes. For low-income beneficiaries, the information about the cumulative, year-to-date total of incurred costs provided by the Part D plan in the EOB will include CMS subsidy amounts that count toward incurred costs.

7. Public Disclosure of Pharmaceutical Prices for Equivalent Drugs (§ 423.132)

Under section 1860D–4(k)(1) of the Act, Part D sponsors will be required to ensure that pharmacies inform enrollees of any differential between the price of a covered Part D drug to an enrollee and the price of the lowest priced generic version of that drug and available under the Part D plan at that pharmacy. As stipulated in our proposed rule, this information will have to be provided at the time the plan enrollee purchases the drug, or in the case of drugs purchased by mail order, at the time of delivery of that drug. Disclosure of this information will not be necessary, however, if the particular covered Part D drug purchased by an enrollee was the lowest-priced generic version of that drug available at a particular pharmacy.

As provided under section 1860D–4(k)(2)(B) of the Act, we are permitted to waive the requirement that information on differential prices between a covered Part D drug and generic equivalent covered Part D drugs be made available to Part D plan enrollees at the point of sale (or at the time of delivery of a drug purchased through a mail-order pharmacy). Accordingly, we proposed waiving the requirement that information on lowest-priced generic drug equivalents be provided to enrollees for covered Part D drugs purchased by Part D plan enrollees when those covered Part D drugs are purchased at:

- Any pharmacy, when the individual is enrolled in an MA private fee-for-service plan that offers qualified prescription drug coverage and provides plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies, and does not charge additional cost-sharing for access to covered Part D drugs dispensed at all pharmacies;
- Out-of-network pharmacies;
- I/T/U network pharmacies; and
- Network pharmacies located in any of the U.S. territories (American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, and the Virgin Islands). We requested comments on the appropriateness of the circumstances we proposed for waiver of the requirements in § 423.132(c) of our proposed rule, as well as any additional circumstances we may wish to consider.

We also proposed waiving the requirement that information on differential prices between a covered Part D drug and generic equivalent covered Part D drugs be made available to Part D plan enrollees at the point of

sale when Part D plan enrollees obtain covered Part D drugs in long-term care pharmacies. We requested comments regarding appropriate standards with regard to the timing of disclosure of generic price differentials to institutionalized Part D enrollees.

Except as otherwise provided below, the final rule adopts the standards for public disclosure of pharmaceutical prices for equivalent drugs set forth in § 423.132 of the proposed rule.

Comment: One commenter was concerned about the administrative burden the disclosure requirement would impose at the community pharmacy level and believed it was essential for us to develop appropriate guidance to minimize potential problems. The commenter noted that the administrative burden required to calculate cost-sharing differences should cause us to consider compliance with the requirements to be impracticable in all pharmacy settings because while many community pharmacies' prescription processing systems currently compare retail prices for brand-name and generic medications, the systems are not equipped to compare the discount price calculated by a Part D plan with the potential discount price by a plan for a generic drug. According to this commenter, obtaining this discounted generic price would require the pharmacy to process and submit a second prescription transaction for the generic, and then require the pharmacy to calculate the difference between the two prescriptions; the need to compare the enrollee's cost-sharing under the two scenarios would add more challenges. Other commenters assured us that this requirement is not burdensome for retail pharmacies.

Response: As provided in section 1860D–4(k) of the Act, Part D plans must provide that each pharmacy in their networks with the exceptions that we note in § 423.132(c) of our final rule complies with the requirement to disclose to beneficiaries information about less expensive therapeutically equivalent and bioequivalent covered Part D drugs. Given this statutory requirement, we cannot waive it wholesale for all community pharmacies. We do not expect this requirement will be burdensome for community pharmacists since, given that, under § 423.132(b) of our final rule, we are requiring disclosure of generic differential information after a claim has been adjudicated and for informational purposes only. We clarify that we do not expect pharmacies to become involved in substituting a generic equivalent in order for Part D plans to comply with the disclosure requirement in § 423.132(a) of our final rule. We expect that Part D plans will work with their network pharmacies to operationalize this requirement, but we do not expect that it will be burdensome to the pharmacy industry given the prevalence of generic substitution and information programs established by private plans in the market today.

Comment: One commenter asked that we define ''lowest price'' as determined by the Part D plan at the point of sale. Another commenter asked that we clarify that ''price'' is defined as what the enrollee would pay at the pharmacy subject to the applicable cost sharing. Two commenters recommended that pricing comparison should be between the brand name drug and the Maximum Allowable Cost (MAC) established by the Part D plan for the generic equivalent to the branded drug. Another commenter suggested allowing an estimated price differential between brand and non-MAC generics to be made available to enrollees rather than the exact cost differential between the price of a covered Part D drug and the lowest priced generic version because of the technical limitations of plans (for example, plans do not have a record of generics in stock at all network pharmacies). This commenter claims that, otherwise, this requirement would involve enormous administrative efforts and costs for Part D plans. This commenter suggested a reasonable alternative would be allowing plans to utilize historical dispensing patterns and costs to have available relative price information in the form of an estimate of the price differential transmitted to pharmacies in the electronic claim response when a prescription is filled, and that Part D plans would contractually require pharmacies to share this information at the point-of-sale.

Response: Under section 1860D–4(k) of the Act, Part D plans must provide that each pharmacy in their networks complies with the requirement to disclose to beneficiaries information about less expensive therapeutically equivalent and bioequivalent covered Part D drugs. Specifically, Part D plans must provide information about the differential between the price of the covered Part D drug to the enrollee (factoring in any applicable cost-sharing) and the price of the lowest-priced therapeutically equivalent and bioequivalent drug available at that pharmacy. We expect that Part D plans will work with their network pharmacies to operationalize this requirement in the most efficient way possible, and in a manner that complies with our requirements under § 423.132 of our final rule.

Comment: One commenter recommended that disclosure of the generic drug price be the lowest priced generic available at that pharmacy because most pharmacies do not carry multiple generic drug options for the same generic entity.

Response: We agree with the commenter and clarify that § 423.132(a) requires pharmacies to disclose the differential between the price of a covered Part D drug and the price of the lowest-priced generic version of that drug available at that pharmacy, consistent with section 1860D–4(k)(1) of the Act.

Comment: One commenter recommended only requiring pharmacists to inform patients of price differentials if they are dispensing a high cost version of a ''multiple source'' drug that is available at that pharmacy. This commenter noted that in many cases these off-patent innovator brands, also known as ''multiple source'' drugs, are less costly than their generic counterparts (for example, some brand name version antibiotics are often equal or lower in price than their generic counterparts). Without this technical correction, these drugs may not be considered by some Part D plans as generics and the pharmacists would not inform the beneficiary that these lower cost ''multiple source'' drugs are available. Another commenter stated that generics should be further defined to include ''multiple source'' brand name drugs.

Response: Section 1860D–4(k) of the Act requires that each pharmacy that ''dispenses a covered Part D drug shall inform an enrollee of any differential between the price of the drug to the enrollee and the price of the lowest priced generic covered part D drug under the plan that is therapeutically equivalent and bioequivalent and available at such pharmacy.'' While we appreciate the commenter's point that off-patent innovator drugs may also be available to enrollees at low prices, and that this information should be disclosed at the point of sale, the statute very specifically applies the requirement to the lowest priced generic covered Part D drug available at that pharmacy. Our definition of ''generic drug'' at § 423.4 of the final rule does not encompass an off-patent innovator drug, however. In addition, given that section 1860D–2(b)(4)(A)(i)(I) of the Act specifically distinguishes between a ''generic drug'' and a ''preferred drug that is a multiple source drug,'' we do not believe it is appropriate to define a generic drug to include a ''multiple

source'' brand-name version of a drug. However, nothing in the statute would prohibit Part D plans from requiring their network pharmacies to provide pricing information about lower priced off-patent innovator drugs, and we encourage Part D plans to do so in the interest of ensuring Part D enrollees get the best prices available for their covered Part D drugs.

Comment: One commenter concerned with the burden on pharmacies to disclose pricing information stated that the disclosure requirement should be limited to cases in which an enrollee asks for this information at the pharmacy.

Response: As provided in section 1860D–4(k) of the Act, Part D plans must require network pharmacies, except for those which we have specifically exempted from the requirement, to disclose information about price differentials. We cannot limit this requirement to circumstances in which an enrollee specifically asks for the information. Furthermore, we believe such disclosure will provide enrollees—many of whom may not know that less expensive generic equivalents are available—with valuable information that will save money for beneficiaries, Part D plans, and Medicare.

Comment: One commenter recommended disclosure only when a brand name drug is prescribed and the prescriber has not stated ''Do Not Substitute.''

Response: As provided in section 1860D–4(k) of the Act, Part D plans must require network pharmacies, except for those which we have specifically exempted from the requirement, to disclose information about price differentials. We cannot limit this requirement to circumstances in which a prescriber has written a prescription for a brand name drug and has not specifically stated that the pharmacy must not substitute the brand name drug for a generic drug. We believe such disclosure will provide enrollees many of whom may not know that less expensive generic equivalents are available with valuable information that will save money for beneficiaries, Part D plans, and Medicare.

Comment: Two commenters suggested that we clarify that the lowest price generic version that is ''therapeutically equivalent and bioequivalent'' is an AB-rated generic equivalent, as AB rated drugs have been proved to be bioequivalent (rather than presumed to be bioequivalent). Another commenter suggested that we limit disclosure requirements to products with ''A'' code, as specified in the FDA Orange Book.

Response: We agree with these commenters and clarify that the disclosure requirement in § 423.132(a) of our final rule applies only with respect to AB-rated alternatives that are therapeutically equivalent and bioequivalent to the covered Part D drug in question.

Comment: A number of commenters recommended requiring mail-order pharmacies to provide price differentials before the prescription is filled and delivered rather than at the time of delivery. The commenters noted that notification by the time of delivery may be too late for beneficiaries to receive possible savings, especially since mail-order pharmacies provide a 90-day supply and generally have lower dispensing rates than retail pharmacies.

Response: We do not believe it is practicable to require a mail-order pharmacy to contact an enrollee with price differential information prior to filling and delivering their prescription. We believe such a requirement will delay the delivery of needed drugs and could potentially compromise beneficiaries' privacy given attempts by mail-order pharmacies to contact plan enrollees. In addition, such a requirement would be inconsistent with the requirement for retail pharmacies in § 423.132(b) of our final rule, which does not require that Part D plans provide price differential information before the drug is purchased. We have therefore retained our requirement, in § 423.132(b) of our final rule, that disclosure must occur at the time of delivery of the drug when a drug is dispensed by a mail-order pharmacy.

Comment: One commenter recommended that we not waive the public disclosure requirement for private fee-for-service plans offering qualified prescription drug coverage because there are many opportunities for generic savings that might not be realized in the absence of this requirement.

Response: Section 1860D–12(d)(2) of the Act specifically requires us to waive the public disclosure requirement for private fee-for-service MA plans that offer qualified prescription drug coverage and provide plan enrollees with access without charging additional cost-sharing for covered Part D drugs dispensed at all pharmacies.

Commenter: One commenter strongly urged that we waive the public disclosure requirement for I/T/U pharmacies because these pharmacies bear beneficiaries' out-of-pocket costs for covered Part D drugs, obviating the need for AI/AN Part D enrollees obtaining covered Part D drugs at these pharmacies to have this price comparison information.

Response: As provided both in our proposed rule and in our final rule at § 423.132(c)(3), we will waive the public disclosure requirement for I/T/U pharmacies.

Comment: One commenter requested that MA-PD plans be allowed to request a waiver of the public disclosure requirement.

Response: As provided in § 423.132(c)(5), we will consider waiving the public disclosure requirement under circumstances other than those specified in § 423.132(c)(1)-(4) to the extent that we deem such compliance to be impossible or impracticable. MA-PD plans seeking a waiver of the public disclosure requirement for any of their network pharmacies will therefore have to demonstrate to us that compliance with the public disclosure requirement in § 423.132(a) is impossible or impracticable. In addition we note that, as provided in section 1860D–21(c), we will waive any Part D requirement for an MA-PD plan that conflicts with or duplicates a requirement under Part C, or the waiver of which is necessary to promote coordination between benefits provided under Parts C and D.

Comment: Another commenter suggested that we specifically waive the disclosure requirement for MA-PD plans that own and operate their own pharmacies because these pharmacies may carry only one version of any particular generic drug at any one time (except when transitioning from one manufacturer's product to another).

Response: We do not believe the commenter has provided us with sufficient information to determine that the public disclosure requirement is impossible or impracticable for Part D plans that own and operate their own pharmacies and should therefore be waived in regulation. However, we note that MA-PD plans may also wish to consider seeking a waiver of the public disclosure requirement if, as provided in section 1860D–21(c) of the Act, they can demonstrate that this requirement conflicts with or duplicates a requirement under Part C, or that such waiver is necessary to promote coordination between benefits provided under Parts C and D.

Comment: Several commenters supported the applicability of disclosure requirements to long-term care pharmacies because many long-term care facility residents and their families would be interested to know if additional savings are possible. Two commenters opposed requiring price

disclosure at long-term care pharmacies because most long-term care beneficiaries do not have a choice regarding long-term care pharmacies and will likely qualify for low-income subsidies for institutionalized Part D enrollees who are full-benefit dual eligible individuals (which means they will have no out-of-pocket costs for covered Part D drugs). Thus, this information will have little effect on the drugs used by this population and will increase administrative burden for long-term care pharmacies.

Response: We agree with commenters who thought long-term care residents and their families would be interested to know if additional covered Part D drug savings are possible through the use of generic drugs, particularly since not all long-term care patients will qualify as full subsidy eligible individuals. We are therefore retaining the requirement we proposed at § 423.132(d)(1) of our proposed rule, but clarify—in § 423.132(d)(1) of our final rule—that long-term care pharmacies will have to provide information about differential price information required under § 423.132(a) of our final rule to Part D plans, which will, in turn, provide that information to their institutionalized enrollees via the explanation of benefits required under § 423.128(e) of our final rule.

8. Privacy, Confidentiality, and Accuracy of Enrollee Records (§ 423.136)

To the extent that the prescription drug plan offered by a PDP sponsor maintains medical records or other health information regarding Part D enrollees, § 423.136 of our proposed rule required the PDP sponsor to meet the same requirements regarding confidentiality and accuracy of enrollee records as MA organizations offering MA plans must currently meet under 42 CFR 422.118, according to the stipulations of section 1860D 4(i) of the Act. We clarify that the requirements of § 423.136 do not apply to PACE organizations and cost plans offering qualified prescription drug coverage, since these plans are subject to similar requirements under § 460.200(e) and § 460.210, and § 417.486, respectively.

PDP sponsors will be required to—

- Abide by all Federal and State laws regarding confidentiality and disclosure of medical records or other health and enrollment information, including the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and the privacy rule promulgated under HIPAA;
- Ensure that medical information is released only in accordance with applicable Federal or State law;
- Maintain the records and information in an accurate and timely manner; and
- Ensure timely access by enrollees to records and information pertaining to them.

Prescription drug plans will be covered entities under the HIPAA Privacy Rule because they meet the definition of ''health plan,'' as defined in 45 CFR 160.103. The HHS Office for Civil Rights (OCR) is responsible for implementing and enforcing the HIPAA Privacy Rule. OCR has authority to investigate complaints, to conduct compliance reviews, and to impose civil money penalties for HIPAA Privacy Rule violations. Thus, any violations by PDP sponsor for its obligations under the Privacy Rule as a covered entity are subject to such enforcement by OCR. OCR maintains a website with frequently asked questions and other compliance guidance at *http://hhs.gov/ocr/hipaa*.

Comment: One commenter thought that we should detail the confidentiality and disclosure requirements set forth in § 423.136 of our proposed rule in the final rule, instead of simply referencing the requirements in § 422.118. This commenter believes that because of the importance of privacy protections, it is necessary that required protections are reiterated in our final rule and that PDP sponsors adequately understand their responsibilities to safeguard the health information of Medicare beneficiaries. Without privacy safeguards built directly in the regulation, beneficiaries could be vulnerable to another amendment.

Response: We agree with this commenter and have incorporated the provisions of § 422.118 directly into § 423.136 of our final rule rather than only referencing the provisions of § 422.118.

Comment: One commenter recommends that we make privacy provisions stronger for PDP sponsors, not only reiterating the protections under § 422.118, but also including specific rules regarding uses and disclosures of beneficiary information that both incorporate the provisions of important laws (such as the notice and authorization provisions of the HIPAA privacy rule) and strengthen the provisions of those laws to better protect the health information of Medicare beneficiaries.

Response: The requirements in § 423.136 of our final rule make clear that PDP sponsors must abide by all Federal and State laws regarding confidentiality and disclosure of medical records, or other health and enrollment information. This obligation includes compliance with the provisions of the HIPAA privacy rule and its specific rules regarding uses and disclosures of beneficiary information. Because section 1860d–4(i) of the Act stipulates that the privacy provisions under section 1852(h) apply to prescription drug plans in the ''same'' manner as they apply to MA plans under Medicare Part C, we do not have the statutory authority to expand upon those provisions as the commenter suggests.

Comment: One commenter recommends that we permit MA organizations and PDP sponsors to prevent pharmacies in their networks and out-of-network pharmacies from releasing prescriber data to third parties. Some MA organizations are concerned that providing data to drug manufacturers will have the negative effect of assisting manufacturers in targeting their marketing of unnecessary, expensive drugs in a more effective manner.

Response: Pharmacies that engage in electronic transactions are covered entities under HIPAA and are thus required to comply with the HIPAA Privacy Rule. As provided in 45 CFR 164.508, such pharmacies, as covered entities, would be prohibited from releasing individually identifiable health information to drug manufacturers for the purpose of the manufacturers' marketing unless a patient specifically authorizes the disclosure of his or her information for this purpose. However, the Privacy Rule protects patient information only, and is therefore not implicated regarding the sharing of information about prescribers.

D. Cost Control and Quality Improvement Requirements for Part D Plans

1. Overview (Scope) (§ 423.150)

Subpart D of part 423 implements provisions included in sections 1860D 4(c), 1860D–4(d), 1860D–4(e), 1860D–4(j), and 1860D–21(d)(3) of the Act and sections 102(b) and 109 of Title I of the MMA. This subpart sets forth the requirements related to the following:

- Drug utilization management programs, Quality assurance measures and systems, and Medication Therapy Management programs (MTMP) for Part D sponsors;
- Consumer satisfaction surveys of Part D plans;
- Electronic prescription program;

- Quality Improvement Organization (QIO) activities;
- Compliance deemed on the basis of accreditation;
- Accreditation organizations;
- Procedures for the approval of accreditation as a basis for deeming compliance.

Below we summarize the proposed provisions and respond to comments. (For a detailed discussion of our proposals, please refer to the proposed rule (69 FR 46666)).

2. Drug Utilization Management, Quality Assurance, and Medication Therapy Management Programs (MTMPs) (§ 423.153)

Proposed § 423.153(a) required each Part D sponsor to establish a drug utilization management program, quality assurance measures and systems, and a MTMP.

We combined these requirements into one section of the regulation because each of these requirements will impact the quality and cost of care provided to beneficiaries. We stated that our intent was to ensure that the prescription drug benefit was provided using state of the art cost management and quality assurance systems. We stated that we also understood the overlapping nature of these requirements and that provisions under one requirement might complement another requirement.

We also explained in the proposed rule that although these requirements were similar in their underlying goals, they could also be quite different, and that while we understood that some members of the industry use various quality assurance measures and systems for controlling utilization and reducing medication errors, less information was available regarding MTMPs.

After receiving many comments on our proposals, our final policy, generally stated, is that cost control and quality improvement requirements describe minimum standards for drug utilization management, quality assurance, and MTMP so as to provide plans with flexibility to develop, implement, and update their programs and systems to reflect changing best practices and to continue to provide beneficiaries with the best quality prescription drug benefit at the lowest possible cost. We expect plans to continuously monitor their programs and processes, identify opportunities for improvement, and develop improvement plans and strategies.

As we stated in the proposed rule, we believe that the different program and system requirements in this subpart frequently overlap and therefore, plans need flexibility to coordinate among the different requirements. Moreover, flexibility is required to ensure that plans can support forthcoming electronic prescribing standards that we envision will dramatically affect the utilization management and quality assurance landscape. Nevertheless, despite the lack of specificity in our requirements, we expect plans to continually pursue innovative improvements for their programs and systems, and maximize technological advances when appropriate.

Ultimately, the evaluation of these programs and systems needs to be based upon their impact on therapeutic outcomes. As part of our commitment to improving therapeutic outcomes through the Medicare Prescription Drug Benefit, we intend to work with industry and other stakeholders to develop a comprehensive strategy for evaluating plan performance that collectively considers multiple standards and services affecting the cost and quality of drug therapy. As industry practices evolve, including the expected expansion of electronic prescribing, we believe meaningful performance measures can be identified that will validate best practices and provide benchmarks that will spur further program and system improvements. Accordingly, we will work with industry to identify new standards for quality and performance that could eventually become plan requirements. Our goal is to ensure that the Medicare Prescription Drug Benefit will always provide beneficiaries with the highest quality prescription drug benefits at the lowest possible cost.

In addition to our efforts to work with industry and stakeholders to develop future performance measures and standards for Part D plans, we also intend to implement a plan for utilizing Medicare prescription drug data to improve the evidence on risks, benefits, and overall costs of drug therapies for the chronically ill and other Medicare beneficiaries. This plan will be developed through a public process and implemented in a manner that preserves the confidentiality of beneficiary information.

a. Drug Utilization Management

Proposed § 423.153(b) provided flexibility to Part D sponsors in their design of drug utilization management, and included minimum requirements for drug utilization management programs. These requirements were: (1) that plans maintain a program that includes incentives to reduce costs where medically appropriate; and (2) that plans maintain policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications. The proposed rule also stated that Part D sponsors must inform enrollees of program requirements, such as those involving allowable refill timeframes, in order to prevent unintended interruption in drug therapy.

In addition, the proposed rule contained a discussion about whether drug utilization management techniques should be under the direction and oversight of a P&T Committee to ensure an appropriate balance between clinical efficacy and cost effectiveness. The discussion on P&T Committees and their oversight of drug utilization management is contained in subpart C of this final rule.

We invited comments on whether there are industry standards for drug utilization management and whether we should adopt any of these standards.

Comment: We received numerous comments on our proposed standards, with several commenters supporting the flexibility we proposed and stating that there are no current, widely-accepted standards in the area of drug utilization management. Others supported additional detail in the regulations and suggested that we should further specify drug utilization management program standards. Some expressed concern that plans could use drug utilization management programs to restrict utilization inappropriately. In addition, several commenters recommended that we require plans to focus equally on over-utilization and under-utilization to ensure appropriate utilization by enrollees and to monitor plan performance in these areas.

Response: Based on a literature review by Booz-Allen-Hamilton[3], and the public comments received on this topic, we are not adopting further specifications for drug utilization management requirements in the final rule. While drug utilization management is common practice, plans appropriately employ a number of different approaches (for example, formularies, step therapy, tiered cost sharing, prior authorization) and different combinations of those approaches, and therefore, while we will consider additional standards in the future, we are adopting the flexibility we proposed in the proposed rule. As we stated in the proposed rule, we believe the competitive bidding and premium setting processes, combined with the requirements for transparency and information availability, will provide powerful incentives for plans to

[3] Booz-Allen-Hamilton. Final Report for Technical Support for the Implementation of Part D. September 15, 2004.

innovate and adopt the best techniques available.

Nevertheless, our requirement for inclusion of incentives to reduce costs when medically appropriate must be interpreted broadly to mean that all drug utilization management techniques must be medically appropriate, and § 423.153(b) requires the utilization management program established by plans to be ''reasonable and appropriate.'' As outlined in the formulary guidance that will follow this final rule, we will review plans' drug utilization management requirements to ensure that beneficiaries are given appropriate access to medically necessary drugs in a timely manner. In order to ensure that plans appropriately employ drug utilization management techniques, and to develop or adopt further drug utilization management performance measures, we agree with commenters who recommended we track plan performance in this area. Therefore, we are adding a reporting requirement at § 423.153(b)(3) and we will specify the information that we will require in separate guidance.

Comment: One commenter stated that there are no standard measures for drug utilization management and recommended that we investigate using HEDIS (Health plan Employer Data and Information Set) measures as well as a number of other specific measures. Another commenter suggested that we use total health care costs as a measure.

Response: As discussed in the previous response, we intend to develop or adopt further drug utilization management performance measures in the future. While we agree that no universally accepted performance measures currently exist, and are therefore not prepared to specify further requirements in regulation, we also understand that there are some performance measures being utilized today and that these could provide valuable information. We intend to evaluate existing measures, such as HEDIS, and could include these or similar performance measures in our formulary guidance or drug utilization management reporting guidelines that will follow publication of this rule. In general, we expect drug utilization management programs to ensure that beneficiaries have appropriate access to medically necessary drugs in a timely manner.

b. Quality Assurance

As with the proposed regulations for drug utilization management programs, the proposed rule for quality assurance measures and systems provided minimum standards for quality assurance measures and systems, while for the most part giving plans flexibility to design such measures and systems. Proposed § 423.153(c) required Part D sponsors to include quality assurance measures and systems for: (1) reducing medication errors; (2) reducing adverse drug interactions; and, (3) improving medication use. It also proposed to require plans to establish requirements for: (1) drug utilization review (DUR); (2) patient counseling; and, (3) patient information record-keeping.

In the proposed rule, we stated that the DUR, patient counseling and patient information record-keeping requirements would generally need to comply with section 4401 of the Omnibus Reconciliation Act of 1990 as codified in § 456.705 and section 1927(g)(2)(A) of the Act, and we stated that we were considering such specific requirements for the final rule. Although those regulations were written specifically for the Medicaid population, we stated that we understood that they describe currently accepted standards for contemporary pharmacy practice, and our intent was to require plans to continue to comply with contemporary standards. We solicited comment on whether the Medicaid standards were in fact industry standards, whether they are appropriate standards for part D, and if they are, how they should be adapted for use in Part D. We also stated our understanding that some members of industry use additional quality assurance measures and systems. We invited comments on whether there were additional industry standards that we might adopt. Furthermore, we proposed that Part D sponsors will be required to have systems and measures established to ensure that network pharmacy providers are complying with the plans' quality assurance requirements. We requested comments on the costs and challenges associated with these systems and measures.

Comment: Most commenters agreed that the relevant parts of OBRA 90 for DUR, patient counseling and patient information record-keeping describe widely accepted standards for pharmacy practice. While no other suggestions for widely accepted standards of pharmacy practice were offered, one commenter indicated that these requirements will not adequately cover appropriate standards for home infusion pharmacies, which the commenter recommended should also require patient interviews and clinical assessments. Alternatively, several commenters recommended that we defer to State laws and State board of pharmacy regulations regarding pharmacy practice standards instead of creating a redundant Federal standard for pharmacy practice.

Response: The overwhelming majority of comments confirmed our understanding that the relevant parts of OBRA90 for DUR, patient counseling, and patient information record-keeping generally describe widely accepted standards of pharmacy practice for both Medicaid and Non-Medicaid patients. We find that almost all of the State boards of pharmacy have adopted regulations for pharmacy practice that, at a minimum, generally reflect these relevant parts of the OBRA 90 requirements. However, upon reconsideration, since our intent was to ensure that plans provided access to network providers that are required to comply with contemporary pharmacy practice standards, and not to create a new Federal standard for pharmacy practice, we agree with commenters that recommended that we defer to existing authority for regulating pharmacy practice. In fact, this is consistent with the Department of Health and Human Service's (HHS) general position of deferring to States for regulating the practice of pharmacy. Therefore, our requirement at § 423.153(c)(1) in the final rule states that plans must provide us with representation that their network providers are required to comply with minimum standards for pharmacy practice established by the States.

While we understand that additional quality standards might apply to specific pharmacy practice-settings such as home infusion pharmacy, specialty pharmacy and long-term care pharmacy practice, we are not prepared to adopt additional, practice-setting specific Federal standards at this time. We believe that current pharmacy practice standards established by the States, whether or not a State has additional standards for specific pharmacy practice-settings, still provide applicable minimum standards for all pharmacy practice-settings. Nevertheless, we encourage plans and their network pharmacy providers to establish and agree upon additional quality assurance standards as necessary, including those required for accreditation by recognized accrediting organizations.

Comment: Several commenters stated that concurrent and retrospective drug utilization review (DUR) systems illustrate successful examples of industry practices that help prevent inappropriate drug therapy. Concurrent DUR systems are used to identify potential inappropriate drug therapy before a patient receives a prescription while retrospective DUR systems can

often identify patterns of potential inappropriate prescribing and drug utilization based upon drug claim history.

Response: Based upon these comments as well as similar information provided in the Booz-Allen-Hamilton report, we agree that concurrent and retrospective DUR must be components of the quality assurance systems and measures to be implemented by Part D plans. Accordingly, we have specified requirements for concurrent and retrospective DUR systems, policies, and procedures at § 423.153(c)(2) and § 423.153(c)(3), respectively.

In the proposed rule, we stated that elements we viewed as desirable for quality assurance systems were: (1) electronic prescribing; (2) clinical decision support systems; (3) educational interventions; (4) bar codes; (5) adverse event reporting systems; and, (6) provider and patient education.

While we did not expect Part D plans to adopt all of these elements, we stated that we expected substantial innovation and rapid development of improved quality assurance systems in the new competitive and transparent market being created by the new Part D benefit.

We invited comments on which, if any, elements of a quality assurance system should be contained in our program requirements. We were particularly interested in best practices in quality assurance, costs and benefits associated with each element, the challenges involved in implementing quality assurance measures and systems, types of data useful for reducing medication errors, associated costs and challenges with collecting this data, and how these data could best be communicated to providers and beneficiaries to improve medication use.

We noted that the MMA does not define or explain the term ''medication error.'' Nevertheless, we stated that we believe a common definition was important. Therefore, we cited the following definition as one that we might use initially in interpretive guidance, which was previously adopted by the FDA in its proposed rule requiring bar codes on human drug products:

''Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice; healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.'' (See 68 FR 12500 (March 14, 2003)).

We indicated that in the future we may require quality measures that include error reports and stated that we could use this information to evaluate plans. In addition, we indicated that we may publish this information for enrollees to use when comparing and choosing their individual plans. Therefore, we invited specific comments on how we could evaluate Part D plans based on the types of quality assurance measures and systems they have in place, on this proposed definition of ''medication error'', on how error rates can be used to compare and evaluate plans, and on how such information could best be provided to beneficiaries to assist them in making their choices among plans.

Comment: A number of commenters recommended we include all elements discussed in the proposed rule including decision support, electronic prescribing, bar codes, adverse event reports, and provider and patient education. Most of them recommended that we require adverse event and medication error tracking systems. However, many commenters recommended that these tracking systems be used internally and that reports not be sent to CMS or made public. These commenters argued that there is too much inconsistency in the definitions used in the field and that an external reporting requirement would actually be counter productive for quality improvement. While several commenters generally thought our proposed definition for ''medication error'' was accurate, these same commenters stated that such a definition would need to be narrowed to prove useful for consistent reporting among the plans.

Response: As to all the elements that we listed in the preamble, we agree with the many industry organizations that there are no well accepted industry standards to make these mandatory requirements. The Booz-Allen-Hamilton report[4] supports this finding. We continue to believe that these are desirable goals and have found that many organizations are already using them. We expect that electronic prescribing will greatly increase the availability of clinical decision support. We intend to work with various stakeholders to further develop these and other quality assurance systems enhancements.

We agree with commenters that there are inconsistencies associated with the reporting of adverse events and medication errors. Moreover, we are not convinced, based upon many of the comments received, that an external reporting requirement for medication errors, even if we provided a more specific and narrow definition of ''medication error'', will lead to improved quality of care. Therefore, instead of requiring plans to report medication errors to us, we require plans to implement internal medication error identification and reduction systems, and we have added this requirement at § 423.153(c)(4). We are also requiring plans to provide us with information concerning their quality assurance measures and systems, in accordance with guidelines published by us. In addition, we encourage plans to utilize the FDA Medwatch form for reporting adverse events, as well as educating prescribers and pharmacy providers about its availability. Finally, although we will not require external medication error reporting at this time, we maintain that our proposed definition of ''medication error'' can still serve as appropriate guidance for internal medication error identification and reduction systems.

c. Medication Therapy Management Programs (MTMPs)

Proposed § 423.153(d) required Part D sponsors to establish an MTMP described in section 1860D–4(c)(2) of the Act that is designed to optimize therapeutic outcomes for targeted beneficiaries by improving medication use and reducing adverse drug events, including adverse drug interactions, that may be furnished by a pharmacist, and that may distinguish between services in ambulatory and institutional settings. We stated that MTMPs may include elements designed to promote (for targeted beneficiaries):

- Enhanced enrollee understanding—through beneficiary education counseling, and other means that promotes the appropriate use of medications and reduces the risk of potentially adverse events associated with the use of medications.
- Increased enrollee adherence to prescription medication regimens (for example, through medication refill reminders, special packaging, compliance programs, and other appropriate means).
- Detection of adverse drug events and patterns of over-use and under-use of prescription drugs.

We proposed that in order to promote these elements and optimize therapeutic outcomes for targeted beneficiaries, we envision MTMPs potentially spanning a range of services, from simple to complex. In addition to those mentioned in the statute, services could include, but may not be limited to, performing patient health status

[4] Ibid.

assessments, formulating prescription drug treatment plans, managing high cost specialty medications, evaluating and monitoring patient response to drug therapy, providing education and training, coordinating medication therapy with other care management services, and participating in State-permitted collaborative drug therapy management.

We specifically sought comment on MTMP best practices, essential components of successful MTMPs, appropriate MTMP providers, service level requirements, quality assurance requirements for MTMPs, information on effective MTMP services that could be publicized and used by beneficiaries, and other effective steps to make valuable, proven MTMP services available to beneficiaries.

Comment: Numerous commenters recommended that we specifically define a minimum package of services that all plans must offer for MTMPs, because plans will not have the economic incentives to offer adequate MTMP services otherwise, or because different plans will offer such different services that the quality of services provided will vary significantly. Although comments suggested a wide variety of possible MTMP services, common elements identified in several best practice examples provided in the comments included: (1) Initial assessment/patient interview; (2) Development of a drug plan identifying goals for therapy; and, (3) Monitoring and evaluation of therapy. Nevertheless, a number of commenters recommended that we maintain the level of specificity contained in the proposed rule. These commenters stated that no widely accepted MTMP standards exist and plans need flexibility to develop and implement MTMPs that can best meet the needs of their specific patient populations and therefore, achieve the best outcomes.

Response: After reviewing extensive comments and conducting additional research, we believe that insufficient standards and performance measures exist to support further specification for MTMP services and service level requirements, and therefore we are adopting the flexibility proposed in the proposed rule. Although best practice examples identified some common elements, neither the Booz-Allen-Hamilton report, nor any comments submitted to us, showed that these MTMPs reflected widely accepted standards of practice. In fact, until the Pharmacist Provider Coalition's recent publication of their definition of MTMP, no widely agreed upon definition of MTMP existed, let alone standards and measures. While we understand the concern with potential disincentives for part D plans to develop robust MTMPs, we are not adopting additional regulatory requirements at this time because it us unclear which specific, additional requirements would enhance MTMPs, and ultimately improve therapeutic outcomes for part D beneficiaries.

We continue to believe that MTMPs can and must offer appropriate services for targeted beneficiaries. However, we are concerned that further premature regulatory requirements at this time might not only fail to improve MTMPs, but could negatively impact their development. Requiring a universal set of minimum services and service levels, without fully understanding how they could effectively be implemented on a much larger platform than illustrated in best practice examples, could result in MTMPs becoming perfunctory services offered just to satisfy regulatory requirements as opposed to patient focused services aimed at improving therapeutic outcomes. For example, several of the best practice examples stressed the importance of collaboration with prescribers to ensure that MTMP is successful. However, simply requiring specific services and service delivery mechanisms will not do anything to ensure successful collaboration. Therefore, we believe that at the outset of the Medicare Prescription Drug Benefit, plans must have maximum flexibility to develop MTMPs that can achieve the statutory goal of improving therapeutic outcomes.

Notwithstanding the lack of current MTMP standards and performance measures, we believe that MTMP must evolve and become a cornerstone of the Medicare Prescription Drug Benefit. With an understanding that the introduction of MTMP requirements can significantly impact the current practice of pharmacy, we intend to utilize the Medicare Prescription Drug Benefit as a platform for driving the quality improvement of prescription drug therapy. We require plans to report details on their respective MTMPs, and we intend to collaborate further with industry to develop measures that can be used to evaluate programs and establish appropriate standards. Our goal is to evaluate MTMPs within the context of an overall strategy that evaluates not only MTMP, but also other quality of care programs, standards, and services, such as drug utilization management, drug utilization review, chronic care improvement programs, and the role of QIOs. In so doing, we believe that we will identify best practices that will evolve into industry practice standards and could eventually be adopted as our standards.

Comment: Several commenters recommended that we require plans to allow beneficiaries to receive MTMP services from their network/non-network provider of choice. In addition, several commenters recommend that we require plans to offer MTMPs that favor face-to-face consultations over other forms of intervention.

Response: Consistent with our overall approach to MTMPs, at this time we believe plans need the discretion to decide on which methods and which providers are best for providing MTMP services available under their specific MTMP. We assume that such providers will include some network pharmacy providers, but plans are not obligated to use any specific providers as long as those providing services for the plan are qualified to provide such services. Furthermore, although we indicated in the proposed rule that we believe pharmacists will be the primary providers of these services, and that we believe beneficiary choice and on-going beneficiary-provider relationships should play a role in determining the appropriate providers, we recognize that such determinations must be made in the context of the specific, overall program design. Moreover, while we understand that face-to-face consultations can offer advantages over other methods of service delivery, it is still but one component of a successful MTMP. Successful MTMPs will need to consider and coordinate not only the method of communication and the providers of services, but also other components such as the content of the service, the qualifications of the providers, the identification of targeted beneficiaries, and the documentation requirements associated with services performed. Because plans are responsible for designing the programs to improve therapeutic outcomes, plans will be in position to make the determinations that will maximize overall MTMP effectiveness, taking into account all factors that influence successful MTMP.

In addition, while section1860D–4(b)(1)(C)(iii) of the Act requires us to establish pharmacy access standards that include rules for adequate emergency access to covered part D drugs, we do not believe the same authority applies to out of network access for MTMP services. Unlike situations when patients face an urgent need for covered Part D drugs but do not have access to a network provider, we do not believe this urgent need rationale reasonably applies to MTMP. In addition, the Congress clearly knows

how to require out-of-network access and did so specifically for Part D drugs in emergency situations. Accordingly, we can not require plans to offer MTMP services through out-of-network pharmacies.

Comment: One commenter noted that MTMP services will fall under the consideration of State boards of pharmacy and how States have defined the practice of pharmacy and scope of services which pharmacists are legally able to provide to patients. Therefore, this commenter requested that we work with States and their boards of pharmacy to prevent conflicts between MTMP under the Medicare Prescription Drug Benefit and State definitions of pharmacy practice and scope of allowable pharmacist activities.

Response: Generally, unless there is a conflict with Federal law, we will defer to State laws and regulations pertaining to the practice of pharmacy. We do not believe our current MTMP requirements pose any conflicts with State laws and therefore, plans need to develop MTMPs that comply with State laws and regulations.

Comment: Several commenters recommended that we clarify that providers can offer MTMP to non-targeted beneficiaries and bill the beneficiaries for these services.

Response: We agree that providers can offer MTMP services to non-targeted beneficiaries because MTMP in these circumstances is not part of the Medicare Prescription Drug Benefit. Providers need to notify beneficiaries receiving these services that the services are not offered as part of the Medicare Prescription Drug Benefit and therefore, the beneficiary is responsible for all of the cost of the MTMP.

Similarly, if plans choose to offer MTMP to non-targeted beneficiaries, beneficiaries must be notified that they are responsible for 100 percent of the cost. Moreover, the costs for these services fall entirely outside the Part D cost sharing structure and do not count for purposes of tracking beneficiaries' total costs, out-of-pocket costs, or for purposes of reinsurance and risk sharing with Medicare.

Comment: Several commenters recommended that we prohibit plans from implementing MTMPs as a utilization management tool geared towards shifting market share as opposed to improving therapeutic outcomes.

Response: We agree that MTMPs are more than utilization management programs focused on shifting market-share. Part D plans must implement MTMPs designed to optimize therapeutic outcomes by improving medication use and reducing the risk of adverse drug events, including adverse drug interactions. Plan sponsors will need to coordinate their MTMPs and utilization management strategies to improve therapeutic outcomes at the lowest possible costs.

In the proposed rule, we proposed that MTMP fees be treated as administrative fees and incorporated into the premium, rather than being billed to the beneficiary on a case-by-case basis. We noted that while section 1860D–4(c)(2)(E) of the Act specifies that the time and resources necessary to implement the MTMPs must be taken into account when establishing fees, it does not specify how these fees should be paid. We stated our belief that fees associated with provision of MTMP services are separate and distinct from dispensing fees discussed in § 423.100. Although section 1860D–4(c)(2)(E) of the Act states that Part D sponsors must disclose to the Secretary the amount of ''any such management or dispensing fees'', it merely governs disclosure and does not require that MTMP be included in the dispensing fee (indeed the Act distinguishes management fees from dispensing fees that are part of individual prescriptions).

Comment: Most commenters agreed with our interpretation that MTMP should be considered an administrative cost as opposed to a benefit, thereby preventing direct beneficiary cost sharing for MTMP services.

Response: We agree that direct beneficiary cost sharing for MTMP services could negatively impact targeted beneficiary participation and therefore, our final policy is to consider MTMP as an administrative cost (included in the plan bid), incident to appropriate drug therapy, and not an additional benefit.

Comment: Many commenters recommended that we include reporting requirements in the final regulation, specifying, for example, that plans provide detailed policies and procedures for implementing their MTMPs and associated performance measures for evaluating the impact on therapeutic outcomes.

Response: We agree with these commenters that we must include a reporting requirement for MTMPs. As we work with industry and other stakeholders to improve the therapeutic outcomes by optimizing prescription drug therapy, we will need detailed information about each MTMP. Therefore, we are adding a reporting requirement at § 423.153(d)(6) and we will specify the information that we will require in separate guidance.

Comment: Several commenters suggested that we specifically involve QIOs with the collecting and analyzing of data from MTMPs and establish a mechanism for QIOs to secure information from medical claims to identify targets.

Response: We believe that QIOs could play a significant role with MTMPs and this will be reflected in our contracts with the QIOs. Specific technical assistance could include collecting and analyzing MTMP data.

Comment: Several commenters responded to our request for incentives that would help drive the creation and evolution of significant MTMPs by suggesting pay-for-performance incentives and minimum renewal criteria, both based upon mutually agreed upon thresholds of patient care.

Response: We have a more complete discussion of pay-for-performance in the quality improvement section of the preamble to the final Title II rule. We are conducting several demonstrations to test this approach and we are very interested in studying this direction for plans. Plans are free to develop such arrangements with their providers, and we encourage them to do so. Such arrangements have existed for a number of years in the Medicare Advantage program. Plans will need to be mindful of any restrictions imposed by the anti-kickback statute, and those needing further clarification may want to use the OIG's advisory opinion process to obtain guidance relating to specific transactions and arrangements.

Comment: CMS should clarify that MTMP services are voluntary and that targeted beneficiaries are under no obligation to participate with programs in order to receive prescription drug benefits.

Response: We agree that beneficiaries must not be obligated to participate in MTMPs. While we hope that beneficiaries will participate to improve their therapeutic outcomes, beneficiaries must not be denied access to prescription drugs based upon failure to participate in MTMPs.

Comment: One commenter recommended that we require Part D plans to separate MTMP services agreements with providers from standard network provider contracts to reduce potential conflict of interest.

Response: Since we do not know who will be providing MTMP services, it is premature for us to require specific terms and conditions for such contracts. While MTMP service providers will likely include some network pharmacy providers, Part D plans will need to specify, in their applications, their approach to determining MTMP fees

which accounts for the time and resources necessary to perform the services. In addition, plans need to comply with any restrictions imposed by the anti-kickback statute.

Comment: One commenter recommended that we change the language at § 423.153(d)(1)(i) from ''must assure'' to ''must have processes in place so that.''

Response: Upon review of the proposed language, we agree that § 423.153(d)(1)(i) must be changed. We have changed ''must assure'' to ''is designed to ensure.'' We believe this language does not impact the intent but better reflects what is required of MTMPs.

Section 1860D–4(c)(2)(A)(ii) of the Act describes targeted beneficiaries as Part D individuals who: (1) have multiple chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure); (2) are taking multiple covered part D drugs; and (3) are identified as likely to incur annual costs for covered Part D drugs that exceed a level specified by the Secretary, and we codified this requirement at proposed § 423.153(d)(2).

We invited comment on further defining ''multiple chronic diseases'' and ''multiple covered Part D drugs,'' and whether we should add further specifications or leave such determinations to the plans. Furthermore, we invited comment on whether we should set the cost threshold for determining targeted beneficiaries or if this determination could also be left up to the plans. Generally, we invited comment on disease, drug and cost issues that we should consider in further refining the definition of targeted beneficiary.

Comment: Many commenters recommended that we specify which chronic diseases, the number of chronic diseases, and the number of covered part D drugs that will qualify a beneficiary for MTMP services. Moreover, several commenters suggested that specific patient populations, such as beneficiaries in long term care, should automatically be considered eligible for MTMP services in all plans. Alternatively, many commenters suggested that such determinations are best left to the individual plans for designing their plan specific MTMPs.

Response: At this time, we believe these determinations must be left to the plans. Although we are not adding further specific requirements for chronic disease and multiple drugs, we do recommend that plans take notice of the statutory examples of chronic diseases when developing MTMPs. We plan to monitor the programs developed by the plans to learn from them as to whether or not further guidance is desirable.

Comment: Many commenters provided recommendations on the level of annual costs for Part D drugs likely to be incurred by a beneficiary that should be used as a threshold for MTMP eligibility. Some commenters argued that any cost threshold is inappropriate because it does not indicate those that could benefit from MTMP and in fact, could exclude beneficiaries that would benefit most. Others recommended various cost thresholds including specific dollar amounts and percentage based thresholds (for example, top 5 percent). Most comments suggested that we should make this determination and not delegate it to the plans.

Response: Despite our discussion in the proposed rule about leaving this determination to the plans, we do not believe we have the authority to delegate the cost threshold determination to plans and therefore, we will set a cost threshold. While cost might not the be best proxy for identifying patients that could benefit most from MTMP, the statute requires us to set a threshold and our goal is to identify a manageable target population so that plans offer truly valuable services to beneficiaries that will benefit from such services. Factors we will consider include typical costs associated with the most common chronic diseases and co-morbidities for Medicare beneficiaries, the relationship between cost and the number of medications a beneficiary is taking, the impact specific cost thresholds have on the size of the target population, and the alignment of incentives for providing MTMP services within the standard part D benefit structure. We intend to provide the specific cost threshold in separate guidance.

Comment: Several commenters recommended that we should require plans to allow providers and beneficiaries (self-referral) to identify appropriate MTMP targets in addition to plans utilizing system edits to identify eligible MTMP targets.

Response: The identification of targeted beneficiaries will be determined by individual plan policies. Therefore, plans will decide if and how providers and beneficiaries can participate with identifying targets. Once again, we believe that successful MTMPs must be coordinated and that plans need to develop appropriate mechanisms for notifying and identifying targeted beneficiaries that are eligible for MTMP services.

Section 1860D–4(c)(2)(C) of the Act requires Part D sponsors to develop their MTMPs in cooperation with licensed and practicing pharmacists and physicians, and we codified this requirement at § 423.153(d)(3).

Comment: Several commenters recommended that we specify that practicing pharmacists and physicians must be licensed in the United States.

Response: Part D sponsors must comply with State licensure requirements for pharmacy practice, and therefore, we believe further specific licensure requirements are not warranted.

Section 1860D–4(c)(2)(D) of the Act requires us to establish guidelines for the coordination of MTMPs with chronic care improvement programs established under section 1807 of the Act for targeted beneficiaries, and we codified this requirement at § 423.153(d)(4).

The Chronic Care Improvement Program (CCIP) is a new program established by section 721 of the MMA, which added a new section, section 1807, to the Act. The new section 1807 creates a method for us to assist beneficiaries with multiple chronic conditions in managing their care. The program is targeted only to beneficiaries in original fee-for-service Medicare not beneficiaries enrolled in MA plans.

We invited comment on how services provided through CCIP could be effectively coordinated with MTMP services provided by PDPs. We also sought comment on how to integrate MTMP services and financial incentives into the CCIP under section 721 of the Act.

Comment: Several commenters recommended that we share CCIP enrollment information with PDPs so that these individuals will be excluded from MTMP services. In addition, several other commenters recommended that we require PDPs to share their drug data with CCIPs.

Response: We agree that Part D plans need to share drug data with CCIPs and have specified this requirement in our regulation text at § 423.153(d)(4). CCIPs need this valuable data in order to provide the comprehensive care management that is intended under the CCIP. However, plans must determine, in conjunction with CCIPs, whether or not it is desirable to offer MTMP services to persons participating in CCIPs. We note that in sharing the data, both the CCIP and the Part D sponsor will need to abide by the HIPAA privacy rules including transmitting only the minimum data necessary. We strongly encourage Part D plans to consult with their privacy counsel to ensure that the

transmission of data complied with all aspects of the HIPAA privacy rules.

In the proposed rule we also discussed the requirement in section 1860D–4(c)(2)(E) of the Act specifying that the time and resources necessary to implement MTMP be taken into account when establishing fees for pharmacists or others providing MTMP services under the plan. We stated that to implement this section, in evaluating the administrative component of a Part D plan's bid, we will ask a Part D sponsor to disclose the fees it pays to pharmacists or others, including an explanation of those fees attributable to MTMP services. The fee information provided to us under this authority will be protected under the confidentiality provisions of section 1927(b)(3)(D) of the Act. Under those provisions, we are prohibited from disclosing the specific fees in a manner that links the fees to the particular pharmacy or other provider providing the MTMP services except to the extent necessary to administer the Part D program, to permit the Comptroller General to review the information, or to permit the Director of the CBO to review the information. If we were to discover situations in which plans systematically did not pay the fees described in their applications-and, if those errors were not corrected upon notification, we might, at our discretion, employ the broad ranges of intermediate sanctions or termination provisions available under subparts K and O of the regulations.

We stated, however, that while we expected to perform the due diligence described above through application review and potentially following up on any complaints, we did not believe we have the authority to mandate that Part D sponsors pay pharmacists or other providers a certain amount for MTMP services. We also stated that we will not adjudicate any specific disputes between Part D and pharmacists or other providers regarding the specific fees due for MTMP services.

Comment: Many commenters recommended that we provide further requirements for MTMP fees, including establishing a fee schedule, identifying a particular documentation and billing mechanism, and requiring plans to reimburse for MTMP services provided by out of network providers.

Response: These details are up to the plans and their arrangements with pharmacists and other providers. We do not believe the MMA provides us with the authority to establish fee schedules or interfere with the contracts between plans and providers. While we are familiar with the recommendation and accompanying efforts to pursue a CPT coding mechanism for MTMP services, which would provide for common billing and documentation procedures, the American Medical Association's (AMA) Current Procedural Terminology (CPT) Editorial Panel will make that determination and it does not directly involve us. Therefore, in the final rule, we are adopting our proposed policy to require sponsors to discuss their MTMP fees in their applications, but neither to mandate any specific MTMP fees nor become involved in payment disputes regarding MTMP between pharmacies and sponsors.

Section 423.153(e) in the proposed rule discussed fraud, waste and abuse programs required by section 1860D–4(c)(1)(D) of the Act. In an effort to consolidate, the requirements and preamble discussion pertaining to fraud, waste and abuse programs, we moved § 423.504(b)(4)(vi)(H) to subpart K, and included as a component of a Part D sponsor's general compliance plan.

d. Exception for Private Fee for Service Plans

Proposed § 423.153(f) implemented section 1860D–21(d)(3) of the Act by exempting private fee for-service MA plans that offer qualified prescription drug coverage from the requirement to establish a drug utilization management program and a MTMP; however, these private fee-for-service MA plans are still required to establish quality assurance measures and systems and a program to control fraud, waste and abuse as described in § 423.153(c) and § 423.504(b)(4)(vi)(H), respectively.

We did not receive any comments on these provisions and they have been adopted in the final rule at § 423.153(e).

3. Consumer Satisfaction Surveys (§ 423.156)

As proposed under § 423.156, we will conduct consumer satisfaction surveys of enrollees of Part D plans in order to provide comparative information about qualified prescription drug coverage to enrollees as part of our information dissemination efforts. Section 1860D 4(d) of the Act specifies that these surveys be conducted in a manner similar to how they are conducted under § 422.152(b) for MA plans by using the Consumer Assessment of Health Plans (CAHPs).

In the proposed rule, we stated that we believed a CAHPs-like instrument (or perhaps a modification of CAHPs for MA organizations offering MA-PD plans) will most likely be the vehicle used to collect this information. In addition, we stated that we anticipated working with the Agency for Healthcare Research and Quality (AHRQ) to develop a survey measuring the experience of beneficiaries with their qualified prescription drug coverage, a sampling strategy, and an implementation strategy. We also indicated that we will provide further information regarding this survey as it is developed.

Comment: Commenters had several suggestions and questions regarding the design and implementation of the survey, including the following: CMS and CAHPs should provide draft models of the survey instruments to the Part D plans for input prior to final draft and distribution; CAHPs/AHRQ should differentiate satisfaction with the benefit versus the service provided by the network pharmacy; if all plans are actuarially equivalent as approved by CMS, how will we differentiate consumer satisfaction; the first surveys should be conducted starting in 2006 with the results available before the fall open season; consumers must be included in the survey design process; and, surveys should be sent and the results analyzed by CMS, prior to the annual May notification to plans about whether or not their contracts will be renewed.

Response: We plan to have a public comment process in the development of the survey, and solicit input from key stakeholders. We expect that consumers will be included in the design process through focus groups, cognitive interviews and testing of the instrument. The purpose of the satisfaction survey is to provide information in a timely manner for purposes of beneficiary plan choice which occurs during the fall of the year. We are still determining the timing for survey administration. One major constraint is pilot testing of the survey cannot begin until early in 2006.

Since the purpose of the survey is to help consumers choose among the plan options, during the development process we will try our best to focus on things that may vary across plans versus satisfaction with the overall benefit. Although the plans are actuarially equivalent, there will be differences in formularies, customer service, informational materials, etc.

Comment: Additional comments focused on the fact that fully integrated MA organizations, unlike other MA organizations and PDP sponsors, own and operate their own pharmacies. As a result, survey instruments may be confusing to beneficiaries enrolled in these organizations if the instrument is designed only for network model plans. In addition, to the extent that survey instruments do not reflect satisfaction ratings with retail pharmacies under contract to network model plans, comparisons between network plans

and integrated organizations will be unlikely to result in apples-to-apples comparisons. In addition, consumer satisfaction ratings in health care are notoriously suspect to regional variation. In reporting satisfaction levels, we should attempt to adjust for these variations.

Response: We agree that making appropriate comparisons and adjustments will be essential to take into account certain factors that may impact satisfaction but are not under the control of the Part D plans. In the development work, we will be exploring what are the appropriate adjusters for this survey.

4. Electronic Prescription Program (§ 423.159)

Section 1860D–4(e) of the Act contains provisions for electronic prescription programs. The statute contains specific provisions on when voluntary initial standards may be adopted (not later than September 1, 2005), and when final standards must be published (not later than April 1, 2008) and then effective (not later than 1 year after the date of promulgation of final standards).

While we included a fairly long discussion of electronic prescribing in the proposed rule, shortly we will issue another proposed rule devoted to the standards that will be used for electronic prescribing and have reserved § 423.159(a) and § 423.159(b) of this final rule for such electronic prescribing standards. Therefore, the proposals we made for such standards are not being addressed in this final rule. Moreover, comments received in response to such proposals may be considered in the electronic prescribing-specific proposed rule. In addition, commenters who wish to provide additional comments on electronic prescribing will be permitted to do so after publication of the electronic prescribing proposed rule.

One standard we are finalizing is the requirement that Part D sponsors have the capacity to support electronic prescribing, once final standards are in effect, including any standards that are established before the drug benefit begins in 2006. We proposed such language at § 423.159(a) of the proposed rule. Since Part D sponsors will in fact have to support electronic prescribing, once standards are in place, we have modified the language in § 423.159(c) to make clear that Part D sponsors must not just have the capacity to support electronic prescribing but will actually have to support it. We received no comments on this proposal and are adopting it at § 423.159(c).

We also proposed at § 423.159(b) to allow an MA-PD plan to provide a separate or differential payment to a participating physician who prescribes covered Part D drugs in accordance with electronic prescription standards. (Note that this provision only applies to MA-PD plans and not to PDPs) Section 102(b) of the MMA makes it clear that this differential payment may occur when a participating physician prescribes drugs in accordance with an electronic prescription program that meets standards established under section 1860D–4(e) of the Act. We solicited comments on the differential payments provision described in § 423.159(b) of the proposed rule as it relates to the application of various legal authorities including ''the physician self-referral prohibition at § 1877 of the Act'' and the Federal anti-kickback provisions at section 1128B(b) of the Act. In order to facilitate electronic prescribing by a Part D sponsor, we also invited public comment on additional steps to spur adoption of electronic prescribing, overcome implementation challenges, and improve Medicare operations.

Comment: Many commenters supported the provision of a separate or differential payment to a participating physician that prescribes covered Part D drugs in accordance with electronic prescription standards.

Response: We agree that participating physicians have a substantial role in electronic prescribing and will have upfront and on-going costs of implementation. For this reason, the regulation permits an MA organization offering an MA-PD to provide a separate or differential payment to a participating physician that prescribes covered Part D drugs in accordance with electronic prescription standards, including both voluntary standards promulgated by HHS and final standards established by HHS once final standards are effective.

Comment: Many commenters also encouraged us to allow MA-PD plans to make similar incentive payments to participating pharmacies and pharmacists.

Response: We agree that pharmacies and pharmacists have a substantial role in electronic prescribing and will have upfront and on-going costs of implementation. The MMA statute provided for such incentives directly to physicians; however MA plans could in compliance with the Federal anti-kickback and Stark self-referral statutes offer incentives to pharmacies and pharmacists through individual plan contract agreements. HHS may consider this issue when developing the pilot programs.

Comment: One comment stated that differential payments should also be permissible by PDPs. While ''PDPs sponsors will not have network contracts with physicians in the way that MA organizations will, PDPs may have service contracts with physicians to provide MTMP services.'' The commenter noted that we have the authority to permit such payments under section 1860D–4(c)(1)(B) of the Act as part of a quality assurance program.

Response: We disagree. The MMA statute was specific in the use of incentives by MA-PD plans to participating physicians that prescribe covered Part D drugs in accordance with an electronic prescription program that meet the standards established under section 1860D–4(e) of the Act.

Comment: Many commenters expressed concern that separate or differential payments should not inappropriately influence physician prescribing behavior or restrict provider choice or decision making. Many also suggested that we provide guidance to plans to guarantee that such incentives do not impact prescribing judgment and that any incentives utilized in e-prescribing programs focus on rewarding improvements in patient safety and quality.

Response: We agree with the commenters that incentives must not inappropriately influence physician prescribing patterns. We will be providing guidance to plans on physician incentives.

Comment: Many commenters agreed that any differential payments provision must be in compliance with other Federal and State laws including the physician self-referral prohibition at section 1877 of the Act and the Federal anti-kickback provisions at section 1128B(b) of the Act. They urged the Secretary to consider extending the applicability of the safe harbor provisions beyond Part D programs and to include monetary and non-monetary remuneration.

Response: As outlined in the preamble in the proposed rule, we are sharing any comments regarding the anti-kickback statute with the OIG. Additionally, in response to comments we have added language at § 423.159(d) that such payments be subject to compliance with applicable Federal and State laws and regulations related to fraud and abuse.

In the proposed rule, we also sought comment on measures of MA-PD plan quality related to the use of electronic prescribing and other MA-PD quality

measures that reflect effective electronic prescribing systems.

We invited comments on the challenges and on possible Federal activities that will promote the effective use of electronic prescribing by providers, including publishing best practices, and making technical information on electronic prescribing products available. In addition, receptivity to the use of electronic prescribing by consumers is not well understood especially among the elderly and disadvantaged populations. We requested additional information on how those populations may view electronic prescribing and what steps may be taken to get them to use this modality and, thus, take advantage of the safety and quality benefits it offers.

We also invited comments on how to promote the use of electronic prescribing by providers, health plans and pharmacies and other entities involved in the provision and payment of health care to Medicare beneficiaries. Beyond the differential payments authorized in § 423.159, we invited comments on what incentives could be used to spur more widespread adoption, especially for early implementers. We also invited comments on what educational efforts or data analyses might be undertaken to help health practitioners understand, or empirically confirm, and ultimately realize, the benefits of electronic prescribing. Lastly, we sought public input on the ways electronic prescribing can further reduce costs to the Medicare program and promote quality of care to beneficiaries.

We received numerous comments in response to our requests.

Comment: HHS received universal support from all those who commented on § 423.159 regarding the establishment of electronic prescribing standards and its potential for improved quality of care through reduced medication errors, better therapeutic compliance and better process and cost efficiencies.

Response: We agree with the commenters that electronic prescribing has great potential to improve the health of Medicare beneficiaries and reduce medication errors.

Comment: Many commenters suggested that HHS should evaluate how electronic prescribing may improve patient compliance, clinical outcomes and patient safety and facilitate other electronic prescribing processes. Additionally commenters provided a variety of areas to focus educational efforts and data analyses.

Response: We agree with the commenters that MA-PD plan quality, related to electronic prescribing, must be evaluated to further promote quality of care for beneficiaries. We will take these suggested areas under consideration as we develop quality measures for MA-PD plans. Furthermore, for quality improvement purposes, we will make any plan information on electronic prescribing available to our QIOs either directly from the Part D plans or through us.

Comment: Many commenters stated that HHS should publish best practices and make technical information on electronic prescribing products available so that providers can make informed comparisons. Many agreed that these efforts will also spur effective adoption and use of electronic prescribing.

Response: HHS appreciates these thoughtful comments and will take them into consideration as we implement electronic prescribing.

Comment: A few commenters responded that electronic prescribing will result in procedural and behavioral changes by beneficiaries. They suggested that HHS work to ensure patients are aware of and comfortable with the new prescribing method and should disseminate information and educate enrollees on the changes resulting from electronic prescribing.

Response: We agree that electronic prescribing will result in procedural and behavioral changes in our beneficiaries. We will consider these suggestions as we work with the Part D sponsors on information dissemination and outreach.

Comment: One commenter stated that HHS should work with National Center for Vital and Health Statistics (NCVHS) to study the use of reduced malpractice insurance premiums as a financial incentive to promote the adoption of electronic prescribing.

Response: HHS will share this comment with the NCVHS.

Comment: Many commenters provided a variety of areas to focus educational efforts and data analyses to spur more widespread adoption.

Response: We will take these suggested areas for data analyses under consideration as we develop our educational efforts and quality improvement strategies by making such information on electronic prescribing available to our QIOs either directly from the Part D plans or through us.

Comment: Many commenters stated that developing standards for electronic prescribing will reduce costs to the Medicare program. Many commenters stated that the primary benefits of electronic prescribing are increased quality of care, reductions in the use of medical resources, and improved patient safety, specifically in the areas of reduced adverse events. Additionally, many stated that electronic prescribing improves the efficiency of processing prescriptions.

Response: We agree with the commenters that these electronic prescribing areas have great potential to reduce costs to the Medicare program.

5. Quality Improvement Organizations (QIO) Activities (§ 423.162)

Section 109 of the MMA expands the work of QIOs to include Part C and Part D. This provision explicitly covers the full range of Part C organizations. QIOs are required to offer providers, practitioners, and Part D sponsors quality improvement assistance pertaining to health care services, including those related to prescription drug therapy.

In the proposed rule, we stated the QIOs will need access to data from transactions between pharmacies and Part D plans. We offered examples of the types of data that would likely be required by QIOs and also discussed our role in potentially aggregating and distributing the data. Finally, we proposed that any information collected by the QIOs will be subject to confidentiality requirements in part 480 of our regulations. For purposes of applying these confidentiality regulations, we also proposed that Part D sponsors fall within the definition of health care facilities and that part 480 would apply in the same manner as that Part applies to institutions.

As the QIOs activities under Part D are developed within the 8th Scope of Work, and basic decisions are made about the collection, storage and use of Part D claims data, CMS will work with QIOs and Part D plans to develop a strategy to provide QIOs with data necessary to accomplish their task and safeguard patient confidentiality.

Comment: One commenter believes that PDPs may need additional data to identify enrollees to be targeted for MTMP services. They believe QIOs could provide that data to plans using information from medical claims submissions.

Response: QIOs cannot share with Part D plans beneficiary-specific identifiable data that it has acquired as part of its function as a QIO, but we could provide the data necessary to identify enrollees to be targeted for MTMP services to the Part D plans if appropriate. QIOs can provide other types of technical assistance to Part D plans.

Comment: One commenter recommends that serious evaluations be

designed to compare the effectiveness of different MTMP services, delivery, and payment methodologies. Another commenter wrote that QIOs could potentially perform a valuable role in collecting and analyzing the data to be made available to plans for use in establishing or revising their MTMP services.

Response: Once Title I has been implemented, we expect that outcome measures will be developed to allow the QIOs to assess the effectiveness of the MTMP services. We expect that both plans and pharmacies will be able to request technical assistance from QIOs to improve their MTMPs.

Comment: One commenter recommended that the last sentence of § 423.162(b) be deleted. [''PDP sponsors and MA plans offering MA-PD plans are required to provide specified information to CMS for distribution to the QIOs as well as directly to QIOs''] They support the voluntary nature in terms of whether a Part D plan must contract with a QIO. They are concerned about the submission of undefined information to CMS for passing through to QIOs as well as directly to QIOs regardless as to whether a Part D plan works with a QIO. In addition, it is unclear to which QIO such information will be provided, particularly since some drug plans may serve more than one State. Another commenter stated QIOs must have access to pharmacy and medical claims for quality improvement projects and oversight of the PDPs.

Response: We do not believe that the last sentence of § 423.162(b) must be deleted. QIOs need, and have the authority under section 1154 of the Act and section 109 of the MMA, to access specified data from the transactions between pharmacies and Part D plans providing the Part D benefit. However, the determination of what actual data, if any, that will be made available to QIOs will be made in subsequent guidance after QIOs activities under Part D are developed within the 8th Scope of Work, and basic decisions are made about the collection, storage and use of Part D claims data. We could provide specific data to QIOs to use for quality monitoring and extract these data from data already required by us for other administrative functions of the Title I program, thus not increasing the Part D plans' burden. We could also make data available to a QIO from plans that do not contract with the QIO but are directly related to the QIO's responsibilities as negotiated with us under its 8th scope of work. QIOs may also have access to additional data provided by plans working directly with a QIO.

Other QIO Activities

Comment: While PBMs have processes in place to monitor pharmacy dispensing and alert a pharmacy in cases where dispensing a medication may not be safe for a particular patient, it is critical the PBM or drug plan not be held accountable or responsible for activities that are beyond its control. Drug plans can be evaluated for having such process measures in place but should not be held accountable for problems outside their control, such as physician, pharmacist or manufacturer errors.

Response: We expect that the QIOs will work with physicians, pharmacists, and plans to improve the quality of beneficiaries' medication therapies. The QIOs' goal is to improve quality of care, not to assign blame. They can assist each of these players to design systems to facilitate the delivery of quality of care.

Comment: One commenter stated that QIOs should establish educational programs to assist drug plans and prescribers in the implementation of best practice guidelines through treatment algorithms.

Response: The QIOs' scope of work is being described in their contracts rather than in the regulation. The contracting mechanism allows flexibility to adjust the QIOs' tasks to be responsive for the need for quality improvement. The QIOs' activities will address quality improvement for both prescribers and plans.

Comment: The confidentiality of information collected by QIOs should be protected, as CMS has proposed.

Response: The QIOs will protect the confidentiality of the collected information, as specified in part 480. We have clarified § 423.162(c) in this final rule to make clear that the provisions of part 480 apply in the same manner as they apply to institutions.

Comment: There were several commenters who expressed concern regarding how QIOs will handle beneficiaries' complaints about the quality of care in Part D. The final rule in § 423.153(c) needs to state clearly that the QIOs will review quality of care complaints and lack of access complaints to requested services, as well as to clarify how this traditional QIO function will be carried out in the unique environment of Part D plans.

Response: Section 423.564(c), not § 423.153(c), states that QIOs must review enrollees' written complaints about the quality of services they have received under the Medicare program, as specified in section 1154(a)(14) of the Act. For any complaint submitted to a QIO, the Part D sponsor must cooperate with the QIO in resolving the complaint. For further discussion, please refer to the preamble to subpart M.

Comment: The final regulation should reflect the information contained in the summary of the 8th scope of work (SOW) for QIOs. The commenter added the regulation should specify that quality improvement projects will be performed by the QIO or by a third party (independent of the Part D plan) contracted by the QIO.

Response: This information is typically conveyed in the SOW of the contract between each QIO and us rather than in the regulation because a contract allows us the flexibility to modify the QIOs' activities without modifying the regulation. The contract is an effective way to ensure that these important tasks are accomplished.

Comment: Educational interventions are best done by QIOs or a third party independent of the Part D plan contracted by the QIO.

Response: QIOs will likely do educational interventions either with their own staff or with subcontractors, but we do not want to exclude other entities from also providing objective, evidence-based educational interventions.

Comment: Oversight of formulary decisions and subsequent review of Part D sponsors' formulary decisions could be key components necessary for QIO's to assess quality, especially in the dual-eligible long term care patients.

Response: We believe that decisions concerning which medications are on a plan's formulary are administrative decisions of the plan. These do not fall within the quality review functions of the QIO. The QIO will review beneficiary complaints that the plan's rules were not executed correctly. We will conduct reviews of plans' applications to ensure that formularies are not discriminatory, as well as review through program monitoring.

Comment: MA organizations delivering benefits through their owned and operated pharmacies are likely to rely on specialized pharmacy information systems that differ from the systems designed for PDP sponsors to communicate with their contract network pharmacies. As a result, it is possible that pharmacy data may be misinterpreted by a QIO. If QIOs will be using data from integrated MA organizations to assess quality, it will be important to work closely with the organizations to understand the data, or to develop more efficient methods to achieve the same result-an appropriate assessment of quality performance.

Response: We expect that QIOs will work cooperatively with plans. Because

QIOs work with identified organizations, they will have the opportunity to understand the context of the data they are analyzing.

Comment: One commenter suggests that QIOs examine the prescription drug claims submitted to the plan, specifically looking at the number of claims that are rejected and appealed.

Response: QIOs' activities focus on quality improvement. The number of claims rejected is an administrative function, and we do not expect the QIOs to be active in this area. It is likely the administrative performance of plans will be assessed by our program monitoring.

6. Treatment of Accreditation (§ 423.165, § 423.168, and § 423.171)

Section 1860D–4(j) of the Act requires that the provisions of section 1852(e)(4) of the Act relating to the treatment of accreditation will apply to Part D sponsors for:

- Access to covered Part D drugs including the pharmacy access requirements and the use of standardized technology and formulary requirements;
- Drug utilization management, Quality assurance, Medication Therapy Management, and a program to control fraud, waste and abuse as described in subpart K § 423.504(b)(4)(vi)(H);
- Confidentiality and accuracy of enrollee records.

Thus, the requirements in § 423.165, § 423.168, and § 423.171 are similar to the requirements found in § 422.156, § 422.157, and § 422.158 for the MA program, except for subject areas that are deemed.

Proposed § 423.165 provided the conditions under which a Part D sponsor may be deemed to meet our requirements permitted under paragraph (b) of that section. We stated that the first condition will be that the plan be fully accredited (and periodically reaccredited) by a private, national accreditation organization (AO) that we approve. The second condition will be that the plan be accredited using the standards that we approved for the purposes of assessing compliance with Medicare requirements.

Consistent with our approach in the MA program, in the proposed rule we proposed that we will analyze on a standard-by-standard basis whether an AO applies and enforces requirements that are no less stringent than those in part 423 for the standard at issue. We proposed that we will determine the scope of the AO's approval (and, thus, the extent to which Part D plans accredited by the organization are deemed to meet our requirements) based on a comparison of the AO's standards and its procedures for assessing compliance with our deemable requirements and our own decision-making standards. We stated that we will make those determinations on the basis of the application materials submitted by AOs seeking our approval in accordance with § 423.168. We also proposed to conduct surveys to validate the AO's enforcement on a standard-by-standard basis.

Proposed § 423.165(d) established the obligations of deemed Part D sponsors. A Part D sponsor will be required to submit to our surveys. We stated that the proposed surveys were intended to validate an AO's process and authorize the AO to release to us a copy of its most current accreditation survey, together with any information related to the survey that we may require (including corrective action plans and summaries of our unmet requirements). We stated that such activities will be part of our ongoing oversight strategy for ensuring that the AO applies and enforces its accreditation standards in a manner comparable to ours.

Proposed § 423.165(e) addressed removal of deemed status and proposed § 423.165(f) explained that we retain the authority to initiate enforcement action against any Part D sponsor that we determine, on the basis of our own survey or the results of the accreditation survey, no longer meets the Medicare requirements for which deemed status was granted. We stated that we expected the AO to have a system in place for enforcing compliance with our standards (such as sanctions for motivating correction of deficiencies), but we also stated that we could not delegate to the AO the authority to impose the intermediate sanctions established by section 1860D–12 of the Act or termination of the contract.

In the proposed rule, we acknowledged that deeming applies only to our enforcement of this regulation, and neither our enforcement of this regulation nor accreditation by an accrediting body undercuts the Office for Civil Rights enforcement of the HIPAA privacy rule.

Proposed § 423.168 discussed the three conditions for our approval of an AO if the organization applies and enforces standards for Part D sponsors that are at least as stringent as Medicare requirements and, if the organization complies with the application and reapplication procedures proposed in § 423.171.

Proposed § 423.168(c) established ongoing AO responsibilities. These responsibilities largely parallel those currently imposed upon accreditors under original Medicare. One exception was the proposed requirement that an AO notify us in writing within three days of identifying, for an accredited Part D sponsor, a deficiency that poses immediate jeopardy to the Part D sponsor's enrollees or to the general public.

Proposed § 423.168(d) established specific criteria and procedures for continuing oversight and for withdrawing approval of an AO. Oversight consists of equivalency review, validation review, and onsite observation.

In the proposed rule, we stated that we could withdraw our approval of an AO at any time if we determine that deeming based on accreditation no longer guarantees that the Part D plan meets the Medicare requirements, that failure to meet those requirements could jeopardize the health or safety of Medicare enrollees or constitute a significant hazard to the public health, or that the AO has failed to meet its obligations under § 423.165 through § 423.171.

Proposed § 423.171 addressed the procedures for approval of accreditation as a basis for deeming compliance. As mentioned, the process that we stated will be used to deem compliance with Part D requirements is virtually identical to the process that is being used for deeming compliance with fee-for-service requirements. One requirement proposed in § 423.171, and which also appeared in regulations governing MA plans at § 422.158(a)(11), but did not appear in regulations governing original Medicare, is the requirement that an AO applying for approval of deeming authority submit the name and address of each person with an ownership or control interest in the AO. We proposed that we will use this information to determine whether the AO is controlled by the organizations it accredits for the purposes of § 423.168. Section 423.171 further provided for reconsideration of adverse determinations of accreditation applications.

Comment: Several consumer groups oppose deeming because they believe it will diminish beneficiary protections. Several different types of organizations, such as pharmacy organizations, and others want to have input into the process, and asked who will be the AOs, how will they operate, and what standards will be used. They also commented that AOs will not be in place prior to the initiation of the program.

Response: Section 1860D–4(j) of Act provides for accreditation. We have

successfully administered accreditation programs in:

- Hospital settings, for example, JCAHCO;
- Home health, for example, JCAHCO, NLN; and
- Nursing homes and managed care, for example, NCQA, JCAHCO.

The advantages of AOs is that they eliminate duplication of efforts between us and AOs, since many private purchasers require AOs. Furthermore, it reduces the burden on government oversight.

AOs must demonstrate that their standards are at least as stringent as those in part 423 of our final regulations. Given that the regulations can only be finalized upon publication of this final rule, we agree with the commenters that AOs cannot be in place before the bids and contract applications for 2006 are due. Thus, at least in the first year of the program, applicants will have to determine on their own that they meet all of our standards. Once these rules are in effect, we can begin to consider applications for AOs; however, other program priorities will influence when we will be able to issue a public notice requesting applications. Currently, we do not believe that any AOs can meet our standards. Furthermore, it must be noted that in the Medicare Advantage program, it was several years before any AOs were accredited.

As to giving stakeholders a chance to comment, our regulation at § 423.168(b) provides that we publish a notice in the **Federal Register** whenever we are considering an AO's application. The public then has 30 days to comment.

We will be glad to meet with stakeholders to discuss these issues. The AOs must meet or exceed each of our standards. They can pass one or all standards, but will only be allowed to administer those standards for which they are approved.

The final rule has adopted the proposed rules on accreditation.

F. Submission of Bids and Monthly Beneficiary Premiums: Plan Approved

1. Overview

Subpart F will implement most of the provisions in sections 1860D–11 and 1860D–13 of the Act, as well as sections 1860D–12(b)(2)(on limitation on entities offering fallback plans), 1860D–15(c)(2)(on geographic adjustment of the national average monthly bid amount), 1860D–21(d) (on special rules for private fee-for-service (PFFS) plans), 1860D–21 (e)(3) (on cost contractors), and 1860D–21 (f)(3)(on PACE) of the Act. In this section we address submission, review, negotiation, and approval of bids for prescription drug plans and MA-PD plans; the calculation of the national average bid amount; and determination and collection of enrollee premiums. References to 42 CFR part 422 of our regulations are to the new MA rules. See Subpart T for additional information on PACE. Bidding is to be distinguished from the application process discussed in subpart K.

Although in this preamble we use the terminology, prescription drug plans and MA-PD plans, the regulations extend to all Part D sponsors (including PACE organizations and cost-based HMOs and CMPs) as these entities—just like PDP sponsors—will be required to submit bids for the prescription drug coverage they plan to offer. Therefore, we have changed the accompanying regulation text to use the terminology, ''Part D sponsor,'' throughout. We have also indicated in the regulation where separate rules would apply to fallback entities.

As discussed in subpart C, the statute provides a framework for the provision of subsidized prescription drug coverage. Within this framework, PDP sponsors and MA organizations have some flexibility to design coverage that is different from defined standard coverage to meet the needs of Part D-eligible Medicare beneficiaries. This framework plays a critical role in bid submissions, and the actuarial evaluation and approval of bids.

As part of our discussion we specify the actuarial equivalency tests plan sponsors will have to meet when offering coverage other than defined standard coverage. Please note that the coverage definitions are discussed in detail in subpart C of the preamble. In order to determine actuarial equivalency, plan sponsors will compare their plans to the defined standard coverage baseline to assess the various tests of actuarial equivalency that we discuss in detail in the sections below.

2. Requirements for Submission of Bids and Related Information

As provided under section 1860D–11(b) of the Act, each applicant to become a PDP sponsor or MA organization will be required to submit a bid for prescription drug coverage for each plan it intends to offer. Most bids will be expected to represent full risk plans, meaning that the prescription drug plan is not a limited risk plan or a fallback prescription drug plan, and is not asking for any modification of the statutory risk sharing arrangements. A bid from a full risk plan may be referred to as a full risk bid. PDP sponsors may choose to participate as limited risk plans, meaning that they provide basic prescription drug coverage and request a modification of risk level (as described in § 423.265(d)) in its bid submitted for the plan. A bid with a modified level of risk is referred to as a limited risk bid. This term does not include a fallback prescription drug plan. Bids will be due to us no later than the first Monday in June for each plan to be offered in the subsequent calendar year. This date stems from the requirement in section 1860D–11(b) of the Act that bid data from potential PDP sponsors be submitted at the same time and in a similar manner as the information described in section 1854(a)(6) of the Act for MA plans. Since section 1854(a)(1) of the Act requires initial data to be submitted on the first Monday of June of each year after 2004, we have also incorporated this date into our regulations. In the case of MA-PD plans, the prescription drug bid will be a component of the unified MA bid described in § 422.254(b)(1) with benefits beyond basic coverage (if any) incorporated into the supplemental benefits portion of the prescription drug benefit bid.

We are clarifying that this bid will represent the expected monthly average cost (including reasonable administrative costs) to be incurred by the plan applicant for qualified prescription drug coverage in the applicable area for a Part D eligible individual with a national average risk profile for the factors described in section 1860D 15(c)(1)(A) of the Act and in § 423.329(b)(1) of this rule. We plan to develop and publish the risk adjustment factors and identify the characteristics of an average individual no later than the date of the 45-day notice for the announcement of 2006 rates, which is February 18, 2005. Any modifications to these characteristics for subsequent years will be announced by the date of the annual 45-day notice. (For further discussion of prescription drug risk adjustment, see subpart G of this preamble.) In the August 2004 proposed rule we solicited comment on the nature of any additional information needed to prepare bids and suggestions for any other methods that the bid submission process could be structured to provide for later pricing data submission.

The costs represented in each plan bid must be those for which the plan will actually be responsible. Given the structure of qualified prescription drug coverage, these costs will not include payments made by the enrollee for deductible, coinsurance (including 100 percent coinsurance between the initial

coverage limit and the out of-pocket threshold), copayments, or payments for the difference between a plan's allowance and an out-of-network pharmacy's usual and customary charge (as discussed in § 423.124(b). It also does not include costs reimbursed by us through the reinsurance subsidy. However, we require the separate identification, calculation, and reporting of costs assumed to be reimbursed by us through reinsurance. For standard coverage, defined or actuarial equivalent, these costs will include the plan's share of costs above the deductible and up to the initial coverage limit, as well as the plan's share of costs above the annual out of pocket limit. If enhanced alternative coverage is provided, the plan costs for supplemental benefits will be distinguished from those for basic coverage. The costs attributable only to basic coverage, once approved, are known as the standardized bid amount.

In § 423.265(c) we will require that, with the exception of potential employer group waivers under section 1860D–22(b) of the Act and section 1857(i) of the Act, late enrollment penalties and low-income premium and cost sharing subsidies, the bid represents a uniform benefit package based upon a uniform level of premium and cost sharing among all beneficiaries enrolled in the plan. This means that all enrollees in a given PDP or MA-PD plan will be subject to the same cost sharing structure and will be charged the same premium for benefits the PDP sponsor or MA organization chose to offer.

We note that while benefits are required to be uniform for all enrollees under the drug benefit, this is not the case for enrollees under a prescription drug discount card program. To avoid any confusion between these related programs, we would like to make this distinction clear. Because of the limited low-income assistance under the card program, card sponsors have been permitted to negotiate lower prices for low-income members. Also, in some cases there may be reduced cost sharing sponsored by manufacturers for low-income members after the $600 in transitional assistance is used that does not apply to other card members. Under the Part D prescription drug program, however, both the negotiated prices and the benefit structure will be the same for all enrollees in a given PDP or MA PD plan. While the low-income subsidies will result in low-income beneficiaries' actual out of pocket costs being lower than for beneficiaries who do not qualify for this assistance, the benefit structure to which the subsidies apply is the same for all enrollees in a plan.

Comment: Two commenters suggested that we assist bidders by making accessible relevant drug utilization data from sources such as Tricare, PBMs, the National Association of Chain Drug Stores and current Medicare Advantage plans with drug benefits.

Response: We either does not have access to such data or does not have the authority for public release. Most of the data suggested by the commenters would be considered proprietary. There are other data sets that are being used to meet industry's requests that we share information from public data sets that could help potential drug plan bidders to better understand or estimate the eligible Medicare beneficiary population's utilization of prescription drugs. They include: 1) data for Federal retirees 65+, enrolled in the Federal Employee Health Benefit national Blue Cross Blue Shield plan; 2) data from the Medicare Current Beneficiary Survey; and 3) Medicaid Pharmacy Benefit Use and Reimbursement in 1999 Statistical Compendium. The latter is prepared from Medicaid Analytic eXtract (MAX) files for calendar year 1999. For more information, or to download these data see *http://www.cms.hhs.gov/pdps/default.asp*.

Comment: Several comments urged that bids be rejected from PDPs that are owned or financially controlled by a drug manufacturer or group of manufactures.

Response: We note the concern that many stakeholders have had over manufacturer acquisition of PBMs in the 1990's. However, the Federal Trade Commission's response by imposing restrictions on manufacturers acquiring PBMs (for example, offer open formularies, include drugs that compete with the parent company's products, etc) has generally led manufacturers to divest from PBMs, or to alter their behaviors in order to prevent antitrust enforcement actions (see Christopher Sroka's November, 2000 report ''Pharmacy benefit managers'' for the Congressional Research Service and Regina Johnson's 2002 piece ''PBMs: Ripe for regulation'' in Volume 57, Issue 2 of the Food and Drug Law Journal). Regardless of future industry activity in this area, the statute does not give us the authority to implement a ban as suggested by the commenters.

Comment: One commenter indicated that Part D plans are required to submit bids no later than the first Monday in June to be offered in the subsequent calendar year. This is not sufficient time for SPAPs that need to coordinate benefits. SPAPs will need to know by June of 2005 what plans will be qualified sponsors and operating in their States.

Response: Section 1854 of the Act amended by the MMA sets the bid submission date as no later than the first Monday of June. PDP sponsors and MA organizations with MA-PDs need the maximum amount of time to put together a bid. PDPs and MA-PDs will need to keep SPAPs informed in order to complete the bid process, so communication between these entities should not be an issue.

Comment: One commenter suggested that plans should be required to provide for coverage of services to residents of Long Term Care facilities that are required by OBRA 1987 and under OBRA 1990. They recommended that this be added to the included costs in § 423.265(b)(1) under submission of bids. The commenter went on to state that Part D plans should not be exempt from providing the same services required under Medicare Part A or Medicaid to nursing facility residents and recommended that we require plans to incorporate the costs of paying for such services into their bid submissions, and that plans state clearly how they intend to pay qualified pharmacists for providing such services.

Response: Part D plans are only obligated to pay the negotiated price for covered part D drugs, which consists of the ingredient cost of the drug and a ''dispensing fee'' and that take into account any discounts, direct or indirect subsidies, rebates or other price concessions received by the Part D plan). The fee will include only those activities related to the transfer of possession of the covered Part D drug from the pharmacy to the beneficiary, including charges associated with mixing drugs, delivery, and overhead. The dispensing fee will not include any activities beyond the point of sale (that is, pharmacy follow-up phone calls) or any activities for entities other than the pharmacy. The dispensing fee does not include any charges associated with administering the drug once the drug has already been transferred to the beneficiary. This means that the pharmaceutical services listed under 1819(b)(4)(A)(iii) are included within the negotiated prices for covered part D drugs only if the term ''dispensing fee'' as defined in § 423.100 captures such services.

Comment: Several commenters asked for guidance regarding the costs that we view as administrative.

Response: Administrative costs are not clinical services unless part of a Medication Therapy Management Program. Administrative costs include such costs as: 1) crossover fees paid to

obtain information from other payors in order to calculate TROOP (True Out-of-Pocket); 2) Medication Therapy Management Program expenses; 3) Marketing & Sales; 4) Direct Administration (for example, customer service, billing and claims administration); 5) Indirect Administration (for example, corporate services, such as accounting operations, actuarial, legal and human resources); 6) Net Cost of Private Reinsurance (that is, reinsurance premium less projected reinsurance recoveries); 7) Medicare User Fees; 8)Uncollected Enrollee Premium; and 9) return on investment. Additional guidance on administrative costs will be given with the release of the bid submission tool. Instructions for the tool will include more detail defining administrative costs and guidance on how they are to be indicated in the bid submission.

Comment: One comment urged us to modify the timeline to permit bidders to submit a bid for approval before June 6, 2005.

Response: While bids can be submitted before the first Monday in June (June 6 in 2005), they cannot be approved before that date because they are reviewed collectively.

Comment: Several commenters urged that the bid submission process use electronic methods and be parsimonious for data requirements.

Response: We agree with the commenters that electronic methods are preferable. Accordingly, bid submitters will upload an electronic Plan Benefit Package (PBP) and bid submission pricing tool to the Health Plan Management System (HPMS). The bid is to represent the expected monthly average cost to be incurred by a plan applicant providing qualified prescription drug coverage in an applicable area for a Part D eligible beneficiary with a national average risk profile. We are cognizant of plan burden and therefore required submission data will be limited to what is absolutely necessary for us to fulfill its bid review, payment, and negotiation obligations.

Comment: One commenter asked if plans will get the rebates from manufacturers for drugs covered by SPAP wrap around.

Response: CMS does not have the authority to dictate how manufacturers pay rebates to plans. However, we would expect that drugs covered by secondary payers would still be subject to rebates.

3. General CMS Guidelines for Actuarial Valuation of Prescription Drug Coverage

As directed by section 1860D–11(c) of the Act, we will develop processes and methods using generally accepted actuarial principles and methodologies for determining the actuarial valuation of prescription drug coverage. Although we plan to provide additional information in the future in the form of interpretive guidance on these processes, we intend on using the following processes and methods for calculating ''actuarial valuation'' and ''actuarial equivalence'' in the context of risk bids:

- Sponsors offering standard coverage with cost-sharing variants either to the 25 percent coinsurance (before the initial coverage limit) or the greater of 5 percent coinsurance or $2 generic/preferred/$5 any other drug (after the out-of-pocket threshold is met) will be required to demonstrate the actuarial equivalence of their variations.
- Sponsors offering basic or enhanced alternative prescription drug coverage will be required to demonstrate that—
  + The actuarial value of total or gross plan coverage of their alternative is at least equal to the actuarial value of total or gross coverage of the defined standard benefit.
  + The actuarial value of unsubsidized coverage of their alternative is at least equal to the actuarial value of the unsubsidized portion of defined standard coverage; and
  + The plan payout at the dollar value of the initial coverage limit under standard coverage, for individuals whose total spending exceeds that limit, is at least equal to that provided under defined standard coverage.
- All sponsors will determine the actuarial value of the defined standard benefit, either because it is—
  + Offered to the beneficiaries;
  + Used as a comparison for either of the following:
    - Standard coverage with actuarially equivalent cost-sharing variants.
    - Alternative coverage; or
  + Used to determine the basic component in enhanced alternative coverage.
- Sponsors that offer enhanced alternative coverage will also be required to determine the actuarial value of coverage beyond basic coverage.
- We will further specify in additional guidelines the data sources, methodologies, assumptions, and other techniques in accordance with generally accepted actuarial principles as either recommended or required in further guidance. We will also specify the data elements (including format) to be sent to us for evaluation. We will then evaluate the analysis and assumptions for compliance and reasonableness. For example, we will evaluate the source, size, and timeframe of data on which assumptions are based, the demographic characteristics of enrollees, the distribution of risk levels, the average costs in each cost-sharing tier, and the update factors used, among other considerations.
- We will also require the separate identification of administrative costs. Since the level of the bid will directly affect the premium paid by the beneficiary and the attractiveness of the plan, we expect that plans will have a strong incentive to keep administrative costs and return on investment at reasonable levels. Any review of administrative costs will likely focus primarily on outliers from the competitive range identified in the bids received. All proposals will contain a description of how certain costs are included in the calculations. Processes and methods for determining actuarial valuation will take into account the effect that providing actuarially equivalent standard coverage or alternative prescription drug coverage (rather than defined standard coverage) has on drug utilization. This includes utilization effects attributable to different benefit structures, such as from tiered cost sharing, as well as those attributable to supplemental benefits. The utilization effect of supplemental benefits on basic benefits will have to be loaded into the supplemental portion of the bid. In other words, since the existence of supplemental coverage will increase total average per capita spending, that increase over the average spending (if coverage were limited to basic coverage) will be included in the portion of the bid attributable to supplemental coverage. Section 1860D–11(c)(1)(D) of the Act specifies ''the use of generally accepted actuarial principles and methodologies.'' We are interpreting this to require that a qualified actuary certify the plan's actuarial valuation (which may be prepared by others under his or her direction or review). Actuarial certification will give better assurance that the actuarial values in the bid were prepared in conformance with actuarial standards and methodologies.
- Section 1860D–11(c)(3)(B) of the Act specifies that PDP sponsors or MA organizations offering MA-PD plans may use qualified independent actuaries in certifying the actuarial values in their bids. (The actuarial valuation may be prepared by others under the direction or review of a qualified actuary). We interpret this provision as requiring PDP sponsors and MA organizations that do

not employ qualified actuaries, to use outside actuaries in their processes. We proposed in the August proposed rule to specify that a qualified actuary is an individual who is a member of the American Academy of Actuaries because members of the Academy must meet not only educational and experience requirements, but also a code of professional conduct and standards of practice. These standards create a common ground for actuarial analysis. Furthermore, a member of the Academy is subject to its disciplinary action for violations of the code and standards. This same requirement is specified in the SCHIP legislation at section 2103(c)(4)(A) of the Act. Moreover, the National Association of Insurance Commissioners (NAIC) imposes significantly stricter requirements on actuaries preparing the financial statements of insurance companies.

Comment: Several commenters asked for flexibility in the actuarial standards. One commenter specifically asked for flexibility in the use of methods and actuarial assumptions by permitting the use of internal data or normative claims databases.

Response: Section 1860D–11(c)(1) of the Act instructs the Secretary to ''establish processes and methods for determining the actuarial valuation of prescription drug coverage including.the use of generally accepted actuarial principles and methodologies''. To the extent it is possible under this paradigm to be flexible, we will be. Use of internal data or normative claims databases is not only acceptable, but encouraged. We will however, review the assumptions and results of your analysis for reasonableness and appropriateness.

Comment: One commenter asserted that being a member of the American Academy of Actuaries should be a requirement, but should not be sufficient by itself.

Response: Our policy position is to require that an actuary have the skills and experience to perform the actuarial certification required. Accordingly, in § 423.265(c)(3) we state that a ''qualified actuary must certify the plan's actuarial valuation, and must be a member of the American Academy of Actuaries to be deemed qualified.'' By requiring membership in the American Academy of Actuaries we are both requiring a minimal standard, and providing an additional assurance that the actuary will be qualified. For the latter comment, the Code of Professional Conduct for Actuaries states ''an Actuary shall perform Actuarial Services only when the Actuary is qualified to do so on the basis of basic and continuing education and experience.''

Comment: Two commenters expressed that there could be problems with the proposal that the costs associated with any increased utilization in the Part D basic benefit arising from enhanced alternative coverage would be included in the supplemental benefit portion of the bid. They assert that the application of this policy as it applies to the Part D program could be problematic because in many instances an enrollee will have supplemental coverage arising from another source that would not be part of enhanced alternative coverage of the sponsor or organization. One commenter gave the example of a beneficiary who may elect basic prescription drug coverage under a PDP or MA-PD plan and may also receive coverage under an employer/union group plan that wraps around the Part D benefit. They argue that in this case, if no supplemental benefits were included in the MA-PD plan or PDP, there would be no way to take into account in the bid the impact of any increased utilization unless it can be reflected in the bid for the basic benefit. This problem could be greater for special needs plans serving dually eligible beneficiaries who are eligible for substantial subsidies under the Part D program. In this instance, if no supplemental benefits are included in the MA-PD or PDP plan, the only avenue for taking increased utilization the may result from the subsidy into account would be the bid for the basic benefit. However, this could result in a bid above the benchmark that would produce a premium higher than the low-income premium subsidy resulting in an increase in the premium obligation for dual eligible enrollees. This situation could threaten the viability of a special needs plan.

Response: Plan bids will take into account the anticipated impact of induced utilization due to the structure of the plan benefit, other insurance coverage, and the low income subsidy. The impact of induced utilization will be addressed directly in the bid for enhanced alternative coverage. Note that this is for Part D only and is different from what is discussed for Part C in the Title II regulation. There are three major mechanisms for adjusting payment to account for the utilization of the actual enrolled population in any given plan, these are risk adjustment, reinsurance, and risk corridors. One intention of risk adjustment is to take into account the utilization of dual eligibles and adjust payment appropriately for the level of utilization in this population. For all bids, the anticipated impact of other insurance coverage on the bid and its effect on reinsurance will be taken into account. Risk corridors will serve to decrease the exposure of plans where allowed costs exceed plan payments for the basic Part D benefit.

4. Determining Actuarial Equivalency for Variants of Standard Coverage and for Alternative Coverage.

When considering the specific requirements for actuarial equivalence and valuation in the Act, we are aware that there is no official definition of actuarial equivalence. Moreover, the concept of actuarial equivalence is applied in multiple contexts. We must address actuarial equivalence requirements regarding cost sharing, expected benefits, and bid submissions. Thus, we are using interpretive guidance to further explain the process and methodology for determining actuarial equivalence and valuation. The processes and methods for determining actuarial equivalence and valuation would be in keeping with generally accepted actuarial principles. We would require prospective PDP sponsors and MA organizations wishing to offer MA-PD plans to include all of the requirements discussed in the following sections in the information submitted with the bid, when applicable. The MMA contains some specific requirements for actuarial equivalence or valuation. These actuarial equivalence tests are discussed below.

a. Actuarial Equivalence as Applied to Actuarially Equivalent Standard Coverage-Cost-Sharing

As required in section 1860D–2(b)(2)(A) of the Act, standard prescription drug coverage must have ''coinsurance for costs above the annual deductible . . . and up to the initial coverage limit that is equal to 25 percent; or is actuarially equivalent . . . to an average expected payment of 25 percent of such costs.'' We interpret this to mean that sponsors would be required to demonstrate that the actuarial value of their alternative cost-sharing as a percent of the actuarial value of both cost-sharing and plan payments for claims up to the initial coverage limit is the same percentage as for 25 percent coinsurance under defined standard coverage. In calculating these percentages, sponsors would reflect the utilization impacts of the two structures, but hold constant formulary (drug list), drug pricing (except to the extent that the plan incorporated differential pricing and cost sharing based on participation

status within the plan's network), and the group whose utilization is modeled. This would allow plans to have variable co-payments or coinsurance, including tiered structures for preferred and non-preferred drugs, in the initial coverage interval as long as the actuarial equivalence test is met. As a simple example, a plan could have a tiered coinsurance benefit with coinsurance higher than 25 percent for brand name drugs and lower than 25 percent for generics. Some beneficiaries with expenses between the deductible and the initial coverage limit would be expected to pay more than 25 percent, and others to pay less, depending on their usage of brand versus generic drugs. Overall, however, the total coinsurance would have to be actuarially equivalent to an average of 25 percent for all beneficiaries with expenses in this interval, even if the total expenditures beneath the initial coverage limit ($2,250 in 2006) are lower than would be expected under defined standard coverage (due to increased use of generics, for example).

If sponsors wanted to provide a variant on defined standard cost sharing after the out-of-pocket threshold is met, an actuarial test similar to that described above for variants on the 25 percent coinsurance would apply. In this case, based on the group of individuals projected to exceed the out-of-pocket threshold, the sponsor would compute total cost sharing once the true out-of-pocket (TROOP) threshold has been met as a percentage of the sum of that cost sharing plus the comparable plan payout. This percentage would have to equal the percentage computed in the same manner using the defined standard benefit (that is, the greater of $2/$5 or 5 percent). We note that any variant in cost sharing could not lead to discrimination against certain beneficiaries, for example, by increasing the cost sharing of a drug used for a particular illness well above the cost sharing for other drugs.

b. Tests for Alternative Coverage

As required by section 1860D–2(c) of the Act, sponsors offering alternative coverage, that is, benefit structures different from standard coverage, must satisfy five tests (three of the five are actuarial equivalency tests). As discussed in subpart C, alternative coverage would include coverage actuarially equivalent to defined standard coverage (basic alternative coverage) or coverage that would include supplemental coverage (enhanced alternative coverage). All alternative coverage would have to meet all five of the coverage standards or tests discussed in section b.1–5 of this preamble. Tests one through three were established by the Congress to ensure that alternative coverage would be at least actuarially equivalent to standard coverage. Tests four and five are additional tests imposed by the Congress through section 1860D–2(c) of the Act.

(1) Test for Assuring at Least Equivalent Value of Total Coverage

As required in section 1860D–2(c)(1)(A) of the Act, a plan could offer alternative prescription drug coverage as long as the actuarial value of total or gross coverage is at least equal to total or gross coverage provided under standard coverage. Based on a typical distribution of enrollee utilization, the average plan payout (including costs reimbursed by Medicare through the reinsurance subsidy) would have to be at least equal to the sponsor's estimate of the payout under defined standard coverage (holding various factors constant as described above under section 4.a.).

Alternative benefit structures, such as a decrease in the deductible with an increase in coinsurance below the initial coverage limit, or a lower initial coverage limit with a corresponding decrease in coinsurance, or a lower initial coverage limit with a corresponding decrease in deductible, could be accommodated as basic alternative coverage as long as the actuarial value of this coverage equaled that of defined standard coverage. Alternative structures could not increase the deductible or provide less than the protection offered against high out-of-pocket expenditures described in section 1860D–2(b)(4) of the Act. To the extent that the alternative coverage exceeds the value of defined standard coverage, the plan would be offering enhanced alternative coverage, that is, alternative coverage that includes supplemental benefits (as discussed in subpart C).

(2) Test for Assuring Equivalent Unsubsidized Value of Coverage

In section 1860D–2(c)(1)(B) of Act, a plan could offer alternative coverage as long as the unsubsidized value of coverage (the value of the coverage exceeding subsidy payments) is at least equal to the sponsor's estimate of unsubsidized value under defined standard coverage (holding various factors constant as described above section 4.a.). We interpret the unsubsidized value of coverage to mean the value of the benefit attributable to the beneficiary share of the premium.

There is a basic question about how this test could be applied during the plan review and approval process. In order to determine the unsubsidized value of coverage, one would have to know the projected reinsurance payments, and the value of the direct subsidy. While the projected reinsurance payments would be known at the time of the submission (since the actuarial value of the benefit is reduced by projected reinsurance payments to produce the bid), the value of the direct subsidy would not be known (since it would require computing the national weighted average bid and bids have not yet been approved). In the face of this problem, one approach could be to remove reinsurance payments as estimated by the sponsor and to use an estimate of the direct subsidy that we would provide. For instance, in the first year we might provide the estimate used for budgeting purposes, and in subsequent years, an estimate based on prior years' actual experience updated for trend. Additional guidance will be released concerning this matter.

Comment: Two commenters suggested that we should waive the second test of actuarial equivalence because if a plan meets all of the other tests the second test would be redundant, and without knowing the true value of direct subsidy the second test would be difficult to conduct.

Response: The second actuarial equivalence test for alternative coverage ensures the equivalent unsubsidized value of coverage. As we are defining this test, the beneficiary premium for alternative coverage must be greater than or equal to the beneficiary premium for standard coverage. Since beneficiary premiums will not be determinable until after all bids have submitted and applied against the national average bid, we interpret the application of this provision to be that the total Part D bid for alternative coverage must be greater than or equal to the sponsor's bid for defined standard coverage. We note that the first test of actuarial equivalence guarantees that the total value (including reinsurance) of coverage for the basic alternative benefit must be equal to the total value of coverage of the standard benefit. The second test then precludes a basic alternative benefit structure that increases government reinsurance costs relative to define standard coverage. We note that the test imposes no additional burden beyond the first test (that is, if you constructed a bid and shown that you meet test #1, you would already have all the information available to show whether you meet test #2). Given that the program is just beginning and we have no practical experience to show that the second test adds no value beyond the first test, we see no basis for waiving this test at this time.

(3) Test for Assuring Standard Payment for Costs at Initial Coverage Limit

Under section 1860D–2(c)(1)(C) of the Act, sponsors are to determine the average payout ''for costs incurred that are equal to the initial coverage limit'' for ''an actuarially representative pattern of utilization.'' This projected payout is compared to a dollar amount that is equal to what defined standard coverage would pay for someone with costs equal to the initial coverage limit. Given the comparison, this raises the question of what represents ''an actuarially representative pattern of utilization.'' As with the other tests, we believe that it would be reasonable for plans to use either anticipated plan utilization or a typical utilization pattern based on the Medicare population. However, given the implicit comparison to payout under defined standard for someone with costs equal to the initial coverage limit, it would not be valid to include individuals with expenses below the value of the initial coverage limit. After excluding individuals with total expenses below the value of the initial coverage limit, the plan would compute the actuarial value of plan payout at the point where total expenses are equal to the initial coverage limit under standard coverage. Under this interpretation, a plan could offer alternative coverage as long as the coverage is designed to provide an actuarial value of plan payout that is equal to at least 75 percent of costs between the standard deductible and initial coverage limit ($1,500 in 2006). In other words, considering only plan enrollees with expected expenses greater than or equal to the dollar value of the standard initial coverage limit, the plan would have to demonstrate that the expected plan payout associated with expenses equal to that dollar value would be at least 75 percent of benefit costs between the deductible and initial coverage limit (75 percent of $2,000 per beneficiary in CY 2006) including taking into account their expected behavioral response to the different benefit structure. This test, combined with the prohibition on increasing the deductible under alternative coverage (described below), would ensure that the benefit below the dollar level of the standard initial coverage limit is always actuarially equivalent to standard coverage. As a result, it is not permissible to trade off benefits above the initial coverage limit for benefits below.

(4) Test for Assuring the Deductible Does not Exceed the Standard Deductible

In keeping with the requirements of section 1860D 2(c)(2) of the Act, alternative coverage could not be structured so that the deductible is any higher than what it is in standard coverage ($250 in 2006).

(5) Test for Assuring the Same Protection Against High Out of-Pocket Costs

As specified by section 1860D–2(c)(3) of the Act, any alternative coverage must provide ''the coverage'' specified for costs above the catastrophic limit in standard coverage. We interpret this to mean that both enhanced and basic alternative coverage would have to offer at least the coverage available above the catastrophic limit through defined standard coverage. We would apply this test in the same way that we do for standard coverage with a variant of cost sharing above the catastrophic limit. That is, examining the group of individuals the sponsor projects would exceed the out-of-pocket threshold, total cost sharing once TROOP has been met, as a percentage of the sum of such cost sharing plus comparable plan payout, must be less than or equal to the percentage computed using the defined standard benefit (that is, the greater of $2/$5 or 5 percent). Again, we note that any variant in cost sharing could not lead to discrimination against certain beneficiaries, for example, by increasing the cost sharing of a drug used for a particular illness well above the cost sharing for other drugs.

c. Value of Qualified Coverage

In accordance with section 1860D–11(b)(2)(B) of the Act, with the bid, each PDP sponsor and MA organization offering an MA-PD plan must submit the actuarial value of qualified coverage in the region for the Part D eligible individual with a national average risk profile for the factors described in section 1860D–15(c)(1)(A) of the Act. We interpret this to mean that the weighted average of the plan's expected risk-standardized costs will represent the plan's cost for the theoretical national average-risk Part D individual. Any increase in costs attributable to increased utilization as the result of enhanced alternative coverage must be excluded from this calculation. Any alternative coverage that does not include supplemental coverage would be, by definition, actuarially equivalent to standard coverage. Any utilization effect that supplemental coverage has on the basic benefit should be priced into the supplemental portion of the bid.

Comment: One commenter wants to ensure that they have the ability to establish flat copayments rather than the 25 percent coinsurance of the standard design. We should permit Part D providers to round flat copayments to the nearest $5 dollar level, as these are the benefit designs commonly offered in the market place.

Response: Any copayment structure must meet the test for either actuarially equivalent standard coverage or for alternative coverage. These tests are available to allow for flexibility in benefit design including use of copays rather than coinsurance. While we would anticipate that some rounding would be consistent with these tests, rounding to the nearest $5 dollar level may create too great a difference between rounded and unrounded values.

Comment: One commenter stated that the regulation text should allow for the value of any enhanced benefit design to reflect both the potential impact of utilization changes and mix shifts to less expensive drugs. Any test of benefit value should also take into account the impact of utilization management, which may increase utilization, but have a favorable impact on total costs.

Response: To the extent that a benefit design other than that of defined standard coverage will have a projected impact on the mix of drugs, this impact will be included in the pricing of that proposed design. We anticipate that utilization management will be held constant in the pricing of defined standard and the proposed design, as well as the population modeled; drug formulary; and drug pricing (except to the extent that the proposed design incorporates differential pricing and cost sharing based on participation status within the plan's network). These issues will be fully discussed in our guidance on ''processes and methods using generally accepted actuarial principles and methodologies''.

5. Information Included with the Bid

a. Bid Format

The exact format for the bid submission is detailed in separate CMS guidelines with the bid submission tool. Section 1860D–11(c)(1)(D) of the Act specifies ''the use of generally accepted actuarial principles and methodologies.'' We require that an actuary (a member of the American Academy of Actuaries) certify the actuarial valuation, which may be prepared by others under his or her direction or review. Actuarial certification would give better assurance that the actuarial values in the bid were prepared in conformance with actuarial standards and methodologies. Section 1860D 11(c)(3)(B) of the Act permits use of outside qualified independent actuaries. We expect that plans would use outside actuaries, especially if they did not have qualified in-house actuaries.

As provided in section 1860D 11(b)(3) of the Act, we have developed (see Draft PDP Bid Instructions and Pricing Tool *http://www.cms.hhs.gov/pdps/*) the bid submission format to facilitate the submission of bids for multiple regions and in all regions, and we have taken this into account in process development. This approach would need to ensure that separate bids were provided for each region in order to calculate the national average monthly bid amount and any geographic adjustment required. Our overall approach would be to increase our flexibility to develop appropriate methodologies in response to program changes, while minimizing burden, rather than codifying these processes in regulation. We believe that we would have the authority to develop these methodologies through interpretive guidance because our regulations state that sponsors provide the actuarial value of their plans in accordance with generally accepted actuarial principles and methodologies.

In most cases the information included with the bid would be sufficient for our review of the acceptability of a proposed plan based on actuarial principles and for negotiation of terms and conditions of an entity's participation in the provision of Part D benefits. However, we may require additional information during the review to support the assumptions and methods accompanying the bid. As provided in section 1860D–11(b)(2) of Act and § 423.265(d) of this rule, the information that would accompany the bid submission would, at a minimum, include the following:

- Information on the prescription drug coverage to be provided, including the structure of the benefit, including deductibles, coinsurance (including any tiers), initial (or subsequent) coverage limits at which coinsurance levels change, and out-of-pocket thresholds. This would also include the plan's formulary, utilization management techniques, and any drugs, or types of drugs, excluded from coverage, and all documents provided to beneficiaries explaining the benefit, including the Evidence of Coverage, and would be certified by an officer of the plan. We solicit comments on the best way to obtain clear information on what drugs are included in the formulary.
- The actuarial value of the qualified prescription drug coverage in the region for a beneficiary with a national average risk profile certified by a qualified actuary.
- The portion of the bid attributable to basic benefits.
- The portion of the bid attributable to supplemental benefits, if applicable.
- The actuarial basis for the portion of the bid attributable to basic coverage and to supplemental benefits, if applicable, certified by a qualified actuary.
- The assumptions regarding reinsurance subsidy payments.
- The assumptions regarding administrative expenses.
- The plan's service area and the plan's network of pharmacies serving that service area.
- (For PDP sponsors only) the level of risk assumed in the bid, including whether the sponsor requires a modification of risk level (see discussion below) and, if so, the extent of the modification. Although our procedures may subsequently seek this information, we may only review it to the extent that the initial submission of bids does not yield the statutory minimum number of full risk bidders in each region and area. Our goal in designing the bidding process will be to maximize the level of risk borne by contracting plans and to minimize the need for fallback plans; and
- Any other information that we would require.

Response to public comment

Comment: Several comments were received concerning privacy protections for information submitted during the bidding process. Two manufacturers urged adoption of the ''restriction on use of information'' standard in § 423.322(b) for bidding information. Moreover, they believe that the Trade Secrets Act (18 USC § 1905) should apply and be inserted into the regulation to cover manufacturer pricing information. Three additional comments were received suggesting that we should limit our requests concerning specific pricing and cost information. These commenters while not referring to the Trade Secrets Act, did seek protection of any information submitted. Additionally, one pharmacy benefits manager and one health insurer expressed concern that bidding information will not be protected from disclosure under the Freedom of Information Act (FOIA).

Response: We believe that information submitted with the bid that is used to pay plans (such as estimations of reinsurance or administrative costs) would be protected under § 423.322(b) and sections 1860D–15(d)(2)(B) and 1860D–15(f)(2) of the Act. These sections protect information that is submitted to us for the purposes of carrying out section 1860D–15 of the Act. Because the direct subsidy in section 1860D–15(a) of the Act is based upon the plan's standardized bid amount, we believe that the portion of the standardized bid which is used in calculating that subsidy would be protected. On the other hand, information submitted with the bid that is not used in calculating the direct subsidy (such as the structure of the formulary or the utilization management techniques to be used by the applicant) would not be protected under sections 1860D–15(d)(2)(B) and 1860D–15(f)(2) of the Act. However, bidders can always seek to protect their information under the Freedom of Information Act and label truly proprietary information ''confidential'' or ''proprietary.'' When information is so labeled, the bidder is required to explain the applicability of the FOIA exemption they are claiming. When there is a request for information that is designated by the submitter as confidential or that could reasonably be considered exempt under Exemption 4, the Department is required by its FOIA regulation at 45 C.F.R. § 5.65(d) and by Executive Order 12,600 to give the submitter notice before the information is disclosed. To determine whether the submitter's information is protected by Exemption 4, the submitter must show that- (1) disclosure of the information is likely to impair the government's ability to obtain necessary information in the future; (2) disclosure of the information is likely to cause substantial harm to the competitive position of the submitter; or (3) the records are considered valuable commodities in the marketplace which, once released through the FOIA, would result in a substantial loss of their market value. Consistent with our approach under the Part C program, we would not release information under the Part D program that would be considered proprietary in nature or that would tend to stifle the availability of discounts or rebates from pharmaceutical manufacturers negotiated by Part D plans.

Bidders may identify trade secrets and confidential business information (CBI) with their submission. However, if they have not we will give them another chance when a FOIA request has been made on their records. In this case we will notify the business submitters that we are in receipt of FOIA requests for their records. We will then provide the business submitters with instructions and ask them to identify any trade secret or CBI in order to justify our application of Exemption 4. We will then review their justifications and highlighted information against FOIA case law to see if we can support their requested redactions. Under Executive Order 12600, if the business submitters

disagree with our Exemption 4 analysis (which includes their justification) of their identified trade secret or CBI, they are provided the opportunity to seek a restraining order or injunction in Federal court prohibiting us from releasing their records under FOIA.

Comment: One commenter suggested that Pharmacy Benefit Managers be required to disclose all rebate arrangements with manufacturers.

Response: It is unclear to whom the commenter wants rebate disclosed to and in what context. The comment was made in reference to bidding and in this case information on rebates will generally be limited to the aggregate level. However, per § 423.272 more detailed information may be reviewed if necessary to ensure the reasonableness and appropriateness of the bid. Uniform requirements for detailed rebate information would unnecessarily increase the burden of the bidder. Detailed rebate information will be collected for reasons other than the bid.

b. Risk Adjustment of Supplemental Premium

The portion of the bid attributable to supplemental benefits (part of enhanced alternative coverage defined in § 423.104(g)) represents the supplemental premium for a beneficiary with a national average risk profile. The payment process provided in section 1860D–15 of the Act will only address risk adjustment of the basic portion of the bid, and there are no other provisions for risk adjusting the supplemental benefit portion of the bid. If not addressed, this would result in plans with average risk scores above 1.0 being under-compensated by enrollees for supplemental benefits, and plans with average risk scores below 1.0 being over-compensated, as illustrated below.

TABLE F–1
SUPPLEMENTAL PREMIUM RISK ADJUSTMENT

	Plan A	*Plan B*	*Plan C*
Plan Average Risk Profile	0.80	1.00	1.10
1.0 Supplemental Premium	100	100	100
Supplemental Premium if Risk-Adjusted	80	100	110
Over or (under) compensation	$20.00	$0.00	$(10.00)

Table F–1 illustrates the case of three equally efficient plans that each estimate the cost of the same supplemental benefits at $100. Plan B has an average risk profile, that is, the arithmetic average of the risk scores of all of its enrollees is equal to 1.0. Plan A and Plan C, however, have healthier and sicker than average risk pools, with enrollee risk scores averaging .80 and 1.10, respectively. Plan A only needs an average risk-adjusted premium of $80 to meet the revenue requirements of providing those supplemental benefits to its healthier enrollees, but would receive $20 more on average from enrollees if it collects the whole $100 unadjusted premium. In contrast, Plan C needs to collect $10 more than it would receive from the unadjusted (1.0) premium to fully fund the expected needs of its sicker enrollees. Consequently, we will require additional information on the projected risk profiles of projected enrollees for accurate valuation of the supplemental portion of the bid with the bid submission. We intend, through the negotiation process, to reach agreement on a supplemental premium based on the bid submission that would account for the risk profile of enrollees and, thus, meet the plan's revenue requirements. Our goal is to maintain a level playing field that would facilitate the fair competition envisioned in the MMA. Review and approval of this information is discussed in section F.3. of this preamble.

c. Modification of Risk in PDP Bids

As provided under section 1860D–11(b)(2)(E) of Act and in § 423.265(d)(4), PDP sponsors may request a modification of certain risk sharing arrangements provided under section 1860D–15(e) of the Act, thus, becoming a limited risk plan. Modification of risk could include an increase in the Federal percentage assumed in the risk corridors or a decrease in the size of the risk corridors. Any modification of risk will have to apply to all PDP plans offered by a PDP sponsor in a region.

Section 1860D–11(b)(2)(E)(i) of the Act states that modification of risk will not be available to MA-PD plans. Therefore, in discussing the possibility of including in the bid a request for a modification of risk, we include only PDP sponsors. Limited risk plans will only be accepted if the access requirements in section 1860D–3(a) of the Act could not otherwise be met through the approval of a sufficient number of full risk plans. These requirements call for at least two qualifying plans offered by different entities, one of which must be a stand-alone prescription drug plan. If other bidders meet these requirements, a bid from a limited risk plan could not be approved and might not be reviewed.

Comment: The proposed rule offers no guidance as to what we view as ''minimal risk.''

Response: While the statute allows ''limited risk'' arrangements to be accepted in order to ensure that the access requirements are met, such arrangements must provide for more than a ''de minimis'' level of risk. We would generally consider anything below 10 percent risk as ''de minimis''. Any proposal for a level of risk above the ''de minimis'' but less than the standard full risk contract will be considered if there was a need to accept a ''limited risk'' arrangement.''

Comment: One commenter suggested that we should allow PDPs who wish to enroll low income subsidy beneficiaries to apply for limited risk, but be treated as a full risk plan.

Response: While it is unclear what the commenter meant by being ''treated as a full risk plan,'' while being limited risk, full risk plans get priority and we will only approve limited risk plans when there are not a sufficient number

of full risk plans to meet the access requirements of section 1860D–3(a). Also, per section 1860D–11(f)(1), approval of a limited risk plan is conditioned on not being able to meet the access requirements but for the approval of such a limited risk plan. Thus, if there are sufficient full risk plans, we will not approve limited risk plans regardless of whether the PDP wishes to specifically enroll low income subsidy beneficiaries.

Comment: One commenter expressed confusion over how the low-income cost sharing amounts enter into the bid ''calculation'' since these amounts help to satisfy revenue needs already identified by the plans as part of the bid. The commenter went on to state that during the early years of the program it will be difficult for plans to estimate the number of low-income beneficiaries expected to enroll and the amounts that would be paid on their behalf. They requested that we recognize that these estimates are likely to be subject to error and include statement in the preamble to the final rules that a good faith standard will apply to these estimates.

Response: The commenter is correct that the low-income subsidy is not part of the bid since it represents a subsidy for enrollee cost-sharing liability rather than plan liability. We ask for PDP sponsors' or MA-PD plans' estimate of their low-income subsidy to assist us in determining an interim payment for this subsidy, which is separate from the direct and reinsurance subsidies. Their actual low-income subsidy payment will be based on the actual experience for this group. Estimates will be reviewed for reasonableness and appropriateness using ''generally accepted actuarial principles and methodologies'' as instructed by 1860D–11(c)(1)(D) of the Act.

Comment: One commenter urged that bids include information on how plans will coordinate with SPAPs for Part D wraparounds at the point of sale.

Response: Specific information elements included in the bid submission tool are not part of the regulatory text and will be released in separate additional guidance on the bidding process.

Comment: One commenter urged us to specify that bids must include information on specific drugs in each formulary tier and their corresponding co-pays, in addition to any prior authorization requirements.

Response: Specific details concerning the response fields will be released with the guidance materials accompanying the bid pricing tool and the Plan Benefit Package; however, formulary tiering structures and prior authorizations requirements will be information that we will review.

Comment: One comment stated that we should provide a sample actuarial pricing form that illustrates the type of information desired.

Response: Additional guidance on actuarial pricing will be made available in a timely manner.

6. Review and Negotiation of Bid and Approval of Plans

a. Authority to Review Bids

We will review the information filed by the PDP sponsor or MA organization in order to conduct negotiations on the terms and conditions proposed in the bid. In addition to general authority to negotiate terms and conditions of the proposed bid submitted and other terms and conditions of a proposed plan, the MMA grants use of the authority to negotiate bids and benefits ''similar to'' the statutory authority given the Office of Personnel Management (OPM) in negotiating health benefits plans under the FEHBP program. We believe that the Congress used ''similar to'' in the statute because of the differences between the two programs. For example, while the OPM authority applies to level of benefits, standard Part D drug coverage is defined. With regard to rates, in some cases the context for FEHBP negotiations is not applicable to Part D. For example, the rates for community-rated plans under FEHBP are related to the rate the entity provides to similarly sized groups, and there is no comparable concept in Part D. Arguably the degree of competition among plans, and price signaling through premium and benefits, might be significantly greater in Part D than in FEHBP. Although these differences do exist there are also similarities. OPM is concerned about trend factors used to establish the premium for experience-rated plans, and we will have similar concerns about the reasonableness of a sponsor's trend assumptions. OPM is concerned about cost-sharing changes proposed by plans, and we will have similar concerns with regard to supplemental benefits. OPM wants to maintain high member satisfaction and ensure top quality service by plans, and we will have similar interests.

Chapter 89 of title 5 USC gives OPM broad discretion to negotiate prices and levels of benefits. For example, 5 USC 8902(i) states that OPM may negotiate with carriers if it believes the rates charged do not ''reasonably and equitably'' reflect the cost of the benefits provided. In addition, OPM has broad authority to negotiate the level of benefits, including the ability to prescribe ''reasonable minimum standards for health benefits plans.'' (See 5 USC 8902(e).) Notwithstanding our broad negotiating authority and our negotiating authority ''similar to'' that of OPM, to the maximum extent feasible and consistent with the appropriate discharge of our responsibilities, we prefer to rely on competition rather than negotiation.

We note that the bid requirements will be negotiated and a denial of a contract based on a failure to come to an agreement on the bid will not be appealable under the administrative procedures for appealing a contract denial beginning with reconsideration in § 423.645. Only the application requirements, which are separate and distinct from bid negotiation, can be appealed as detailed in subpart N.

Comment: One commenter urged that we conduct a thorough review of Part D providers' estimates of reinsurance to ensure a ''level playing field.''

Response: We will review estimates of reinsurance. Per section 1860D–11(c)(1) of the Act ''an actuarial valuation of the reinsurance subsidy payments'' will be conducted. Moreover, section 1860D–11(d) and (e) require a review of the entire bid including the estimates of reinsurance. Additional detail for this review will be released in documentation supporting the bid submission process.

b. Bid and Benefit Package Review

We have the authority to negotiate in four broad areas: (1) administrative costs; (2) aggregate costs; (3) benefit structure; and, (4) plan management, if dissatisfied with some or all aspects of bid submissions. We will evaluate administrative costs for reasonableness in comparison to other bidders and in comparison to a PDP sponsor's other lines of business. We will examine aggregate costs to determine whether the revenue requirements for qualified prescription drug coverage are reasonable and equitable. We will be interested in steps that the sponsor is taking to control costs, such as through various programs to encourage use of generic drugs. We will examine and discuss any proposed benefit changes. Finally, we will discuss indicators and any identified issues with regard to plan management, such as customer service.

In addition to the negotiation process, we will ensure that bids and plan designs meet statutory and regulatory requirements. In general, we will examine bids to determine whether the bid meets the standard of providing qualified prescription drug coverage, as described in § 423.104(b) of this rule and in subpart C of this preamble. We will examine the actuarial analysis accompanying the bid to ensure that it

has been prepared in accordance with our actuarial guidelines and properly certified. We will examine bids to determine whether the revenue requirements for qualified prescription drug coverage are accurate and reasonable, and that the requirements relating to actuarial determinations are met. We note that section 1860D–11(e)(2)(c) of the Act requires that the portion of the bid attributable to basic prescription drug coverage must be supported by the actuarial basis and reasonably and equitably reflect revenue requirements for benefits provided under the plan, less the sum of the actuarial value of reinsurance payments. We will also review the structure of premiums, deductibles, copayments, and coinsurance charged to beneficiaries and other features of the benefit plan design to ensure that it is not discriminatory. We will review cost sharing both above and below the out-of-pocket threshold with regard to its impact on groups of beneficiaries. We will also look to see that there is no differential impact on groups of beneficiaries by geographical location within the plan's region or service area attributable to different levels of cost sharing between preferred and non-preferred network providers.

As required under section 1860D–11(e)(2)(D)(i) of the Act and in § 423.272(b)(2), the structure of the benefit design (including cost sharing provisions and formulary design) must not be discriminatory; that is, it must not discourage enrollment by any Part D eligible enrollee on the basis of health status, including medical condition (related to mental as well as physical illness), claims experience, receipt of health care, medical history, genetic information, evidence of insurability, and disability. In general, this means that we will review benefit plans for features that, when applied, have differential impacts on beneficiaries with particular medical conditions. Factors we will consider in determining whether a benefit structure is discriminatory include, but are not limited to: (1) the benefit design—including the initial coverage limit, the tiered cost-sharing, the use of categories and classes in a formulary, and the choice of drugs provided in each category. (For example, if the tiered cost-sharing for drugs used to treat HIV is much higher than the cost-sharing for other types of drugs, we will view this benefit structure to be discriminatory); (2) the use of any discriminatory limits such as 90-day limits or requirements for pre authorization; and (3) supplemental benefits such as supplemental coverage of drugs that will encourage a healthier population to join the PDP. As provided in section 1860D–11(e)(2)(D)(ii) of the Act, plans using formulary designs based on categories and classes that are consistent with the guidelines established by the U.S.P. as discussed in subpart C, will be recognized as satisfying the non-discrimination design related to formulary structure as it pertains to categories and classes. However, adopting the USP model categories and classes will not prohibit us from reviewing other aspects, including the use of any limits or tiers, as discussed above.

c. Approval of the Supplemental Premium

As provided under section 1860D–11(e)(2)(C)(ii) of the Act, we will determine that the portion of the bid attributable to supplemental benefits reasonably and equitably reflects the revenue requirements for that coverage under the plan. Unless the supplemental portion of the bid (which is paid by the enrollee in the form of the supplemental premium) is risk adjusted for the average level of risk among enrollees, plans with average risk scores above or below 1.0 will be over compensated or under compensated by enrollees for supplemental benefits. Therefore, on the basis of this authority, we will require additional information, consisting of estimates of the projected risk scores of the plan's enrollees in the subsequent year, to be submitted by each plan for purposes of negotiating the appropriate risk adjustment of the supplemental portion of the bid. We will review and negotiate that information, and will approve a uniform supplemental premium reflecting the average risk factor for the plan's expected enrollment.

d. Rebate Reallocation for MA-PD plans

The negotiation process for MA-PD plans could include the resubmission of modified benefit structures (other than changes in that portion of their supplemental benefits related to drugs) once we know the outcome of the national average monthly bid calculation and its impact on beneficiary premiums. Part D drug benefits, including benefits offered through supplemental Part D coverage) could not be changed during this process because any changes will have an impact on government reinsurance payments and, therefore, on the portion of the bid related to basic drug benefits. The MMA requires that all MA bid and benefit package submissions be provided to us no later than the first Monday in June. In the prescription drug program enrollee premiums must be based on a percentage of the national average monthly bid amount that can only be calculated once all bids have been received, if not actually approved. (While the enrollment weights are determined from the previous year's reference month, the bid amounts are not.) Therefore, the prescription drug portion of benefit packages submitted by MA-PD plans will be based on estimates of monthly beneficiary premiums. Some of these MA-PD plans will have allocated portions of their Part C rebates to buy-down of the Part D premium. Once the final national average monthly bid amount and the base beneficiary premium have been calculated, some of these rebate allocations in the bids could be either excessive or insufficient to achieve the desired premium level.

Excessive rebate allocation will result in a portion of the rebate that is not provided to the beneficiary as required by law, since a premium of less than zero is not permitted. Compliance with the statute will require a reallocation of the excessive portion of the rebate credit back to other allowed uses of the Part C rebate, that is, to supplemental benefits (including reduced cost sharing other than cost sharing for Part D drugs) or to credits to the Part B or supplemental premiums. On the other hand, insufficient rebate allocation may result in minimal premiums that may be seen as burdensome by plans, enrollees, and the financial institutions managing electronic funds transfer.

The statute does not address this situation, but section 1860D–11 of the Act does grant us broad authority to negotiate the terms and conditions of the proposed bids and benefit plans. Our regulatory approach will be to allow the negotiation process for MA-PD plans to include the resubmission of modified benefit structures once the outcome of the premium finalization process is known. MA PD plans will be able to redistribute their Part C rebates to correct for the difference between the projected and final national average monthly bid amounts and to achieve the previously proposed level of Part D premiums. Under no circumstances could plans submit modified bids.

For example, an MA-PD organization submitted its bid and benefit package based on the assumption that the levels of the national average monthly bid amount and its prescription drug standardized bid will result in a $35.00 monthly beneficiary premium for basic coverage, and that it will use $35.00 of its Part C rebate to completely buy down the Part D premium. If the national average monthly bid amount is determined to be higher than expected, the plan's bid will end up below the

benchmark and its base beneficiary premium will be adjusted by subtracting the difference between the bid and national average monthly bid amount. Therefore, the plan's monthly beneficiary premium will be less than the projected premium, for instance, $34.00, and the $35.00 amount allocated from the Part C rebate for Part D premium buy-down will be excessive. In that case, we will require the MA organization to amend its benefit package to reallocate the excessive $1.00 of the Part C rebate credit to additional supplemental benefits (other than for Part D drugs) or to Part B or supplemental premium credits. These adjustments will be mandatory in order to ensure that the entire amount of the rebate was provided to the beneficiary in some form.

Under an alternative scenario, the national average monthly bid amount is determined to be lower than expected and the plan's bid ends up above the benchmark. In this case, the plan's base beneficiary premium will be adjusted by adding the difference between the bid and national average monthly bid amount. Therefore, the plan's monthly beneficiary premium will be higher than projected, for instance $36.00, and the $35.00 amount allocated from the Part C rebate for Part D premium buy-down will no longer be sufficient to eliminate the Part D premium as planned. In that case, we will allow the MA organization to amend its benefit package to reallocate an additional $1.00 of the Part C rebate credit from additional supplemental benefits (other than for Part D drugs) or from Part B or supplemental premium credits to eliminate the Part D premium. These adjustments will be optional since the Part C rebate has already been provided to the enrollee. We will not permit an MA organization to simply eliminate a minimal premium instead of reallocating the rebate because doing so will mean that the cost of providing the prescription drug benefit had been overstated. However, the MA organization could elect to charge the new increased premium and to amend its benefit package submission accordingly.

Comment: One comment suggested that we should also allow reallocation of rebate dollars to round off premiums and to support to support the availability of MA-PD plans to dual eligibles.

Response: Title II MA-PD rebate dollars (note this is to be distinguished from manufacturer rebates) could certainly be used to round off premiums (§ 422.266(b)(2)), and as stated our regulatory approach will be to have a negotiation process for MA-PD plans to include the resubmission of modified benefit structures once the outcome of the premium finalization process is known. Such a reduction in the Part D premium will, however, have to be uniform for all plan enrollees.

e. Private Sector Price Negotiation and Formulary Design

The Act envisions that most price negotiation including discounts, rebates, or other direct or indirect subsidies or remunerations will take place between PDP sponsors or MA organizations (or their subcontractors) and pharmacies and pharmaceutical manufacturers. We believe the Congress used the terms direct and indirect to be all inclusive in defining subsidies. Section 1860D–11(i) of the Act precludes us from interfering with negotiations between drug manufacturers and pharmacies, or PDP sponsors, or requiring a particular formulary or pricing structure. In other words, price negotiation with manufacturers will be conducted by the private drug benefit managers and plans that are already familiar with negotiating prices of prescription drugs on a local, regional or national basis. Moreover, we expect that providing information on discounted drug prices to beneficiaries will encourage further competition on lower prices. Because beneficiaries will choose a drug plan based on drug prices and formulary coverage, the plans have strong incentives to negotiate lower prices on drugs that beneficiaries use just as private benefit managers currently do on behalf of the Federal government, State governments, and employer and retiree plans. We expect that in addition to price levels for drugs, these negotiations will also include such terms as prohibitions on substitutions of drugs if the net result will be higher costs for patients or the plans. The nature of the negotiations that we will conduct with bidders is discussed later for full-risk and limited-risk bids, and in subpart Q of this preamble for fallback plans.

We expect that the private negotiations between PDP sponsors and drug manufacturers will achieve comparable or better savings than direct negotiation between the government and manufacturers, as well as coverage options that better reflect beneficiary preferences. This expectation reflects the strong incentives to obtain low prices and pass on the savings to beneficiaries resulting from competition, relevant price and quality information, Medicare oversight, and beneficiary assistance in choosing a drug plan that meets their needs. This is similar to the conclusion of other analyses, for example, CBO's recent statement that ''Most single-source drugs face competition from other drugs that are therapeutic alternatives. CBO believes that there is little, if any, potential savings from negotiations involving those single-source drugs. We expect that risk-bearing private plans will have strong incentives to negotiate price discounts for such drugs and that the Secretary would not be able to negotiate prices that further reduce Federal spending to a significant degree. ''In accordance with the Medicaid best price exemption provided under section 1860D–2(d)(1)(c) of the Act and codified in § 423.104(h)(2) of our rule, drug plans may even be able to negotiate better prices than those paid under Medicaid. It also reflects Medicare's recent experience with drug price regulation for currently-covered drugs, in which regulated prices for many drugs have significantly exceeded market averages.

By not allowing us to require any particular formulary, the statute ensures that the Pharmacy and Therapeutics committees of prescription drug plans and MA PD plans have the flexibility to make changes in their classifications and lists of preferred drugs based on the most current evidence-based information (subject to the limitations of § 423.120(b)). Additional CMS guidelines on formulary review will be made available. However, in summary we will evaluate plan formulary categories and classes in comparison to the model guidelines developed by U.S.P. In addition to evaluating any discriminatory features, as discussed above, we have the authority to develop minimum standards and to negotiate the terms and conditions of the bid under section 1860D–11(d) of the Act. We also have the authority to promulgate additional contract terms (section 1860D–12(b)(3)(D) of the Act). Finally, we believe the structure of the Part D benefit, as laid out in section 1860D–2 of the Act, with a requirement for catastrophic coverage, anticipates a structure where beneficiaries receive coverage for medically necessary drugs. Therefore, we will evaluate the number of categories in formularies that do not meet the model guidelines and the choice of drugs available in those categories for meeting the needs of the Medicare population. After the initial year of the program, we will also review the history of plan formulary appeals to identify issues with the plan's formulary. We will conduct additional research on evaluating formularies and drug benefit designs and we would welcome comments on evaluation. As noted previously, we may also review plan cost sharing (that is, tiers). Our

formulary review will follow four important principles:

1. Rely On Existing Best Practices: Our review will rely on widely recognized best practices for existing drug benefits serving millions of seniors and people with disabilities to ensure non-discriminating, appropriate access;

2. Provide Access to Medically Necessary Drugs: We will require that drug plans provide access to medically necessary treatments for all and do not discriminate against any particular types of beneficiaries based on their expected drug costs;

3. Flexibility: We will allow plans to be flexible in their benefit designs to promote real beneficiary choice while protecting beneficiaries from discrimination; and

4. Administrative Efficiency: We will set up a process to conduct effective reviews of plan offerings within a compressed period of time.

Comment: Several comments were made regarding formulary structures that are likely to substantially discourage enrollment, with the majority merely expressing support for our regulatory text. Ten comments were received expressing concern over the definition of ''substantially discourage'', three of which called for dropping the word ''substantially'' from the regulation. One commenter specifically argued that step therapy for psychopharmacology should be considered as substantially discouraging. Another commenter simply stated that step therapy should be reviewed for discriminatory impact.

Response: The term ''substantially'' comes directly from the statute in section 1860D–11(e)(2)(D)(i) of the Act and therefore we do not believe it should be eliminated as some commenters recommended. According to research conducted for the Agency by Booz Allen Hamilton (''Drug Utilization Management and Quality Assurance Best Practices and Standards''), step therapy is one method of benefit design currently used by industry for the purpose of managing costs by requiring more cost effective drugs to be used before more expensive options are prescribed. Other research indicated the widespread use of this technique. For example, in its June 2004 ''Drug Trend Report,'' Express Scripts, a large pharmacy benefits manager, stated that the use of step therapy had risen from 4.5 million to 9.8 million lives between 2002 and 2004 for their members. Moreover, they report that step therapy with psychotropics, in particular antidepressants, is common among these members. Step therapy is also common among State Medicaid programs. Indeed, a 2003 report by the Georgetown University Health Policy Institute on behalf of the Kaiser Commission on Medicaid and the Uninsured found that 28 Medicaid agencies in 2003 used step therapy in their drug programs. The review process will examine the use of step therapy as a utilization control, but a categorical ban would be inconsistent with Congressional intent in Section 1860D–4(c)(1(A) of the Act, which calls on PDPs to have ''a cost-effective drug utilization management program, including incentives to reduce costs when medically appropriate.'' As we have outlined, step therapy is one common method of drug utilization management. The Congress was aware that utilization management included step therapy, and they were also aware of that some stakeholders have objections to it as evidenced by the testimony given during the Subcommittee on Health of the Committee on Energy and Commerce hearing ''Designing a Twenty-First Century Medicare Prescription Drug Benefit'' on April 8, 2003. We will review step therapy and other formulary structures to ensure that they are not substantially discouraging. Accordingly, we will rigorously review formularies in a number of ways as part of the bid negotiation process. This review will include, but not be limited to: (1) reviewing the classes and categories in relation to the USP model; (2) reviewing the formulary to make sure that all appropriate treatments are available for certain complex diseases such as HIV; (3) where possible and appropriate, comparing the formularies and utilization management programs (including step therapies) to applicable treatment guidelines to make sure they support current treatment standards; and (4) comparing formularies between plans to identify outlier practices, which will include comparing plans for amount and specific drugs that they are including in step therapy, quantity limits and prior authorization.

Comment: One commenter indicated concern that SPAPs will incur significant costs if PDP sponsors' formularies are inadequate. We should establish a formulary evaluation criterion that would trigger a detailed evaluation of the adequacy for the formulary.

Response: Formularies will be evaluated according to the provisions of the statute. Regardless of the impact of specific plan formularies, we have estimated that Part D will save SPAPs approximately $3 billion between 2006—2010 (see the regulatory impact statement for more detail).

f. Bid Level Negotiation

The FEHBP standard in 5 USC 8902(i) requires us to ascertain that the bid ''reasonably and equitably reflects the costs of benefits provided.'' In addition, we note that section 1860D–11(e)(2)(c) of the Act requires that the portion of the bid attributable to basic prescription drug coverage must ''reasonably and equitably'' reflect revenue requirements . . . for benefits provided under that plan, less the sum ... of the actuarial value of reinsurance payments.'' Analogous to the manner in which FEHBP views its management responsibilities, we see this requirement as imposing the fiduciary responsibility to evaluate the appropriateness of the overall bid amount.

In general, we will evaluate the reasonableness of bids submitted by at-risk plans by means of the actuarial valuation analysis. This would require evaluating the plan's assumptions regarding the expected distribution of costs, including average utilization and cost by drug coverage tier, for example, in the case of standard coverage: (1) those with no claims; (2) those with claims up to deductible; (3) those with claims between the deductible and the initial coverage limit; (4) those with claims between the initial coverage limit and the catastrophic limit; and (5) those with claims in excess of the catastrophic limit. We could test these assumptions for reasonableness through actuarial analysis and comparison to industry standards and other comparable bids. Bid negotiation could take the form of negotiating changes upward or downward in the utilization and cost per script assumptions underlying the bid's actuarial basis.

Arguably, appropriate assurance that plan bids reasonably and equitably reflect the revenue requirements associated with providing the Part D benefit requires knowing the final drug price levels the plans are paying that are implicit in their bids. Consequently, in addition to looking at final aggregate prices, if we found that a plan's data differed significantly from its peers without any indication as to the factors accounting for this result, we could also ask bidders to provide information about rebates and discounts they are receiving from manufacturers and others, in order to ensure that they are negotiating as vigorously as possible. Section 1860D 11(b)(1)(C) of the Act allows us to ask for necessary ''information on the bid''. In other words, we will be able to inquire as to the ''net cost'' of drugs since this is the key dollar value we will need to make accurate ''apples to apples'' comparisons on drug prices between

PDPs. Under this approach, if the particular bids appear to be unusually high (or low), we could go back to the bidders and request that they explain their pricing structure, the nature of their arrangements with manufacturers, and we might ask further questions and take further action to perform due diligence to ensure that there is no conflict of interest leading to higher bids. For instance, we will look at certain indicators, such as unit costs or growth rates in the bid amounts to see if they are in keeping with private market experience to the extent feasible for a comparable population (for example, retirees). (In this case, we will be using the authority in 5 USC section 8902(i) to negotiate bids that are ''consistent with the group health benefit plans issued to large employers''.) If the overall bids were unjustifiably high, we will have the authority to negotiate the bids down to a level that is more in keeping with bids from other sponsors. We could exercise our authority to deny a bid if we do not believe that the bid and its underlying drug prices reflect market rates. Our strong expectation, however, is that we will be able to rely on the incentives provided by competitive bidding, and we will use our authority under this part only on the rare occasion we find that a plan's data differs significantly from its peers without any indication as to the factors accounting for this result.

Comment: Several comments were received on the MMA provision of ''authority similar to the authority of the Director of the Office of Personnel Management'' for the Federal Employee Health Benefits Program (FEHBP) when negotiating bids for Part D. One commenter referenced that in the preamble of the proposed rule, we stated that we were considering regulations similar to those used by Office of Personnel Management (OPM) in 48 CFR Chapter 16, which they note is comprised of 24 distinct parts and due to the lack of clarity with regard to the provisions of the OPM regulations were referring to they would be unable to comment. One health insurer asked that we clarify how our intended oversight would differ from the Similarly Sized Subscriber Groups (SSSGs) requirements in the FEHBP. Another commenter asserted that OPM negotiates an annual dollar cap on administrative expenditures that can be funded through premiums and that similar negotiations with MA plans would not be appropriate given that the MMA works on a competitive model. Two commenters suggested that broad use of the OPM authority would violate the noninterference clause in the MMA and that we should not review every plan during the bidding process in detail on pricing structure and the nature of arrangements with manufacturers. One commenter agreed with the Agency's interpretation of this authority in the proposed rule noting that nothing in our interpretation would ''set the price for any individual drug or even plans if aggregate price levels for groups of drugs were higher than prices observed among peer plans''.

Response: The section 1860D–11(d)(2)(B) of the Act authority will be used to review bids and negotiate changes consistent with the statute and regulation. Specifically, we intend to evaluate the reasonableness and appropriateness of the actuarial assumptions made in the bid. We will examine bids to determine whether the revenue requirements for qualified prescription drug coverage are accurate and reasonable. We also will examine administrative costs for reasonableness. We will review profit for reasonableness and appropriateness. We also will review the structure of the benefit plan design in terms of such features as premiums, deductibles, co-payments, and coinsurance charged to beneficiaries to ensure that it is not discriminatory.

There appears to have been confusion caused by our request for comments on 48 CFR Chapter 16. These OPM regulations assume applicability of the Federal Acquisition Regulation, which is not applicable to at-risk or limited risk Part D plans. Therefore we are not adopting any of the OPM regulations at this time. We will note however that our negotiating authority ''similar to the authority...of the Office of Personnel Management'' (section 1860D–11(d)(2)(B) of the Act) is in addition to our general authority to ''negotiate the terms and conditions of the proposed bid submitted and other terms and conditions of a proposed plan'' (Section 1860D–11(d)(2)A) of the Act). We have clarified the regulations to reflect these two separate authorities.

With regard to the application of a SSSG concept to Part D, we will note that the Part D program generally relies on competition to ensure reasonable bids. There is no authority to tie a sponsor's rate methodology to that used for a SSSG as applied under FEHBP with regard to community-rated plans. Therefore, we do not believe that this type of cross product line comparison will be appropriate at this time.

One comment correctly pointed out that there is no cap on administrative costs under Part C or Part D similar to the cap in effect in FEHBP experience rated plans. It is assumed that competition among plans will generally ensure reasonable bids. The Congress, however, did not leave the determination of rates entirely to market forces. We are required to determine that the reasonable and equitable test is met and is given negotiating authority to ensure this result. The initial review will focus in part on low and high cost outliers, and on bids in areas with little competition. It must be noted however, that bid outliers are not necessarily inappropriate, nor are bids within the measure of central tendency automatically correct. Indeed, an outlier bid may be reasonable and appropriate after additional review and explanation while an ''average'' bid could be based on incorrect actuarial assumptions. In summary, all bids will be reviewed for their reasonableness whether an outlier or not.

Two commenters seemed to suggest that they believe that the bid review authority will be used as a back door price control mechanism in direct violation of the non-interference provision of section 1860D–11(i) of the Act, which directs the Secretary to not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and to not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs. In the proposed rule we interpreted the non-interference provision as prohibiting us from setting the price of any particular drug or from requiring an average discount in the aggregate on any group of drugs (such as single-source brand-name drugs, multiple-source brand name drugs, or generic drugs), but allowing us to require justification of aggregate price levels. In addition, although we are prohibited from negotiating the price levels of drugs, it is authorized to negotiate the level of the overall bid. We will evaluate the reasonableness of costs submitted by at-risk plans bids through actuarial valuation analysis, and noted that this might require information regarding the plan's assumptions about expected distribution of costs, including average utilization and price by drug coverage tier, for: (1) those with no claims; (2) those with claims up to deductible; (3) those with claims between the deductible and the initial coverage limit; (4) those with claims between the initial coverage limit and the catastrophic limit and 5) those with claims in excess of the catastrophic limit. Through actuarial analysis, these assumptions will be tested for reasonableness, and compared to industry standards and other

comparable bids. We also want to clarify that we do not intend on universally requiring plans to submit detailed information on pricing structure and the nature of arrangements with manufacturers. Requests for additional and more detailed information will only be triggered questions involving the initial bid submission. We are confident that additional bid submission guidance will limit such occurrences from happening. We believe that this interpretation ensures that we fulfill our duty to review bids for reasonableness while avoiding any direct interference in the negotiations between manufacturers, pharmacies, and PDP sponsors.

Under the previous Medicare+Choice program, we permitted Medicare+Choice organizations to waive premiums or to offer mid-year benefit enhancements to their benefit packages. However, in order to maintain the integrity of the bidding process, we believe that it is no longer appropriate to allow either MA organizations or PDP sponsors to waive premiums or offer mid-year enhancements as they will be de facto adjustments to benefit packages for which bids were submitted earlier in the year.

These adjustments would be de facto acknowledgement that the revenue requirements submitted by the plan were overstated. Allowing premium waivers or mid year benefit enhancements would render the bid meaningless. Excessive amounts included in the bid will be subject to recovery by the government in the risk corridor calculations following the coverage year.

Consequently, we interpret the statutory provisions on competitive price negotiation as prohibiting us from setting a regulated price of any particular drug or imposing by regulation an average discount in the aggregate on any group of drugs (such as single-source brand-name drugs, multiple-source brand name drugs, or generic drugs), but as allowing justification of aggregate price levels for groups of drugs. In addition, we could, under the specific circumstances previously discussed, negotiate regarding the level of the overall risk bid. This approach will allow us to exercise the authority similar to FEHBP as visualized in the MMA to ensure that per capita rates charged reasonably and equitably reflect the cost of the benefits provided, and that beneficiaries receive the full benefits of vigorous price negotiation by their drug plans.

g. Approval of Plans

After negotiations on the terms and conditions of the bid, we must approve or disapprove the bid. After negotiations, we will approve a plan only if—

- The plan is found to be in compliance with requirements specified in this regulation;
- The plan meets the actuarial valuation requirements; and
- The plan design does not discourage enrollment by certain eligible beneficiaries.

In § 423.272(c), we approve limited risk plans only if fewer than two qualifying prescription drug plans offered by different entities, one of which must be offered by a stand-alone PDP sponsor, were submitted and approved in a region. We will approve only the minimum number of limited risk plans needed to meet these access requirements and will give priority to plans bearing the highest levels of risk; however, we may take into account the level of the bids submitted by these plans. Except as authorized under section 1860D–11(g) of the Act and in § 423.863 with regard to fallback plans, we will not, under any circumstances, approve a plan that elected to bear no risk or a de minimis level of risk.

Comment: One comment urged that we should reject bids that result in only one PBM operating as a subcontractor to all the plans in a given region.

Response: The statute does not give us the authority to do this. The statute mandates that beneficiaries have the choice of at least one PDP in an area in addition to whatever MA-PD options are available. The number of PBMs that contract with the PDP sponsors and MA organizations has no bearing on the access requirements.

h. Special Rules for PFFS Plans

As provided in section 1860D–21(d) of the Act, and codified in § 423.272(d), PFFS plans that offer prescription drug coverage are exempt from review and negotiation (under sections 1860D–11(d) and (e)(2)(C) of the Act) of their prescription drug bids and premium amounts but are otherwise subject to all other requirements under this part, with the following exceptions. While we will not negotiate PFFS bids, those bids must meet the actuarial valuation requirements applicable to all risk bids. These plans are not required to negotiate discounted prices for prescription drugs. If they do negotiate, the requirements under § 423.104(h) related to negotiated prices will apply. If the plan provides coverage for drugs purchased from all pharmacies, without charging additional cost sharing, and without regard to whether they are participating pharmacies, § 423.120(a) and § 423.132 of this rule (requiring certain network access standards and the disclosure of the availability of lower cost bioequivalent generic drugs) will not apply to the plan. PFFS plans are also exempt from drug utilization management program and medication therapy management program requirements.

Finally, we note that section 1860D–21(d)(7) of the Act provides that costs incurred for off-formulary drugs will not be excluded in determining whether a beneficiary has reached the out-of-pocket threshold if a PFFS plan does not use a formulary. We believe that section 1860D 21(d)(7) of the Act is a tautology and simply states that PFFS plans without formularies, by definition, cannot have non formulary drugs to exclude from the out-of-pocket threshold calculation.

7. National Average Monthly Bid Amount

In § 423.279, we outline the calculation of the national average monthly bid amount. For each year, beginning in 2006, we will compute a national average bid based on approved bids in order to calculate the national base beneficiary premium. As a practical matter, we realize that we might need to calculate and announce the national average monthly bid amount before negotiations on all bids were completed in order to allow time for finalization of premiums and benefit packages. Therefore, we anticipate that we will identify a date by which the national average monthly bid amount will be published, and we will use the bids that had passed a certain level of approval as of that date as the basis for the calculation.

As provided in section 1860D 13(a)(4)(A) of the Act, in computing the national average monthly bid amount, we will exclude bids submitted for MA private fee-for-service (PFFS) plans, specialized MA plans for special needs individuals, PACE programs under section 1894 of the Act (pursuant to section 1860D–21(f) of the Act) and reasonable cost reimbursement contracts under section 1876(h) of the Act (according to section 1860D–21(e) of the Act). The exclusion from the calculation of bids of PFFS, cost plans, specialized MA plans, and PACE suggests that they are different from, and not comparable to, the average bid in some way. We interpret this difference to be based solely on price levels because the legislation—

- Does not define any other basis for determining these bids;
- Continues to compare these bids to the national average bid amount to determine adjustments to enrollee premiums; and

- Generally, provides for payments to such plans (including risk adjustment) in the same manner as to non-excluded plan types—except that PFFS plans receive reinsurance payments according to estimates—and not actual costs and are not eligible for risk corridor payments.

Therefore, these excluded plan types will still submit bids on the same basis as all other plans, that is, the 1.0 risk prescription drug plan beneficiary, even though these bids are not included in the national average bid amount at this time.

The national average bid amount will be equal to the weighted average of the standardized bid amounts for each PDP and for each MA-PD plan described in section 1851(a)(2)(A)(1) of the Act. The national average monthly bid amount will be a weighted average, with the weights being equal to the proportion of Part D eligible individuals enrolled in each respective plan in the reference month (as defined in § 422.258(c)(1)). For calendar year (CY) 2006, we will determine the enrollment weights on the basis of assumptions that we will develop. In the August 2004 proposed rule we outlined that one possible approach would be to use the following procedure to assign weights to individual bids for PDPs and MA-PD plans for CY 2006:

- Obtain total Medicare enrollment by region, and enrollment in each (local) MA plan that offers a drug benefit by region. These enrollments will be as of a specific date, for example, March 31, 2005.
- Assign each (local) MA-PD plan in each region a weight equal to its MA enrollment.
- Subtract the MA enrollment from the total Medicare enrollment for each region to arrive at the PDP-eligible enrollment.
- Divide the PDP-eligible enrollment for each region by the number of companies offering PDPs in each region to arrive at the weight for each company in each region.
- For each company in a region, divide the company weight by the number of plans offered by that company to arrive at the PDP weight.
- The regional average monthly bid amount will be calculated by weighting each plan's bid by its assigned weight.
- The national average monthly bid amount will be calculated by weighting each regional average monthly bid amount by the region's proportion of Part D eligible individuals (Medicare enrollment) and summing these products.

Using this methodology, after subtracting MA enrollments, each company offering PDP(s) in a region gets equal weight. An exception might occur based on capacity limits indicated by MA-PD plans. This assumes that beneficiaries will select a company, and then select a plan from that company. It also dilutes the effect of any potential artificially high bids designed solely to increase the national average monthly bid amount. If a company offers multiple plans in a region, each plan gets an equal allocated share of its company's assigned weight.

New MA-PDs will get a zero weight. This treatment is consistent with the weight assignment specified in the statute for subsequent years. Starting with the second year, all new plans will get zero weight because they have no prior year enrollment. We request comments on the ''unequal'' inclusion of plans in the calculation of the national average monthly bid. We note that many MA PDs will operate in small geographic areas with small potential enrollment, and so we believe that the impact of this approach for new local MA-PDs is likely limited. We recognize, however, that this approach is perhaps more problematic related to the treatment of the new regional MA-PD plans, as these plans in a given region are likely to have larger enrollment than local MA-PD plans. This particular approach implicitly assigns persons in new MA PD plans (both local and regional) to the PDP weights, hence giving potentially too much weight to the PDPs.

Alternatively, assigning equal weights to PDPs and new MA PD plans (even if limited to just the regional MA-PDs) could likely assign too much weight to the new regional MA PD plans, which at least in 2006 are expected to have lower enrollment. Another possible alternative would be to base weights on regional MA-PD plan projections of enrollment, subject to our assessment of reasonableness of the estimates. In this approach we would use the proportion of projected enrollment for each plan as weights. However, particularly in the first year or so, projections may be quite inaccurate, leading to a distorted and unrepresentative benchmark. In the proposed rule we requested comments on these and other alternative approaches for how to weight bids in 2006.

Note that in this methodology the assigned weights are price inelastic, that is, the recommended weight assignment methodology implies that price is not a factor in plan selection. We recognize that in reality this is not the case, but in the absence of data on which to base the relationship between price and plan choice in this population for this benefit we cannot model the effect of price variations on demand. We believe that the fairest method that is feasible for 2006 is simply to assume an equal weight for each plan.

In subsequent years, the weights for the weighted average would be calculated as a percentage with the numerator equal to the number of Part D eligible individuals enrolled in the plan in the reference month and the denominator equal to the total number of Part D eligible individuals enrolled in all plans (except for those plans whose bids are not include in the national average bid amount, as described above) in the reference month. It represents the proportion of the Part D eligible enrolled individuals in the plan. We would multiply the portion of each plan bid attributable to basic benefits by its proportion of total Part D enrolled individuals and sum each product to arrive at the national average monthly bid. In § 423.279(c), we would also establish an appropriate methodology for adjusting the national average monthly bid amount to take into account any significant differences in prices for covered Part D drugs among PDP regions. As part of carrying out the Congress' requirement that our geographic adjustment methodology be ''appropriate,'' we believe the method would first require gathering data from PDPs and MA-PDs on regional drug prices. Therefore, we may not implement a geographic adjuster for the first few years of the program unless we have acquired sufficient information on pricing to accurately characterize that variation. If we were to determine that there is significant geographic variation in prices, we anticipate that we would announce the adjustment factors in advance of the bidding process for any year in which geographic adjustment would be applied to bids in the calculation. This would be subject to notice and comment like any other change in payment methodology and therefore would be announced in the 45-day notice in advance of the bidding process for that year. If we were to determine that there is only minimal price variation, we would not implement a geographic adjuster for the national average monthly bid calculation. Additionally, we would implement any geographic adjuster in a budget neutral manner to avoid a change in aggregate payments from the total amount that would have been paid if we had not applied an adjustment.

Comment: We received five comments on the proposed weighting methodology for the first year. One health insurer suggested that any of the CMS proposals would be acceptable. Another

commenter focused on the PDP portion of the first approach, supporting the equal weighting of PDP sponsors. Another health insurer urged that all MA plans be counted, reasoning that virtually all MA plans would offer Part D. They also stated their support for giving no weight to new MA-PDs. An industry association suggested that new MA plans, including regional PPOs and PDPs, should be weighted based on their projected enrollment as suggested in the final alternative proposed in the proposed rule. Another health insurer urged that we assign MA-PD weights based on projected enrollment, but they did not comment on weighting for PDPs.

Response: Although none of the approaches outlined in the proposed rule, or by commenters, are perfect we have decided that using MA enrollment from a reference month for MA-PDs (new MA-PDs are assigned a zero weight) and assigning equal weighting to each sponsor (other than fallback entities) for the PDP-eligible enrollment in the region is the superior choice. This option most closely mimics how the enrollment weighting will be calculated in the future given that it uses reference month data for MA-PDs and assigns new MA-PDs a zero weight. The PDP portion of the method is the fairest method for 2006, given that we cannot know enrollment prior to the launch of the drug benefit program. Alternative weighting methodologies using projected enrollment are fraught with problems. How would the validity of such projections be assessed? What if the aggregate plan projections exceeded the total number of Part D eligibles in the region? No commenter offered any suggestions for dealing with such dilemmas. We note these comments suggested the need to clarify that the weighted average does not work unless restricted to Part D plans that submit bids and are included in the national average bid amount. Accordingly, we modified § 423.279 to clarify that the denominator does not include Part D eligible individuals enrolled in fallbacks, MA private fee-for-service plans, specialized MA plans for special needs individuals, PACE programs under section 1894 of the Act, and contracts under reasonable cost reimbursement contracts under section 1876(h) of the Act.

Comment: One commenter believes that MA-PDs would consistently have lower bids and including them in the benchmark would disadvantage PDPs. They suggest that MA-PDs and PDPs have separate benchmarks.

Response: Section 1860D–13(a)(4)(A) of the Act instructs the Secretary to ''compute a national average monthly bid amount equal to the average of the standardized bid amounts (as defined in paragraph (5)) for each prescription drug plan and for each MA-PD plan described in section 1851(a)(2)(A)(i) of the Act.'' Therefore we cannot have separate benchmarks for MA-PDs and PDPs.

Comment: One commenter stated that we should calculate a unique benchmark for Specialized Needs Plans in recognition of the higher prescription drug costs these plans will have in providing coverage to the high-risk population that they serve.

Response: In § 423.279(a) we state that bids from specialized MA plans for special needs individuals will not be included in the national average monthly bid amount or benchmark. However, the payments to the special needs plans as with all plans will be risk adjusted to take into account the differences in enrolled populations.

Comment: Several comments were received concerning geographic adjustment. Three health insurers urged that geographic adjustment be implemented immediately. Another health insurer suggested that geographic adjustment not be implemented until we have acquired sufficient information on pricing to accurately characterize any variation. One commenter urged us to explore other unit price data beyond the Federal Employee Health Benefits Program data from Blue Cross Blue Shield because using a single data source may misstate actual regional variations. One health insurer urged that adjustments be made both within and between regions. Another health insurer asked that regional variations in prescription drug costs be examined based on utilization, not price.

Response: Section 1860D–15(c)(2)(A) of the Act directs the Secretary to establish an appropriate methodology for adjusting the national average monthly bid amount (computed under section 1860D–13(a)(4) of the Act) to take into account differences in prices for covered Part D drugs among PDP regions.'' To meet the appropriateness standard we will not implement a geographic adjustment until we have acquired sufficient information on pricing to accurately characterize any variation. We reiterate that we will announce the adjustment factors in advance of the bidding process for any year in which geographic adjustment would be applied to bids in the calculation. We would also note that our authority for geographic adjustment is based on differences in price not utilization. Section 107(a) of the MMA requires a report and recommendations on adjusting for geographic differences in both price and utilization (not explained by the risk-adjuster). This report is due not later than January 1, 2009.

8. Rules Regarding Premiums

In § 423.286, the monthly beneficiary premium will be the result of the calculation of a national base beneficiary premium subject to certain adjustments. Congressional intent was to arrive at an average monthly beneficiary premium in CY 2006 representing a certain percentage of the average total estimated benefit provided by the drug plans on a national basis (including benefits subject to Federal reinsurance subsidies). Taking into account that projected reinsurance subsidies are excluded from plan bids, the applicable percentage becomes approximately 34 percent, which is applied to the national average monthly bid amount.

To determine the uniform plan premium, in § 423.286(d), we will adjust the base beneficiary premium for certain plan characteristics including whether the plan's bid will be above or below the national average bid, and whether the plan offers supplemental benefits. (Since the bid has to be approved and premiums established for the entire year, we are interpreting the phrase ''if for a month'' in section 1860D–13(a)(1)(B)(i) of the Act and 1860D–13(a)(1)(B) (ii) of the Act as referring to the beneficiary premium as a monthly amount.) The base premium is adjusted to reflect the full difference between the plan's standardized bid amount and the national average monthly bid amount (which may be adjusted for regional price differences if evidence for such differences exists as determined in § 423.279(c)). To the extent that the plan's standardized bid amount is below the national average monthly bid amount, the base premium is adjusted downward by the difference. To the extent that the plan's standardized bid amount is above the national average monthly bid amount, the base premium is adjusted upward by the difference. The base premium will also be adjusted by adding the premium amount approved after negotiations for risk adjustment of the supplemental benefits, if any (as discussed above). Table F–2 illustrates a calculation of the base beneficiary premium and the adjustment for the difference between the bid and the national average monthly bid amount.

TABLE F–2
PREMIUM ILLUSTRATION

Benchmark	Plans in Region	Bids	Beneficiary Premium		
National Average Monthly Bid Amount[1]	Plans	Approved Plan Bid	Amount by which Bid Exceeds Benchmark	Amount by which Bid is Below Benchmark	Applicable Percent of Nat'l Premium +/- Difference
	Plan 1	123	14.00	0.00	$51
109	Plan 2	109	0.00	0.00	$37
	Plan 3	99	0.00	(10.00)	$27
Est. Reinsurance Percentage			25.80	(Assumed)	
Applicable Percent =			0.3437	(25.5 /(100–25.80)	
Base Beneficiary Premium =			37.00	(109 * .3437)[2]	

[1] Assumes no geographic adjustment
[2] Rounded to nearest dollar

The sum of the base beneficiary premium, the adjustment for difference between the bid and the national average bid, and the supplemental benefit premium will be the monthly beneficiary premium. The monthly beneficiary premium (except for any supplemental premium) will be eliminated or reduced for low-income subsidy-eligible individuals, as described in section 1860D–14 of the Act and § 423.780. (This adjustment reflects the fact that the government will pay all or a portion of the monthly beneficiary premium for subsidy-eligible individuals.)

In § 423.286(d)(3), the monthly beneficiary premium will be increased for enrollees subject to the late enrollment penalty. The penalty amount for a Part D eligible individual for a continuous period of eligibility (as described in § 423.46) will be the greater of an amount that we determine is actuarially sound for each uncovered month in the same continuous period of eligibility; or 1 percent of the base beneficiary premium for each uncovered month in that period. The beneficiary premium amount is cumulative which means that each month the beneficiary is subject to a penalty, the penalty accumulates. Once the beneficiary enrolls in Part D, that accumulated penalty will be added to their premium amount each month. So for example, if the penalty amount is 1 percent of the estimated base beneficiary premium above, or $0.37 per month in 2004, and is subject to 12 months of this penalty, the beneficiary would pay an additional $0.37 * 12 or $4.44 per month for as long as they are enrolled in Part D. During the first several years of the program, we currently expect that we would specify the penalty amount would be 1 percent of the base beneficiary premium per month. Once we have sufficient data on experience under the program for individuals who enroll after their Initial Enrollment Periods, we would be able to determine the appropriate penalty amount, that is, either one percent or a greater amount to be adopted.

We note that achieving very high (indeed, virtually universal) access to prescription drug coverage for beneficiaries who participate in Part D was a key Congressional consideration in enacting MMA.

Except as provided with regard to any enrollment penalty, low-income assistance, or employer group waivers under section 1857(i) of the Act and section 1860D–22(b) of the Act and § 423.458(c) (as discussed in subpart J of the preamble to our rule), the monthly beneficiary premium for a prescription drug plan or MA-PD in a PDP region must be the same for all Part D eligible individuals enrolled in the plan. The monthly beneficiary premium charged under a fallback plan is discussed in § 423.867 of our rules and in subpart Q of this preamble.

Comment: Section 1860D–13(a)(1) of the Act establishes that the monthly beneficiary premium is the base beneficiary premium adjusted to reflect the differences between the plan's bid and the national average bid. Two commenters argued that the statute anticipated that Part D providers may bid so far below the national average bid as to have a negative premium. Both commenters assert that we were wrong to interpret in the August 2004 proposed rule that negative premiums were not allowable by statute. Both proposed that it would be a greater benefit to beneficiaries if CMS were to require a Part D provider with such a low bid ''to return the value of the savings'' to the beneficiary in the form of an enhanced benefit that would be covered by the enhanced direct subsidy.

Response: We agree with the commenters' textual interpretation of the formula in the statute. Factoring out the impact of risk adjustment, the direct subsidy in absolute dollars is uniform to all plans. For the negative premium plans, the proposed rule would have offered such plans less than everyone else. We agree with the commenters that highly efficient plans that bid below the benchmark should not receive less. However, it is clear that the statute did not necessarily envisage negative premiums for there are no clear directives on how the negative premium dollars should be treated. We believe that direct rebates to beneficiaries might run into Federal anti-kickback law issues, although a definitive opinion from the Office of Inspector General has not been issued. There are other

potential issues with a direct rebate. For example, it is likely that some significant portion of the plan enrollees will lose the rebate check or never cash it, thus resulting in an overpayment to the plan sponsor. Direct deposit of the rebate in the enrollee's bank would address this problem, but would generate significant administrative costs. Nevertheless, neither of the commenters argued for beneficiary remuneration. Indeed, both expressed a desire for the negative premium dollars to be allocated to supplemental benefits, a position we agree with. This would require allowing a ''renegotiation'' of the benefit package once the national average bid (and the negative premium) are known, to incorporate the negative premium as supplemental benefits for which there would be no additional enrollee premium. Any marginal effects in the basic bid would be negotiated at the same time. As supplemental benefits, the dollars must be accounted for in the benefit package, and there will be no risk sharing on the amount. The review and negotiation of bid and approval of plans submitted by potential PDP sponsors or MA organizations planning to offer MA-PD plans (§ 423.272) and the rules regarding premiums (§ 423.286) in this subpart have been amended to reflect this change.

9. Collection of Monthly Beneficiary Premiums

a. Means of Collection

In § 423.293(a), the beneficiary will have the same options on the method for premium payments as under Part C. Section 1860D–13(c)(1) of the Act applies the provisions of section 1854(d) of the Act (as amended by the MMA) to Part D premium collection. The beneficiary will have the option of having the amount withheld from his or her Social Security benefit check similar to the way Part B premiums are withheld. Beneficiary premium payments could also be paid directly to the PDP sponsor or MA organization through an electronic funds transfer mechanism (for example, an automatic charge of an account at a financial institution or a credit or debit card account). We could specify other means of payment, including payment by an employer or under employer-based retiree health coverage (as defined in section 1860D 22(c)(1) of the Act) on behalf of an employee or former employee (or dependent). All premium payments withheld from Social Security checks will be credited to the appropriate Trust Fund (or Account) and will be paid by us to the PDP sponsor or MA organization involved. Premiums from beneficiaries enrolled in fallback plans will not be collected by the plan. Instead, these premiums will be withheld from Social Security checks (or from other benefits as permitted under section 1840 of the Act). Beneficiaries who do not receive Social Security checks or otherwise have premiums deducted from other benefits or annuities will pay us directly. Failure to make premium payments could result in disenrollment as provided under section 1854(d)(1) of the Act and § 423.44(d) of our regulations.

b. Collection of Late Enrollment Penalties

Concerning collection of the late enrollment penalty calculated under § 423.286(d)(3), after the early years of the program we will estimate and specify the portion of the penalty that will be attributable to increased actuarial costs assumed by the PDP sponsor or MA organization (and not taken into account through risk adjustment provided under § 423.329(b)(1) or through reinsurance payments under § 423.329(c)) as a result of that late enrollment. When the premium is withheld from social security benefits, we will pay only the portion of the late enrollment penalty attributable to the increased actuarial costs to the PDP sponsor or MA organization. When the premium is paid directly to the plan, we will reduce payments otherwise made to the PDP sponsor or MA organization by an amount equal to the amount of the enrollment penalty not attributable to increased actuarial cost. (Fallback plans will not receive any enrollment penalties applicable to their enrollees because they are not at risk.)

At least in the initial years of the program we do not anticipate paying plans additional funds related to late enrollment individuals. In the initial years there will not be a significant number of people who can have delayed enrollment for a significant period of time. Moreover, in the initial years of the program the risk corridors are more generous and afford more protection. Consequently we do not think it is necessary to provide a portion of the enrollment penalty to plans until experience indicates that actual risk has increased.

Comment: Several States urged that § 423.293(a) include State Pharmacy Assistance Programs (SPAPs) as a payment option for premiums.

Response: Section 423.293(a) references paragraph (c) of the section, which in turn references § 422.262(f)(1). Beneficiary premiums in § 422.262(f)(1) allow premiums to be paid by the beneficiary through Social Security withholding, electronic funds transfer; or by an employer, employment-based retiree health coverage or by other third parties such as a State, which will include SPAPs. This rule is being adopted as final in the MA final rule, and will therefore have final effect for the Part D rule as well. Therefore, SPAPs will be able to pay premiums on behalf of enrollees.

Comment: One advocacy group asked that credit cards not be allowed to pay Part D premiums. It is their position that funds transfer mechanisms are error prone.

Response: Section 1860D–13(c)(1) of the Act states that the provisions of section 1854(d) of the Act apply to PDP sponsors in the same manner as they apply to MA organizations and beneficiary premiums under Part C. Section 1854(d)(2)(B) of the Act states that an MA organization ''shall permit each enrollee ... to make payment of premiums ... through an electronic funds transfer mechanism (such as automatic charges of an account at a financial institution or a credit or debit card account).'' Given that the Congress specifically stated electronic funds transfer will include credit or debit card accounts, we cannot prohibit their use.

Comment: One commenter asked if cost plans could be allowed to have their premiums deducted from SSA checks.

Response: An enrollee of a cost plan with Part D may pay their Part D premiums through reduction of their SSA check. The statute however, does not give us the authority to mandate an SSA check payment option on the Part C side, but we are capable of permitting withholding if acceptable to concerned parties.

Comment: We received several comments concerning the late enrollment penalty. While there was universal support for having a late enrollment penalty, there were disagreements regarding the amount of the penalty. Four commenters suggested that 1 percent of the base beneficiary premium may not be sufficient to control for adverse selection, but none had a recommendation for a higher amount. By contrast, another commenter suggested that beneficiaries will likely enroll late due to confusion. They therefore concluded that the late enrollment penalty should be less than 1 percent of the base beneficiary premium. One commenter urged us to collect data as quickly as possible to calculate a penalty amount that fairly reflects any higher costs associated with beneficiaries who delay their enrollment.

Response: Although, Part D enrollment is voluntary it is sound policy to try limiting adverse selection, or the tendency for persons with high utilization or risk to enroll in health insurance while healthy persons with no or low utilization do not, thus creating an unbalanced or biased population. To provide an incentive to enroll, the Congress created a late enrollment penalty in Section 1860D–13(b) of the Act, which is the greater of ''an amount that the Secretary determines is actuarially sound for each uncovered month'' or is ''1 percent of the base beneficiary premium''.

There is a paucity of relevant research in this area. Our only potentially relevant experience comes from the Part B late enrollment penalty, which is 10 percent per 12-month period. On average about 5 to 6 percent of Medicare Part A enrollees are not enrolled in Part B. It should be noted however, that a significant proportion of eligibles not enrolled in Part B are either working aged or are living overseas. Additionally, the utilization patterns and risks for Part B services and Part D drugs are different. Therefore, the Part B experience may not predict beneficiary behavior for Part D. Accordingly, we will set the late enrollment penalty at 1 percent of the base beneficiary premium and revisit the issue when appropriate data are available.

G. Payments to Part D Plan Sponsors For Qualified Prescription Drug Coverage

1. Overview (§ 423.301)

Subpart G of part 423 implements section 1860D–15 of the Act and the deductible and cost sharing provisions of section 1860D–14(a) of the Act. This section sets forth rules for the calculation and payment of our direct and reinsurance subsidies for Part D plans; the application of risk corridors and risk-sharing adjustments to payments; and retroactive adjustments and reconciliations to actual enrollment and interim payments. References to § 422 of our regulations are to the new MA rules. In general, the payment rules in this subpart do not apply to fallback plans—which are discussed in subpart Q

2. Definitions

We proposed definitions of a number of terms used in the computation of payments under this subpart, such as ''allowable reinsurance costs'', ''actually paid'' and ''coverage year'' in § 423.308 of our regulations, but discussed these separately in the appropriate sections of this preamble. We did this because these terms are complex and are best clarified in the context of the discussion of the pertinent provisions. We wish to clarify that a covered Part D drug for gross prescription drug costs means a Part D drug, as defined in § 423.100, that is included in a prescription drug plan's or MA-PD plan's formulary, or treated as being included in a plan's formulary as a result of a coverage determination or appeal under § 423.566, § 423.580, and § 423.600 of our rule.

3. General Payment Provisions (§ 423.315)

The payment provisions required by section 1860D–15 of the Act include the following four different payment mechanisms: 1) the direct subsidy; 2) reinsurance subsidies; 3) risk corridor payment adjustments; and 4) payments to cover certain premium, cost-sharing, and extended coverage subsidies for low-income subsidy eligible individuals.

The first payment mechanism involves monthly payments that (along with reinsurance subsidies) subsidize on average 74.5 percent of the value of the basic prescription drug benefit, thereby maintaining beneficiary premiums for basic coverage on average at 25.5 percent. The direct subsidy is determined based on a national bidding process. Sponsors who wish to offer plans submit bids on a standardized basis. After our review and approval, these bids become the basis for the direct subsidy that is equal to the plan's standardized bid, risk adjusted for health status as provided in § 423.329(b), minus the base beneficiary premium (as determined in § 423.286(c) and as adjusted for any difference between the standardized plan bid and the national average monthly bid amount (as described under § 423.286(d)(1))). The risk adjustment applied to the bid compensates the plan for individual enrollee differences in health status from the average beneficiary and thus reduces the impact from any adverse risk selection. Further adjustments to the direct subsidy payments will be made to account for actual enrollment and updated health status information.

The second and third payment mechanisms will substantially reduce the uncertainty and risk of participating in this new program. Since the Medicare prescription drug benefit is new, there is uncertainty surrounding the utilization, costs, and risk profiles (participation rates and characteristics) of potential enrollees. Federal reinsurance subsidies and risk corridor payment adjustments work along with the risk adjustment included in the direct subsidy to substantially reduce the uncertainty and risk of participating in this new program. Through reinsurance subsidies, in which we act as the re insurer, we will subsidize a large portion of any catastrophic expenses (defined as expenses over an individual's out-of-pocket limit) through a reinsurance subsidy. Through risk corridor arrangements, exposure to unexpected non-catastrophic expenses will be limited. These risk sharing arrangements are structured by the statute as symmetrical risk corridors, that is, agreements to share a portion of the losses or profits resulting from expenses above or below expected levels, respectively.

Finally, according to section 1860D–14 of the Act, PDP sponsors and MA organizations will receive payments to cover certain premium, cost-sharing, and extended coverage subsidies for low-income subsidy eligible individuals. With the exception of interim estimated payments of cost-sharing subsidies, these payments are discussed separately in subpart P of this preamble and in § 423.780 of our regulations.

Certain payments will be exceptions to these general payment provisions. Under private fee-for-service (PFFS) plans, reinsurance will be calculated differently and risk sharing will not be available. Reinsurance subsidies and risk sharing will not be available for fallback plans, which are paid in accordance with contractual terms related to actual costs and management fees tied to performance measures.

Comment: One commenter responded with support for immediate implementation of a reinsurance demonstration that would increase opportunities to fill in the donut hole in the Part D benefit and allow for a more predictable revenue flow that would support enhanced benefits for beneficiaries.

Response: The Conference Committee noted, ''the conditions under which the government provides reinsurance subsidies may create significant disincentives for private sector plans to provide supplemental prescription drug coverage. To address this concern, the conference agreement suggested use of the Secretary's current Medicare demonstration to ''allow private sector plans maximum flexibility to design alternative prescription drug coverage.'' CMS's authority to conduct Medicare demonstrations is provided in section 402 of the Social Security Amendments of 1967 (42 U.S.C. § 1395b–1). Under section 402(b), the Secretary is authorized to waive requirements in title XVIII that relate to reimbursement

and payment. The conferees specifically stated that CMS should demonstrate the effect of filling in the gap in coverage by reimbursing participating plans a capitated payment that is actuarially equivalent to the amount that plans would otherwise receive from the government in the form of specific reinsurance when an individual plan enrollee reaches the catastrophic attachment point ($3,600). They clarified that CMS would not be permitted to waive the minimum benefits provided by the plans. In the August proposed rule we stated in the executive summary that we were considering establishing a demonstration to evaluate possible ways of achieving extended coverage.

We intend to conduct a reinsurance demonstration that represents an alternative payment approach. We are working on the design of the budget neutral demonstration and issue separate guidance in the near future.

4. Requirement for Disclosure of Information (§ 423.322)

a. Data Submission.

As provided under sections 1860D 15(c)(1)(C), 1860D–15(d)(2) and 1860D–15(f) of the Act and in § 423.322 of our regulations, we will condition program participation and payment upon the disclosure and provision of information needed to carry out the payment provisions. Such information will encompass the quantity, type, and costs of pharmaceutical prescriptions filled by enrollees that can be linked to individual enrollee data in our systems; that is, linked to the Medicare beneficiary identification number (HIC#). In the August proposed rule we asked for comments on the content, format and optimal frequency of data feeds. We stated that more frequent feeds (that is monthly or quarterly) would allow us to identify and resolve data issues and assist the various payment processes.

We have evaluated our minimum data requirements with regard to prescription drug claims. Our goal is to have the least burdensome data submission requirements necessary to acquire the data needed for purposes of accurate payment and appropriate program oversight. Our view is that we will need at least the following data categories for 100 percent of prescription drug claims for the processes discussed below:

- Beneficiary identification (for example, HIC#, date of birth, gender, name)
- Prescription identification information (for example, RX identification number, NDC, quantity dispensed, fill number, date of service)
- Cost information (for example, ingredient cost, dispensing fee, sales tax, total gross cost)
- Payment information (beneficiary amount paid, low income cost sharing subsidy amount, secondary/other payer amount, supplemental amount)

We assume that ingredient cost and dispensing fee reflect point of sale price concessions in accordance with purchase contracts between plans (or their agents, such as PBMs) and pharmacies, but do not reflect subsequent price concessions from manufacturers, such as rebates. We will need these data on prescription drug claims for appropriate risk adjustment, reconciliation of reinsurance and low-income subsidies, calculation of risk sharing payments or savings, and program auditing. Data will also be required for assessing and improving quality of care. We asked for comments on the nature and format of data submission requirements based on the following requirements:

- The risk adjustment process will require 100 percent of drug claims in order to develop and calibrate the weights for the model for this new benefit. Consequently, PDP sponsors and MA organizations offering MA-PD plans will be required to submit 100 percent of prescription drug claims for Part D enrollees for the coverage year. Risk adjustment will require the submission of prescription drug agent identifying information, such as NDC codes and quantity, in order to allow the standardized pricing of benefits in the model. Because we will use standardized pricing in the model, cost data on each prescription is not a requirement for risk adjustment, although it is needed for other purposes.
- The reinsurance subsidy payment process will require 100 percent of claims for each enrollee for whom the plan claimed allowable reinsurance costs. (Although reconciliation of the reinsurance subsidy does not require NDC codes or quantities, it does require member, cost and date of service data.) All claims for enrollees with expenses in excess of the out-of-pocket limit will be necessary to verify that the costs are allowable because the totality and order in which the claims are incurred will define which claims will be eligible for reinsurance payments. While the start of reinsurance payments begins with claims after the out-of-pocket threshold has been reached, which is $5,100 in total spending (2006) for defined standard coverage, it may be associated with a higher dollar total spending amount under alternative coverage. Whatever the level, we will need to receive all claims by date of service including the amount of beneficiary cost sharing in order to determine the occurrence of the out-of-pocket threshold. Any plan-incurred costs for claims for supplemental benefits cannot be included in determining whether the out-of-pocket threshold has been met.
- The risk sharing process will require 100 percent of claims for all enrollees for the calculation of total allowable risk corridor costs. The plan will need to segregate costs attributable to supplemental benefits from those attributable to basic benefits since supplemental benefit costs are not subject to the risk corridor provisions. Again, all claims will be necessary to verify that the costs are allowable because the order in which the claims were incurred will help determine whether the claims were solely for basic coverage. For instance, a claim processed between a beneficiary's deductible and initial coverage limit (in standard coverage) will count towards risk sharing, but another claim (processed identically but immediately after the initial coverage limit has been reached) will not. Unlike the reinsurance subsidy, which is limited to individuals with expenses in excess of the out-of-pocket threshold, risk sharing involves costs (net of discounts, chargebacks and rebates, and administrative costs) for all enrollees for basic coverage, but only those costs that are actually paid by the sponsor or organization. Because all plans participate in risk sharing, potentially all claims for all Part D enrollees in all plans must be reviewed. Like the reinsurance reconciliation, risk sharing does not require NDC codes or quantities, but does require member, cost, and date of service data.
- The program audit process will require at least a statistically valid random sample of all Part D drug claims. We believe that several points of reference including HIC#, cost, date of service, and NDC code will be required for unique identification of individual claims in any random sample drawn from the population. If we receive 100 percent claims to support the payment processes, this sample could be drawn from our records. We believe it will be useful to obtain the prescribing physician's National Provider Identifier (NPI) number, as required by the administrative simplification provisions of HIPAA, in the elements of collected data for purposes of fraud control once it is available. (Nothing in this data collection discussion should be construed as limiting OIG authority to conduct any audits and evaluations necessary for carrying out our regulations.)

Comment: One commenter urged us to ensure that prescription transaction data, be made available to the QIOs. Without this information the commenter contends, it will be extremely difficult for QIOs to execute the direction of the Congress in section 109 of the MMA, to offer assistance to practitioners and plans for the purpose of improving the quality of pharmacotherapy received by older and disabled Americans enrolled in the Medicare outpatient drug benefit.

Response: Additional guidelines will be released dealing with QIO access to Part D data. QIOs do, however, have their own independent authority to collect claims data. Therefore, as we stated in the proposed rule, we believe we would have the authority to share claims data with QIOs if necessary.

Comment: One commenter stated that claims creation and submission for the pharmacy claims as proposed would probably be even more expensive, given the volume of data and the number of data elements. They encouraged us to be parsimonious in collecting data, with the understanding that plans would retain full data for audits.

Response: We will endeavor to reduce burden to the maximum extent possible. We will require only the data elements necessary to carry out the operations of the Part D program.

Comment: For the timeframe for data submissions, one commenter stated that unless all plans can provide information electronically, weekly data cycles would be too burdensome. Monthly or quarterly data cycles are more in line with other plan financial processes. Another commenter suggested that annual submission would be adequate with additional data submitted on a quarterly basis. A PBM commented that they have the capability of submitting drug utilization data to us on a monthly basis in any format required. They also noted that all of the data elements listed as proposed requirements in the proposed rule are available in their point-of-sale system. Two commenters recommended that data transmission use either the NCPDP or the American Society of Automation in Pharmacy (ASAP) standard formats. They reasoned that such standards are commonly used today and would have minimal impact on existing software applications.

Response: We agree that data submissions should be based on an established standardized format, and will be requiring data submissions in the NCPDP format. The data required will be from both incoming claims and the remittances to those claims. Some of the paid amounts that need to be reported are not on the NCPDP format (for example, the low income cost-sharing subsidy). Therefore, plans will be responsible for calculating and retaining these amounts while calculating appropriate payments and cost-sharing for each claim. We will require that the data related to drug claims be submitted no less frequently than monthly. Further details on data submission will be issued in separate guidance.

b. Allowable Costs

Section 1860D–15(b)(2) and 1860D–15(e)(1)(B) of the Act and § 423.308 of our regulations, specify that to determine ''allowable costs'' for purposes of both the reinsurance and risk corridor payments, only the net costs actually paid after discounts, chargebacks, and average percentage rebates, as well as administrative costs, are to be counted. In the proposed rule we discussed requiring average percentage rebates, which upon reflection would represent only a rough estimate on the part of a Part D plan. We wish to clarify that in order to carry out our responsibilities we will require reporting of aggregate (as opposed to at the beneficiary or claim level) rebates at the product level on a quarterly basis. Adequate lead time will be provided. Additional information will be provided through our payment guidelines.

In the proposed rule we noted, also for rebates, that we understand that much of the rebate accounting is not applied in the context of point of sale claims data, but rather in periodic accounting adjustments, and that rebates are frequently reported along with administrative fees paid by the manufacturer. We wish to clarify that we will expect reporting of all rebate dollars with no allowance for separate administration fees in order to prevent inaccuracies in reporting. We note that plans must require and keep accurate records on all price concessions. All cost reporting will be subject to inspection and audit (including periodic audits) by us and the OIG. Part D plans sponsors seeking to limit access to rebate information under this provision to Part D business only are advised to seek out separate contracts with manufacturers for their Part D and other lines of business. To the extent either we or the OIG discover that a sponsor has been overpaid for reinsurance or risk sharing (that is, the records do not support the payments made, or there is insufficient documentation to determine whether the payments are correct), we may recoup the overpayments. The reopening and overpayment provisions are discussed at the end of this part G.

We also wish to clarify our interpretation of allowable costs in the context of repackaged drugs. AWP is commonly used as the basis through which a plan sponsor or fallback plan calculates payments to pharmacies, and is used to when sponsors provide competitive bids for the Medicare Part D prescription program. AWP is typically published based on the NDC for a particular product, and is specific to the drug, strength, distributor and package size. However, AWP can vary between differing packages sizes of a drug and strength from a single distributor, as well as between multiple distributors that product a common drug, as in the case of generic products. AWP may not be published for some products that are repacked for a specific buyer, such as a mail-order pharmacy or a pharmacy chain. Furthermore, if a pharmacy benefit manager or managed care organization owns a pharmacy (including a mail-order, specialty, or clinic facility) and refers members to that facility, it essentially purchases product from itself. In these cases, special care must be taken to ensure that payment is made for a prescription ingredient cost that is an accurate reflection of the product that the facility purchases in terms of manufacturer, strength, and acquisition price.

The Department of Health and Human Services' Office of Inspector General issued the April 2003 report ''Compliance Program Guidance for Pharmaceutical Manufacturers'' that addresses AWP. The guidance report states that: ''... it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the ''spread'' to induce customers to purchase its product.'' We believe that the same principle of non-manipulation of AWP applies to sponsors of the Part D benefit. Any repricing or restatement of price of a pharmaceutical product is subject to audit, and potentially constitutes fraudulent behavior if the repricing or price restatement is done with the intent of increasing the profits of that sponsor or mail order facility by increasing the reimbursement due by the Federal government.

Comment: One commenter believes that administrative fees for administering rebates should not be included in the assessment of rebate fees.

Response: We disagree with the commenter. As stated in the proposed rule such accounting will be incompatible with the need to report all price concessions for purposes of determining allowable reinsurance and risk corridor costs. In the preamble to the proposed rule, we said that to the extent the administrative fees paid to

Part D plans (or their subcontractors, such as PBMs) are above the fair market value of the services rendered, this differential will be considered a price concession. Similarly, to the extent a Part D plans pays manufacturers or others administrative fees, and these fees are below fair market value, this would also be considered a price concession. In sum, as fiduciaries of the Medicare trust fund, we have a responsibility to ensure that price concessions are not masked as administrative fees, and therefore, we continue to believe that administrative fees are important in determining the reinsurance and risk-sharing payments.

Comment: One comment urged clarification of definition of ''allowable costs'' so to exclude manufacturer-sponsored compliance and appropriate use programs.

Response: Allowable costs are prescription drug costs excluding administrative costs, but including dispensing fees costs related to the dispensing of covered Part D drugs that are actually paid by the PDP sponsor. Thus any service, such as a compliance program, that is paid for in conjunction with drug costs as an administrative component of managing the drug benefit is not be considered an allowable cost for the PDP sponsor.

Comment: One commenter asked for clarification on how fair market value is to be determined.

Response: The fair market value of administrative fees paid to a Part D plan will typically be evaluated in relation to the values reported by other Part D plans. In other words, the fair market value will be the average or normal value of administrative fees within this market. However, this may not be an exclusive methodology. For example, if administrative fees paid to all plans were found to be improperly inflated they would not reflect fair market value and we would devise an alternative methodology.

Comment: One commenter requested that we require plans to attest to the accuracy of information submitted to manufacturers in order to ensure that rebates and discounts are based on accurate claims.

Response: We strongly encourage plans to attest to the accuracy of information submitted to manufacturers. However, we do not have the authority to require an attestation as the commenter suggests.

Comment: One commenter recommended the second approach to rebate accounting in the proposed rule whereby a plan would calculate a ratio of total rebate amounts to total spending and reinsurance-related spending to total spending to derive the share of rebates to be allocated to reinsurance. The commenter believes this option is administratively straightforward and would result in a reasonably accurate estimate of these discounts, chargebacks, and rebates.

Response: We will require reporting of actual rebates requested and paid down to the product level on a quarterly basis. Additional guidance will be released subsequent to publication of the final rule that specifically deals with rebate accounting rules.

c. Coverage Year

In § 423.308 the term ''coverage year'' is defined as a calendar year in which covered Part D drugs are dispensed if the claim for such drugs (and payment on such claim) is made not later than 3 months after the end of the year. In other words, drug claims paid past the close of the 3-month period will not be considered part of that coverage year (or the next), and will not be used to calculate that year's payments or in reconciling risk adjustment payments for the year.

This limit will be imposed in order to provide timely closure for payment determination processes such as reinsurance, risk corridors and employer subsidies. While the period of 3 months will be significantly less than the fee-for-service Medicare medical claims standard of 18 months, we believe that a shorter period is warranted due to the highly automated and point of sale nature of prescription drug claim processing. We understand that the vast majority of prescriptions are not filled without the claim being simultaneously processed and therefore, there is a much shorter claims lag to be considered. We believe that the number and value of drug claims that will potentially be missed will be immaterial, consisting primarily of paper claims. The 3-month close-out window will not limit the liability of the plan or its claims processing contractor for reimbursing any lagging claims, but will simply establish a timely cut-off for finalizing payments. We note that rebates for the coverage year must be credited against that coverage year's costs. Although we are closing the year for claims purposes after 3 months, the plan must account for and report to us all rebates that occur throughout the coverage year and send us all the data within 6 months after the end of the coverage year.

A shorter period for claims will allow for payment processes that are dependent on the knowledge of total allowable costs for each coverage year to be concluded on approximately the same schedule as other reconciliations involving enrollment or risk adjustment data. On this schedule, calculations of risk sharing could begin as soon as six months after the close of the payment year. If the claims submission standard were a longer period, final reconciliations will be significantly delayed. We requested comments on this timetable, specifically whether we should adopt a shorter or longer period than 3 months, and including data with which to estimate the proportion and value of drug claims that could be excluded with a 3-month close-out window.

Comment: Two commenters argued that the definition of the coverage year in § 423.308, being three months after the end of the year, would not be enough time for certain drug claims, such as those from out-of-network providers or those submitted by paper. They went on to say that claims made after the 3-month closeout should be appropriately accounted for. Another commenter stated that the majority of claims are submitted and paid within the 90 day window described in the rule. They went on to say that from a processor standpoint no more time is needed and based on observed claims patterns at least 98 percent of the drug claims are paid within 3 months. One industry association expressed support for the proposal to define coverage year to encompass drugs dispensed within a calendar year and for which claims have been paid no later than three months after the end of the calendar year. The commenter believes establishing finality in this manner is absolutely essential to promote financial stability by allowing timely determination of risk sharing amounts.

Response: According to Booz Allen Hamilton's August 2004 report ''Determination of Allowable Costs'' the industry standard is for claims to typically be submitted within a three month window period. We agree with the two latter comments that the definition of the coverage year is both logistically feasible and promotes timely payment. We also note that the coverage year is 3 months for claims run-out (§ 423.308), but plans have 6 months to submit data (§ 423.343). This gives plans the extra time necessary to compile the data necessary for retroactive reconciliation. We will adopt the definition of coverage year as proposed.

5. Determination of Payment (§ 423.329)

a. Direct Subsidies

As directed in section 1860D–15(a)(1) of the Act and codified in § 423.329(a), we will provide direct subsidies to PDP sponsors and MA organizations offering MA-PD plans. These subsidies will be in

the form of advance monthly payments. Payments will be equal to the plan's standardized bid, risk adjusted for health status as provided in § 423.329(b), minus the base beneficiary premium (as determined in § 423.286(c) and adjusted for any difference between the standardized plan bid and the national average monthly bid amount (as described under § 423.286(d)(1))). The standardized bid will be the portion of the plan's bid attributable to basic coverage. This portion will be risk adjusted by multiplying by our prescription drug risk score attributable to each enrollee. Between the government direct subsidy and the adjusted base beneficiary premium, the plan will receive its entire risk-adjusted standardized bid in advance each month. Payment for supplemental benefits will come from enrollees in the form of additional premium. By statute, the sponsor must bear all risk for such supplemental benefits. In the proposed rule we said ''We would note that a plan's total per capita payment could never exceed its bid, risk-adjusted for the beneficiary's health status. This would be the case even if the difference between the plan's bid and the national average monthly bid amount were greater than the beneficiary monthly premium, mathematically resulting in a ''negative premium'' amount. We do not believe that the statute envisions plan payments in excess of negotiated costs, since this would violate the revenue requirements provisions discussed in the subpart F of this preamble''. As outlined in detail in subpart F of this final rule, we have changed our policy. We now state that if the standardized bid amount is less than the national average monthly bid by an amount so great that it is in excess of the base beneficiary premium, the direct subsidy payment calculated above will be increased by the amount of the negative premium. We, therefore, have modified § 423.329(a)(1) to indicate that the direct subsidy payment may be increased by the excess amount of a negative premium as described in § 423.286(d)(1), if applicable.

b. Risk Adjustment

In section 1860D–15(c)(1) of the Act, we are directed to develop and publish a prescription drug risk adjustment methodology taking into account the similar methodologies under § 422.308(c)(1) to adjust payments to MA organizations for benefits under Part C on the basis of costs incurred under original Medicare. In § 423.329(c) we establish this risk adjustment methodology. We will develop and publish this risk adjustment methodology in the 45-day notice for the announcement of 2006 Medicare Advantage rates. Section 1860D–15(c)(1)(D) of the Act requires us to publish the risk adjustment for Part D at the same time we publish risk adjustment factors under section 1853(b)(1)(B)(i)(II) of the Act. Because these risk adjustment factors under subpart C can only be published after 45-day advance notice under section 1853(b)(2) of the Act, in general we will use the same notice procedures we use under Part C for risk adjustment. We believe this will promote consistency and uniformity in the process, and, especially for MA-PD plans, allow entities to review notices published on the same day for purposes of commenting on or learning about risk adjustment. As usual, the 45-day notice will solicit public comment on any change in proposed payment methodologies. We are expecting that this new prescription drug risk adjustment methodology will initially be based on the relationship of prescription drug utilization within the entire Medicare population to medical diagnoses, and that it will be applied at the individual beneficiary level. Our longer-term plan would be to refine the risk adjustment model to account for predictable risk based on both medical and drug claim data.

Section 1860D–15(c)(1)(C) of the Act and § 423.329(b)(3) of this rule authorize us to specify and require the submission of data from PDP sponsors regarding drug claims that can be linked at the individual level to part A and part B data in a form and manner similar to the Medicare Advantage process provided in § 422.310 and such other information as we determine necessary. Similarly, MA organizations that offer MA-PD plans must submit data regarding drug claims that can be linked at the individual level to other data that these organizations are required to submit to us. A primary requirement, therefore, is receiving claims linked to the Medicare beneficiary HIC#. Other data submission elements are discussed in section 4(a) of this part of the preamble. We expect to link these data at the plan level and will then require the inclusion of the PDP or Medicare Advantage contract identifier (H#) as well as the plan benefit package identifier. We will use this data to further refine our prescription drug risk adjustment factors and methodology in order to make payments that accurately reflect plan risk.

As we noted in the August proposed rule, any risk adjustment methodology we adopt must adequately account for low-income subsidy (LIS) individuals (and whether such individuals incur higher or lower-than average drug costs). We stated that our risk adjustment methodology should provide neither an incentive nor a disincentive to enrolling LIS individuals, and we requested comments on this concern and suggestions on how we might address this issue. Our particular concern has been that a risk adjustment methodology, coupled with the statutory limitation restricting LIS payments for premiums to amounts at or below the average, could systematically underpay plans with many LIS enrollees (assuming LIS enrollees have higher costs than average enrollees). As noted in the proposed rule, the initial risk adjustment system, which will be budget neutral across all Part D enrollees, must not under compensate plans for enrolling LIS beneficiaries. In fact, to the extent that an initial risk adjustor might at the margin tend to overcompensate for LIS beneficiaries, plans would have a strong incentive to disproportionately attract such beneficiaries. Plans could attract LIS beneficiaries both by designing features that are attractive to such beneficiaries and also by bidding low.

Comment: We received several comments generically expressing concern over the risk of insuring the low-income subsidy population exacerbated by the induced demand likely to be created by the low income subsidy itself. Several commenters specifically agreed with our proposal to deal with this issue via risk adjustment. No commenters rejected the proposal. All the commenters noted that it is critical for the risk adjustment methodology to pay fairly and appropriately for all enrollees, including income subsidy individuals. Commenters requested additional details about the risk adjustment methodology.

Response: We agree that the Part D risk adjuster must accurately predict the drug expenditures for various population subgroups, including low income beneficiaries. The best way to achieve this goal is to calibrate the risk adjustment model on a sample of beneficiaries that includes low income beneficiaries, which we intend on doing. We have experience in dealing with an analogous situation with the Part C risk adjustment model, where beneficiaries in long term care institutions are known to have significantly higher expenditures than community enrollees before health status is accounted for. In order to accurately risk adjust for this population, we have generated a version of the risk adjustment model that explicitly accounts both for these higher expenditures and for the different

relative costs of diseases for the long term institutionalized population compared to the community population. For induced demand, we have Federal Employee Health Benefit Program and State Medicaid program data that will permit us to model this effect. One commenter familiar with these data noted that ''it seems reasonable that the risk adjustment process be used to correct any underpayments due to LIS induced demand.'' Additional details will be provided with the guidance accompanying the release of the risk adjustment factors.

Comment: We also received comments concerning specific elements of the risk adjustment model. One health insurer asserted that medical diagnoses may not adequately predict drug utilization. A PBM commented that some drugs are a very good marker of disease, while other drugs can be used to treat a variety of conditions. A manufacturer suggested that we should use data on prior medication expenditures and include demographics and diagnoses.

Response: Work by Wrobel and colleagues (Health Care Financing Review Winter 2003–2004) using data from the Medicare Current Beneficiary Survey and Medicare claims data found a diagnostic based risk adjustment model was a powerful predictor of drug expenditures. Our current risk adjustment model does not use drugs as a marker of disease but use diseases to predict drug spending (see *www.cms.hhs.gov/pdps/riskad.zip*). A more detailed description of the elements of the Part D risk adjustment model will be provided in the Advance Notice of Payment Methodology. However, anyone interested in understanding how risk adjustment works can read ''Risk Adjustment of Medicare Capitation Payments Using the CMS-HCC Model'' in the Health Care Financing Review, Volume 25, Number 4 (Summer 2004). These articles are publicly available online at *www.cms.hhs.gov/review/default.asp*.

The Part D risk adjustment model will use demographics and diagnoses. As Part D program data becomes available we will incorporate other indicators to enhance the predictive power of the model. This may include, if appropriate, indicators of prior use of medication. We will provide the usual opportunities for public comment on subsequent iterations.

c. Risk Adjustment Budget Neutrality

In accordance with section 1860D–15(c)(1)(A) of the Act and § 423.329(b)(1), our risk adjustment methodology will be implemented in a budget-neutral manner. A requirement for budget neutrality assumes that there is a known budget. We interpret the statute to require that the risk adjustment methodology must not result in a change in aggregate amounts payable in section 1860D–15(a)(1) of the Act, that is, the risk adjustment methodology must be ''budget neutral'' to some aggregate of direct subsidy payments made before risk adjustment. (Since direct subsidy payments are made only to full-risk or limited risk plans, this budget by definition will not include payments to fallback plans.)

For comparison, in the current MA program the budget for risk-adjustment budget neutrality is defined to be the aggregate government payments made to plans under the 100 percent demographic payment system. Since the health-status-risk-adjustment methodology currently results in lower aggregate payments than the demographic methodology, MA budget neutrality distributes among participating plans the difference between total payments under the 2 methodologies via a factor that allocated the difference in the same proportion as the allocation of risk-adjusted payments. However, there is no corresponding predetermined limit to aggregate payments in Title I, that is, to the aggregate government direct subsidy payments made before risk adjustment, so there is no amount to use as a basis for comparison in determining budget neutrality.

In the MA program, the reason for the difference between the total payments under the demographic methodology and total payments under health status risk adjustment is that the average health status of enrollees in MA is different than the average health status for the program as a whole (that is, MA plus original Medicare). In Part D, there is no equivalent to original Medicare since beneficiary access subsidized coverage through enrollment in private plans. The Part D risk adjustment system will be based on these enrollees. Since there is no group of beneficiaries outside the system like there is under Part C, total payments with and without risk adjustment are always equal or budget neutral. Therefore, we believe that risk adjustment as applied to Part D benefits must be budget neutral to the risk of the individuals who actually enroll without any additional adjustment. We did not receive any specific comments on this, and therefore will adopt as proposed.

d. Reinsurance Subsidies

- Allowable Reinsurance Costs

As provided in section 1860D–15(e) of the Act and § 423.329(c), we will reduce the risk of participating in this new program by providing reinsurance subsidies. Subsidies will be limited to 80 percent of allowable reinsurance costs for drug costs incurred after an enrollee has reached the annual out-of-pocket threshold. The annual out-of-pocket threshold will be $3,600 in 2006. Under standard coverage this corresponds to total gross covered prescription drug costs of $5,100, and will be increased annually as provided in section 1860D–2(b)(4)(B)(i)(II) of the Act and 1860D–2(b)(4)(B)(ii) (with regard to rounding).

In meeting the various actuarial tests required of alternative coverage, there could be instances where a sponsor wanting to provide basic alternative coverage will have to enhance plan benefits in order to meet the test of equal total actuarial value relative to defined standard coverage. This could occur with the use of a tiered co-pay benefit structure that could shift utilization to a cheaper set of drugs, thus allowing plans to lower cost sharing to achieve the same total dollar value as defined standard coverage. In these instances, since cost sharing is reduced relative to defined standard coverage, the out of pocket threshold will be associated with a higher total drug costs than the $5,100 under standard coverage in 2006. For sponsors offering enhanced alternative coverage, the out-of-pocket threshold will also be associated with higher total drug spending. In this instance, however, it will be due to fact that the plan's supplemental benefits will be displacing part of the cost sharing that enrollees will otherwise have incurred.

Allowable reinsurance costs are a subset of gross covered prescription drug costs. Gross covered prescription drug costs are those costs incurred under the plan, excluding administrative costs, but including costs related to the dispensing of covered Part D drugs during the year and costs relating to the deductible. These costs are determined whether paid by the individual or under the plan, and regardless of whether the coverage under the plan exceeds basic prescription drug coverage. Allowable reinsurance costs, on the other hand, are the subset of these costs that are attributable solely to basic or standard benefits and that are actually paid by the sponsor or organization or by (or on behalf of) an enrollee under the plan. Actually paid means that these costs must be net of any discounts, chargebacks, and average percentage rebates, and will exclude any amounts not actually incurred by the sponsor. The reinsurance payments are then calculated by determining the portion of

allowable reinsurance costs that are incurred after the enrollee has reached the out-of-pocket threshold ($3,600 out of pocket in 2006). The reinsurance subsidy will provide 80 percent of such excess amount.

• Payment of Reinsurance Subsidy

Since allowable reinsurance costs (the subset of gross covered drug costs that are attributable to basic coverage only and are actually paid by the sponsor or plan) can only be fully known after all costs have been incurred for the payment year, we proposed to make payments on an incurred basis to assist PDP sponsors and MA organizations with cash flow. We also proposed that we would consider payments of reinsurance amounts on a monthly prospective basis based on the reinsurance assumptions submitted and negotiated with each plan's approved bid. In the August proposed rule we also stated that regardless of which process we used for making reinsurance payments, as discussed below, if, at the end of the year, the data demonstrates the sponsor was overpaid through the interim payments—or if there is insufficient evidence to support the reinsurance payments claimed—we would recover the overpayments either through a lump sum recovery or by reducing future payments during the coverage year. Similarly, if the data demonstrates that the sponsor was underpaid, we would pay the sponsor.

Comment: Numerous comments were received on the methodology of reinsurance payments. There was a general consensus supporting prospective monthly payments, with some commenters suggesting that the payment be at 1/12th of the net present value of estimated allowable reinsurance costs in each month of the coverage year. One commenter urged that plans should be able to choose between incurred and prospective payment. One commenter suggested that plans should invoice daily for reinsurance costs rather than have prospective monthly retrospective payments. Another commenter supported claims payments on an incurred rather than prospective or retrospective basis, and reimbursement on a monthly basis as proposed. Only one comment was received supporting determining payment with either a plan-specific or averaging approach

Response: Based on public comment, as well as on considerations of our current systems capabilities, our initial methodology will entail making monthly prospective payments of estimated allowable reinsurance costs submitted with the bid. We will establish and calculate these payments at the plan level so that reinsurance estimates reflect individual plan risk and the impact of plan supplemental benefits (if any) on when catastrophic benefits and reinsurance payments are triggered. At the end of each calendar year, we will reconcile plans' allowable incurred reinsurance costs for the year with the year's prospective plan payments; we will then reimburse plans for any underestimation of costs or recover any agency overpayments. More details will be made available in CMS additional guidelines on the payment methodology. We have modified § 423.343(d)(1) to clarify that CMS data requirements for reconciliation will be specified in separate guidance. We note that two commenters suggested that payments should be made on an incurred basis. We believe that advancements in information systems could make this logistically feasible. We wish to clarify that we reserve the right to alter the payment methodology. Any future changes would be announced through the Advance Notice of Methodological Changes and be subject to public comment.

• Adjustments to Reflect the True Out-of-Pocket Threshold

The statute provides that the reinsurance subsidy would be paid only for the plan's share of individual expenses in excess of an enrollee's TrOOP threshold. As indicated above, if the PDP sponsor offers enhanced alternative coverage or an MA-PD plan offers benefits beyond basic coverage as part of its supplemental benefits, the plan's spending for these benefits would not count toward the TrOOP threshold. Since benefits beyond basic coverage reduce cost sharing that would otherwise be incurred, they shift the effective prescription drug catastrophic limit beyond the associated total spending under the standard benefit ($5,100 in 2006) and raise the effective reinsurance attachment point at the same time.

In addition, to the extent that plan cost sharing is paid or reimbursed by secondary insurance coverage or otherwise, that cost sharing does not count toward the out-of-pocket threshold. Beneficiaries are required to report the existence of secondary coverage or other types of coverage we identify and plans must identify these payments and ensure that true out-of-pocket spending is accounted for accurately in claims processing. This is more fully discussed in subpart C and subpart J of this preamble.

Comment: One commenter noted that claims covered under supplemental coverage do not count towards TrOOP. The commenter believes that reinsurance should be triggered at the point that each enrollee hits $5,100 rather than $3,600 in out-of-pocket because there will otherwise be a strong disincentive to offer plans with enhanced coverage.

Response: We agree that the delayed reinsurance attachment point that results from the provision of supplemental benefits is one issue that must be considered by Part D plan sponsors. However, section 1860D–15(b)(2) of the Act defines allowable reinsurance costs to be ''no more than the part of such costs that would have been paid under the plan if the prescription drug coverage under the plan were basic prescription drug coverage, or, in the case of a plan providing supplemental prescription drug coverage, if such coverage were standard prescription drug coverage.'' Therefore, by statute, claims for supplemental benefits cannot be counted toward allowable reinsurance costs and we have no discretionary authority in this area.

• Adjustments for the Insurance Effect of Supplemental Coverage

In the proposed rule we stated that supplemental benefits increase the level of total drug spending after which reinsurance payments begin (reinsurance attachment point). Assuming 2 identical groups of enrollees for utilization, one enrolled in enhanced alternative coverage and one in defined standard coverage, the total allowable reinsurance costs for the group with standard coverage would be greater than for the group with enhanced alternative coverage. Thus, one might hold that the differences in benefit packages are accounted for without the need for further adjustment. If one would examine average total spending for both groups, however, one would find that the average spending under enhanced alternative coverage would be greater than the average under defined standard coverage because of the impact of the insurance effect (or ''moral hazard'', that is, the tendency of increased coverage resulting in increased utilization due to decreased financial stake in the costs associated with utilization). All other things being equal, this higher total spending would result in higher allowable reinsurance costs than would otherwise occur if the total spending under enhanced alternative coverage were comparable to that under standard coverage. We therefore proposed requiring (in the definition of allowable reinsurance costs) that allowable reinsurance costs be adjusted to reflect the impact of this induced utilization. We would make this adjustment to comply with the

requirement in section 1860D–15(b)(2) of the Act that in no case shall the allowable reinsurance costs exceed the costs ''that would have been paid under the plan if the ... coverage ... were standard prescription drug coverage''.

Comment: One commenter responded that they were not clear that an adjustment for the insurance effect of supplemental coverage would be needed. They recommended that we consider allowing time to study this issue, both to determine if an adjustment is appropriate at all and if it is what the adjustment should be. Another commenter stated that this issue is very complex and offered to discuss it further with us. Another health insurer noted that if a health plan develops rates for a commercial group, the rate for supplemental benefits developed for that group will include the revenue needs for the supplemental benefits as well as the plan's increased revenue needs to the extent that the expected costs of providing the basic benefit are expected to increase as a result of the supplemental coverage. They inquired as to how this practice would be applied to Part D.

Response: We continue to believe that an adjustment for the insurance effect of supplemental coverage is necessary. The effect of reduced cost sharing resulting in increased demand for medical services (including drugs) is firmly established in the economics literature and has been discussed for decades (see Charles Phelps and Joseph Newhouse's seminal review in the August 1974 issue of The Review of Economics and Statistics and more recently Phelps' 1997 text ''Health Economics''). Specific to the Medicare population, Margaret Artz and colleagues report in the August 2002 issue of the American Journal of Public Health that regardless of insurance type per capita prescription drug expenditures increased as generosity of coverage increased in their analysis of data from the Medicare Current Beneficiary Survey. Accordingly, plans that offer supplemental benefits will be required to provide an induced utilization estimate with their bid, and we have adopted this provision without modification. Additional CMS guidelines will be provided on estimating the induced utilization.

- Reinsurance Subsidies to Private Fee-For-Service Plans

As provided under section 1860D–21(d)(4) of the Act and in § 423.329(c)(3), we will base reinsurance payments for PFFS plans on an alternative methodology. Rather than negotiating reinsurance assumptions submitted with the PFFS plan bid or otherwise adjusting for potential price level differences between PFFS and other MA organization bids, we will estimate the amount of reinsurance payments that will be payable if the plan were an MA-PD plan described in section 1851(a)(2)(A)(i) of the Act. In doing so we will take into account the average reinsurance payments made under § 423.329(c)(2) for basic benefits for populations of similar risk under such MA-PD plans. Estimated payments will not be subject to any reconciliation process to compare the amounts paid to the actual allowable reinsurance expenses, and will not allow for payment recoveries in the event that actual allowable reinsurance costs exceed payments.

6. Low-Income Cost-Sharing Subsidy Interim Payments

As provided under section 1860D–14 of the Act and in § 423.780 of the regulations, we will provide additional assistance for certain low-income beneficiaries in the form of premium, deductible and cost-sharing subsidies. Since actual expenses incurred by these low income beneficiaries can only be fully known after all costs have been incurred for the payment year, we proposed to make estimated payments on an interim basis to assist PDP sponsors and MA organizations with cash flow. Under § 423.329(d)(2)(i), we proposed to provide for interim payments of low-income deductible and cost-sharing amounts on a monthly prospective basis based on estimates of low-income cost sharing submitted and negotiated with each plan's approved bid.

We also noted in the August proposed rule that low-income cost sharing would not necessarily be incurred evenly throughout the coverage year and that we were considering the most appropriate methodology for distributing interim payments. Since equal payments would be most compatible with our systems, in the first two years of the program (and for the first two years of new plans thereafter) we said in the proposed rule that we were considering an approach paying 1/12th of the net present value of estimated low-income cost sharing in each month of the coverage year. This net present value would be calculated on the basis of all estimated costs due at the end of the year and discounted by the most recently available rate for one-year Treasury bills. An alternative approach outlined in the proposed rule would have required the submission of a schedule of the estimated timing of incurred low-income cost sharing along with the plan bid. For example, we might take schedules from each plan or we could propose an incremental schedule (X percent of the total in January, Y percent in February, etc.). We also noted that the prospective payment of estimated costs might create an incentive to overstate low-income cost sharing, and that we are interested in ensuring that our interim payments are not excessive. We stated in the proposed rule that we would welcome comments on these approaches and on the appropriate treatment of interest in any methodology.

Again, we proposed that any reconciliation at the end of the year would need to be based on the sponsor providing adequate information in order to determine the subsidy amounts for the year. If the sponsor could not provide such information, interim payments would be recovered. In addition, the low-income payments would be subject to the same inspection and audit provisions applying to the other payments made under section 1860D 15 of the Act.

Comment: Several commenters supported prospective monthly payments for the low-income subsidy based on estimates provided in the accepted bid submissions. Two commenters suggested that low-income subsidies should be paid to plan sponsors on an incurred basis.

Response: We will make low-income cost sharing subsidy payments on a prospective basis using estimates submitted and negotiated with the approved bid and will reconcile these payments after the end of the coverage year with claims data. We agree with the majority of commenters that this method best protects plans from cash flow problems. More information will be provided with CMS guidelines on payment methodology. We have modified § 423.343(d)(1) to clarify that our data requirements for reconciliation will be specified in separate guidance.

Comment: One PBM urged that PDPs should be compensated for premium underpayment if the low-income subsidy amount does not meet or exceed their premium.

Response: The PDP will get paid its full premium. In cases where the low-income subsidy amount is less that the plan's premium, any low-income beneficiary enrolling in the plan is responsible for making up the difference between the low-income premium subsidy and the plan's premium.

Comment: Two commenters stated that some SPAPs would want to supplement the premium subsidy so that their beneficiaries do not have to pay first and be reimbursed by the SPAP. They suggested that Section

423.329 should include a requirement for plans to implement a process, similar to the Medicare Part B buy-in process, which will allow States to pay Medicare Part D premiums on behalf of SPAP beneficiaries.

Response: Such authority already exists. Collection of monthly premiums are covered in § 423.292. Section 1860D–13(c) of the Act instructs that the provisions of 1854(d) shall apply to PDP sponsors and premiums under this part be paid in the same manner as they apply to MA under part C. Payment options under § 422.262(f)(3) include any ''other third parties such as a State''. Moreover, we are required to establish standards for effective coordination between Part D plans and SPAPs for payment of premiums and coverage, as well as payment for supplemental prescription drug benefits. Further information on these standards will be issued in separate guidance.

Comment: One commenter urged us to share all low-income subsidy payment data under § 423.315(d) directly with the SPAPs.

Response: Since nothing in the MMA addresses disclosure of data to SPAPs, we believe that FOIA rules apply to these data. Therefore, it is possible that we cannot disclose this data under exception 4 of FOIA, but such a determination would be done on a case-by-case basis following standard FOIA procedure.

7. Risk Sharing Arrangements

a. Risk Sharing Methodology and the Target Amount

As provided under section 1860D–15(e) of the Act and in § 423.336, we would establish risk corridors. Risk-sharing payments would limit exposure to unexpected expenses not already included in the reinsurance subsidy or taken into account through risk adjustment. These would be structured as symmetrical risk corridors that are agreements to share a portion of the losses or profits resulting from expenses for basic benefits either above or below expected levels, respectively. However, plans would always be at full financial risk for all spending on supplemental drug coverage. In addition, in accordance with section 1860D–21(d)(5) of the Act and section 1860D 15(g) of the Act, the risk sharing provisions are not available to PFFS and fallback plans.

The expected level of expenses for basic benefits included in the standardized bid is known as the ''target amount''. The target amount for any plan would be equal to the total amount of direct subsidy payments from us, and premium payments from enrollees to that plan for the year based upon the risk-adjusted standardized bid amount, less the administrative expenses and return on investment assumed in the standardized bid. Since the standardized bid is the portion of the accepted bid amount attributable to basic prescription drug coverage, the target amount can be thought of as ''prepayments'' of prescription drug expense for basic benefits. The standardized bid has also taken into account (and excludes) any utilization effects of offering supplemental coverage. The objective of risk sharing would be to compare total actual incurred prescription drug expenses to the prepayments, to compute the difference, and to reimburse or recover a portion of the difference.

In § 423.336(a)(2)(A), we establish risk corridors, defined as specified risk percentages above and below the target amount. For instance, in § 423.336(a)(2)(ii), for 2006 and 2007, the first risk corridor is defined as 2.5 percent above the target amount and the second as 5 percent above the target amount. This means that, for 2006 and 2007, the first risk corridor is between 100 percent and 102.5 percent of the target amount and the second risk corridor is between 102.5 percent and 105 percent of the target amount. A third risk corridor is above 105 percent of the target amount.

The term, symmetrical risk corridors—means that the same size corridors exist below the target amount as above it. The actual upper or lower limits of each corridor equal the target amount plus or minus the product of the risk percentage times the target amount.

b. Allowable Risk Corridor Costs

The costs applicable to the computation of risk sharing are known as allowable risk corridor costs. These costs are defined in section 1860D–15(e)(1)(B) of the Act and in § 423.308 as the part of costs for covered Part D drugs that are only attributable to basic benefits. Allowable risk corridor costs cannot include costs attributable to benefits outside the basic benefit. We interpret this as both the actual differences in benefits structure and the insurance effect of supplemental coverage on basic coverage. In section 1860D–15(e)(1)(B) of the Act, reference is made to section 1860D–11(c)(2) of the Act that provides for a utilization adjustment using as its reference point standard prescription drug coverage. We are interpreting this to mean the statutorily defined standard prescription drug coverage described in subpart C. Also, allowable risk corridor costs must actually be paid by the sponsor or organization under the plan and must be net of any chargebacks, discounts or average percentage rebates. The allowable risk corridor costs also do not include any administrative expenses (including return on investment) of the sponsor or organization. (Administrative expenses would not include costs directly related to dispensing of Part D drugs during the year.) Note that unlike allowable reinsurance costs, allowable risk corridor costs do not include any amount paid by the enrollee. In § 423.336(a)(1), we state that allowable risk corridor costs must be adjusted in accordance with section 1860D–15(e)(1)(A) of the Act, by subtracting expenses reimbursed through other separate payments. Thus, reinsurance payments made under § 423.329(c)(2) and the non-premium low-income subsidy payments made under § 423.782 in subpart P of these regulations to the sponsor of the plan for the year must be subtracted. The PDP sponsor or MA organization would already have received compensation for these costs, and thus they do not fall within the construct of risk corridors that are directed at limiting exposure to unexpected expenses.

If adjusted allowable risk corridor costs exceed the prepayments by a certain amount, we would reimburse a percentage of the difference to help plans with a portion of the unanticipated expenses associated with their drug coverage. On the other hand, if prepayments exceed adjusted allowable risk corridor costs, we would reduce future payments or otherwise recover a percentage of the difference to reduce the impact on the Trust Fund of excessive bids.

- In order to arrive at a value for actual risk corridor costs that can be appropriately compared to the target amount, allowable risk corridor costs would be adjusted to remove expenses reimbursed through total reinsurance payments and non-premium low income subsidy payments. The statute indicates that allowable risk corridor costs must be reduced by reinsurance payments and by the subsidy payments for low income individuals. The subsidy payments for low-income individuals under section 1860D–14 of the Act include subsidies for both premium and for cost sharing. We interpret ''the total subsidy payments made under section 1860D–14'' under section 1860D15(e)(1)(A)(ii)(II) of the Act in the context of ''costs incurred by the sponsor or organization'' in the definition of allowable risk corridor costs. Since premiums are not a cost, we limit our interpretation of ''the total subsidy payments'' to payments related to cost sharing.

We note that when adjusted allowable risk corridor costs are calculated by subtracting only non-premium subsidies the results are the same as for an identical plan without any subsidy-eligible individuals. However, if the adjusted allowable risk corridor costs are calculated by subtracting total low-income subsidies (that is, for premiums, cost sharing and coverage above the initial coverage limit), the risk sharing calculation results in lower recouped costs on the part of the plan and a different outcome from that in a plan without subsidy eligible individuals. Since there must be no difference in these amounts, the calculation subtracting only non-premium subsidies must be the appropriate one. We believe that to do otherwise would result in a major disincentive for PDP and MA-PD plans to enroll individuals eligible for the low-income subsidies, and we do not believe that this would be the logical outcome that was intended by the statute. We are adopting this provision as proposed.

c. Changes in Risk Corridor Limits and Percentages (§ 423.336(a) and (§ 423.336(b))

The risk corridors and the percentage of risk to be shared would be set at certain levels for 2006 and 2007 with flexibility for us to increase the risk sharing percentage if bids, and therefore target amounts, are off during the early years of the program by a certain percentage set by the statute in section 1860D 15(e)(2)(B)(iii) of the Act. During 2006 and 2007, plans would be at full risk for adjusted allowable risk corridor costs within 2.5 percent above or below the target. Plans with adjusted allowable costs above 102.5 percent of the target would receive increased payments. If their costs were between 102.5 percent of the target (1st threshold upper limit) and at or below 105 percent of the target (2nd threshold upper limit), they would be at risk for 25 percent of the increased amount; that is, their additional payments would equal 75 percent of adjusted allowable costs for spending in this range. If their costs were above 105 percent of the target they would be at risk for 25 percent of the costs between the first and second threshold upper limits and 20 percent of the costs above that amount. That is, their additional payments would equal 75 percent of the difference between the first and second threshold upper limits and 80 percent of the adjusted allowable costs over the second threshold upper limit. Conversely, if plan spending fell below the 97.5 percent of target, plans would share the savings with the government. They would have to refund 75 percent of the savings for any costs less than 97.5 percent of the target amount but at or above 95 percent of the target level, and 80 percent of any savings below 95 percent of the target.

In § 423.336(b)(2)(iii) the program will cover a higher percentage of the risk for costs between the 1st and 2nd upper threshold limits would apply in 2006 and 2007 if we were to determine that: (1) 60 percent of Part D plans have adjusted allowable costs that are more than the first threshold upper limit for the year; and (2) these plans represent at least 60 percent of beneficiaries enrolled in such plans. In this case, additional payments to plans would increase from 75 percent to 90 percent of adjusted allowable costs between the first and second upper threshold limits. Conversely, there would be no change in savings shared with the government if costs fell below 97.5 percent of the target level.

For 2008 to 2011, the risk corridors and the percentage of risk to be shared would be modified so that PDP and MA PD sponsors would assume an increased level of risk. Plans would be at full risk for drug spending within 5 percent above or below the target level. Plans would be at risk for 50 percent of spending exceeding 105 percent and at or below 110 percent of the target level. Additionally, they would be at risk for 20 percent of any spending exceeding 110 percent of the target level. Payments would be increased by 50 percent of adjusted allowable costs exceeding the first threshold upper limit and up to the second threshold upper limit and 80 percent for any additional costs exceeding the second threshold upper limit. Conversely, if plan spending fell below the target, plans would share the savings with the government. They would have to refund 50 percent of the savings if costs fell between 95 percent and 90 percent of the target level, and 80 percent of any amounts below 90 percent of the target.

For years after 2011, we would establish the risk threshold percentage as deemed necessary to create incentives for plans to enter the market. The only required parameters would be that the first threshold risk percentage could not be less than 5 percent and the second threshold risk percentage could not be less than 10 percent of the target amount.

d. Risk Sharing Payments or Recoveries

In § 423.336(c), we will make payments or recover savings after a coverage year after obtaining all of the information necessary to determine the amount of payment. In § 423.336(c)(1), the PDP sponsor or MA organization offering a MA-PD plan would provide us with the information necessary to calculate the risk sharing as discussed in section 3(a) of this part of the preamble within six months. This would include prior final reconciliation of reinsurance and low-income subsidies since allowable risk corridor costs must be reduced by the total reinsurance payments and non-premium low-income subsidies for the year. Once this information has been received, under § 423.336(c)(2) we would either make lump-sum payments or adjust monthly payments in the following payment year based on the relationship of the plan's adjusted allowable risk corridor costs to the predetermined risk corridor thresholds in the coverage year. We would not make payment if we did not receive the necessary information from the PDP sponsor or MA organization. In addition, as stated, below, we are considering certain corrective actions to recoup risk-sharing payments, in the event of lack of information.

Comment: One State suggested that any savings accrued to the government via risk sharing should be shared with the States.

Response: Risk sharing is symmetrical, meaning that if it were permissible to share cost savings, the States would also have to assume responsibility for the portion of the cost for specified risk percentages above the target amount. Nevertheless, the Congress intended for risk sharing to be between the Federal Government and the plans with no State involvement whatsoever.

8. Retroactive Adjustments and Reconciliation (§ 423.343)

In § 423.343(a) and § 423.343(b) retroactive adjustments are made to the aggregate monthly payments to a PDP or MA-PD for any difference between the actual number and characteristics, including health status, of enrollees and the number and characteristics on which we had based the organization's advance monthly payments. Reconciliation of actual payments made would be done as needed. In order for total payments to be properly accounted for in all steps, the order of reconciliation processes would be first, enrollment; second, risk adjustment; third, low-income cost sharing; fourth, reinsurance; and finally, risk sharing.

Under § 423.343(c) and (d), we provide for a final reconciliation process to compare the payments for reinsurance subsidies and low-income cost-sharing subsidies made during the coverage year to actual allowable reinsurance expenses and low-income cost sharing and to make additional payments or payment recoveries

accordingly. The form and manner in which actual allowable reinsurance costs would be submitted for reconciliation will be discussed in additional CMS guidelines on payment methodology. PDP sponsors and MA organizations offering a MA-PD plan would provide us with the information necessary to finalize reinsurance payments as discussed in section 3(a) of this part of the preamble within six months of the end of a coverage year. Once complete data were received for a coverage year, we would compare 80 percent of the allowable reinsurance costs attributable to that portion of gross covered prescription drug costs incurred in the coverage year after an individual has incurred costs that exceed the annual out-of-pocket threshold to the monthly reinsurance payments and compute the difference. We would then either make lump-sum payments or adjust monthly payments throughout the remainder of the payment year following the coverage year to pay out or recover this difference.

If an entity did not provide us with sufficient documentation for us to reconcile payments, we would reconcile by recovering payments for which the entity lacked documentation. For example, if we make interim payments during the year for the low-income subsidy, but at the end of the year, the PDP sponsor or MA organization cannot provide documentation demonstrating the amounts of beneficiary cost-sharing, the reconciliation process would involve recouping the interim payments for such subsidy. The need to provide sufficient documentation to support final payment determinations applies even in the event of a change of ownership. Thus, new owners of a PDP sponsor or MA organization would be responsible for obtaining the documentation necessary to support payment, and the reconciliation process would be used to recover any payments for which the new owner lacked documentation. We believe this authority stems from the direction of the Congress that each PDP sponsor and MA-PD organization ''provide the Secretary with such information as the Secretary determines is necessary to carry out this section,'' (section 1860D–15(f)(1)(A) of the Act) and that ''payments under this section . . . are conditioned upon the furnishing to the Secretary in a form and manner specified by the Secretary, of such information as may be required to carry out this section,'' (section 1860D–15(d)(2)(A) of the Act)).

In the proposed rule we discussed potential remedies that should be imposed in the event a PDP sponsor or MA organization offering an MA-PD plan fails to provide us with adequate information regarding risk-sharing arrangements. In the case of risk corridor costs, the organization or sponsor may owe the government money if, for example, prepayments exceed adjusted allowable risk corridor costs. In this case, failure to provide information could result in a shortfall to the government, since the entity would not have the information necessary for the Secretary to establish the proper amount owed. Therefore, we will assume that the sponsor's or organization's adjusted allowable risk corridor costs are 50 percent of the target amount. We will use a 50 percent threshold because we believe this threshold would constitute a lower limit; and it would be unlikely for any organization or sponsor to have costs lower than 50 percent of their total payments. Additional guidelines will detail our methodology for reconciliation for these payments.

9. Reopening (423.346)

We believe that the provision in 1860D 15(f)(1) of the Act providing the Secretary with the right to inspect and audit any books and records of a PDP sponsor or MA organization regarding costs provided to the Secretary would not be meaningful, if upon finding mistakes pursuant to such audits, the Secretary were not able to reopen final determinations made on payment. In addition, we believe that sections 1870 and 1871 of the Act provide us with the authority to reopen final determinations of payment to PDP sponsors and MA organizations. Therefore, our reopening provisions patterned after those used in Medicare claims reopening, found in Part 405 of the regulations, subparts G and H. Including reopening provisions will allow us to ensure that the discovery of any overpayments or underpayments could be rectified. Under our provisions, reopening could occur for any reason within one year of the final determination of payment, within four years for good cause, or at any time when there is fraud or similar fault. We could initiate a reopening on its own, or a sponsor or organization could request reopening, but such reopenings will be at our discretion. The Supreme Court has determined that in the context of reopening cost reports, a fiscal intermediary's decision not to reopen a final determination is not subject to judicial review, see Your Home Visiting Nurse Services, Inc. v. Shalala, 525 U.S. 449, 456 (1999), and we believe the same reasoning would apply in the context of Part D.

Good cause will be interpreted in the same manner as in Part 405 (see Medicare Carriers Manual section 12100). Thus, good cause will exist, if (a) new and material evidence, not readily available at the time of the determination, is furnished; (b) There is an error on the face of the evidence on which such determination or decision is based; or, (c) There is a clerical error in determination. In order to meet the standard under (a) the evidence could not have been available at the time the determination was made. A clerical error constitutes such errors as computational mistakes or inaccurate coding. An error on the face of the evidence exists if it is clear based upon the evidence that was before us when it reached its initial determination that the initial determination is erroneous. Thus, for example, good cause would exist in cases where it is clear from the files that rebates or administrative costs were not appropriately accounted for, where computation errors had been made, where a sponsor or organization included non-Part D drugs in their calculations, where individuals not enrolled in the plan were included in calculating payment, and in similar situations. Reopening could occur at any time in cases of fraud or similar fault, such as in cases where the sponsor or organization knew or should have known that they were claiming erroneous Medicare payment amounts.

Comment: One commenter asked for clarification on the criteria that we intend to follow in evaluating whether to reopen a determination during the first year under § 423.346.

Response: The criteria for reopening under § 423.346 is no different in the first year. Reopening could occur for any reason within one year of the final determination of payment, within four years for good cause, or at any time when there is fraud or similar fault. We could initiate a reopening on its own, or a sponsor or organization could request reopening, but such reopenings will be at our discretion. Good cause will exist, if: (1) new and material evidence, not readily available at the time of the determination, is furnished; (2) there is an error on the face of the evidence on which such determination or decision is based; or, (c) there is a clerical error in determination.

10. Payment appeals (§ 423.350)

Several commenters were concerned with resolving payment accuracy issues. Section 1860D–15(d)(1) of the Act gives broad authority to the Secretary to develop payment methods and we intend on using this authority to establish a payment appeals process to

help allay the aforementioned concerns. Accordingly, we have added § 423.350 to establish a payment appeals process whereby payment determinations involving the following may be subject to appeals:

- the reconciled health status risk adjustment of the direct subsidy as provided in § 423.343(b);
- the reconciled reinsurance payments under § 423.343(c);
- the reconciled final payments made for low-income cost sharing subsidies provided in § 423.343(d); or
- the final risk-sharing payments made under § 423.336.

We wish to clarify that the payment appeals process only applies to perceived errors in the application of the payment methodology described in this subpart and subsequent CMS guidelines. Under no circumstances may this process be used to submit new payment information after the established deadline. Part D plans are expected to submit payment information correctly and within the timelines we established.

I. Organization Compliance with State Law and Preemption by Federal Law.

1. Overview

In our proposed regulation at § 423.401 we implemented the requirements of section 1860D–12(a) of the Act that address licensing, the assumption of financial risk for unsubsidized coverage, and solvency and capital adequacy requirements for unlicensed sponsors or sponsors who are not licensed in all States in the region in which it wants to offer a PDP.

The provisions of this section specified the following:

- A sponsor must be organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each State that it offers a PDP.
- There can be a waiver of the State licensure requirement for the reasons and under the conditions set forth under section 1860D 12(c) of the Act.
- To the extent an entity is at risk, it must assume financial risk on a prospective basis for covered benefits that are not covered by reinsurance. The PDP sponsor could obtain insurance or make other arrangements for the cost of coverage provided to enrollees to the extent that the sponsor is at risk for providing the coverage.

Below we summarize some of the proposals outlined in the August 2004 proposed rule, respond to public comment, and indicate any changes we have made to the final rule. For a full explanation of the proposals we refer readers to the August 2004 proposed rule.

a. Overview

We proposed at § 423.410 to implement the provisions of section 1860D–12(c) of the Act that address waiver of certain requirements to expand choice. Generally, section 1860D–12(c) of the Act specifies that in order to expand access to prescription drug plans, we may waive the State licensure requirement using many of the same standards that are permitted under Part C for provider-sponsored organizations (PSOs). The MMA also added some special rules for PDPs that are in addition to the PSO waivers available under Part C. Finally, the MMA allows for regional plan waivers under circumstances similar to those permitted under Part C for regional plans. We proposed requirements for regional plan waivers in § 423.115.

b. Waivers Incorporated from 1855(a)(2)

Section 1860D–12(c) of the Act provides that a prospective PDP sponsor may request a waiver from State licensure requirements from us under the waiver provisions at sections 1855(a)(2)(B), 1855(a)(2)(C) and 1855(a)(2)(D) of the Act. Because the Congress directed us to use many of the same grounds for approving waivers used in accordance to sections 1855(a)(2)(B), 1855(a)(2)(C), and 1855(a)(2)(D), we proposed adopting the regulatory provisions in § 422.372. These provisions allow a waiver when the State has failed to complete action on a licensing application within 90 days of receipt of a substantially complete application. This rule was adopted in proposed § 423.410(c)(1).

Proposed § 423.410(c)(2) included the standard of § 422.372(b)(2) (Denial based on discriminatory treatment). Under this proposed regulation, a waiver could be granted if a determination by CMS were made that: (1) the State denied an application based on requirements that are not generally applicable to PDP sponsors or other entities engaged in a similar business; or (2) the State required as a condition of licensure that the PDP sponsor offer any product or plan other than a prescription drug plan.

Proposed § 423.410(c)(3) incorporated the standard of § 422.372(b)(3) and stated that a waiver may be granted if the State denied an application on the basis of procedures or standards relating to solvency that are different from the solvency requirements established by us. In § 423.420, we proposed that we would use an application process in which the waiver applicant would be required to submit certain documents that indicate that the State is imposing procedures or standards relating to solvency that are different from CMS standards.

c. Additional Waivers Available under 1860D–12 of the Act.

In addition to the waivers available to PSOs under 1855(a)(2)(B), (C) and (D) of the Act, the MMA also created additional waiver opportunities for PDPs. The first of these was included in proposed § 423.410(c)(4) (implementing section 1860D–12(c)(2)(A)(ii) of the Act), which provides that we may grant a waiver when a State imposes requirements other than those required under Federal law.

The second and third of these (implementing section 1860D–12(c)(2)(B) of the Act) were included in proposed § 423.410(d) and (e). We proposed granting a waiver in the following scenarios:

- When a State does not have any licensing process for PDP sponsors.
- If a State does have a licensing process for years beginning before January 1, 2008, a waiver will be granted if the PDP sponsor merely submits its completed application for licensure to the State.
- We also proposed regional plan waivers at § 423.410(b).

d. Other Sections of the Proposed Rule.

The proposed rule also included § 423.420 (solvency standards for all entities receiving a waiver of State licensure); § 423.425 which proposed that an approved waiver does not deem the sponsor to meet other requirements for a sponsor under Part 423 of the regulations, and § 423.440, which proposed prohibiting State imposition of premium taxes and included the rules for Federal preemption of State law.

2. Waiver of Certain Requirements in Order to Expand Clhoice

The statute requires, at section 1860D–12(c)(3) of the Act, that the waivers granted under the provisions of section 1855 of the Act, as well as under section 1860D–12(c)(2)(B) of the Act, must also meet the conditions of approval established at section 1855(a)(2)(E), 1855(a)(2)(F) and 1855(a)(2)(G) of the Act. Accordingly, we implemented the procedures for approving a waiver in regulations at § 423.410(f). Please see our final regulations at § 423.415 and our discussion in section 2b of this preamble for requirements specific to entities wishing to offer a prescription drug plan in more than one State.

In proposed § 423.410(f)(1), we established that except in States without a licensing process for PDP sponsors and in the case of regional plan waivers described in proposed § 423.410(b)

(§ 423.415 in the final rule), a waiver applies only to a specific State and is effective for 36 months and cannot be renewed. In the final regulation we have made clarifying changes by adding new § 423.415 which is specific to regional plan waivers. As was proposed in § 423.410., in § 423.415(d) of the final rule we indicated that regional waivers are valid until the State has completed processing the application, but in no case can a regional plan waiver extend beyond the end of the calendar year for which it is received. We proposed implementing section 1855(a)(2)(F) of the Act at § 423.410(f)(2) by specifying that (except for regional plan waivers) we would grant or deny a waiver application under this section within 60 days after we determine that a substantially complete waiver application has been filed. We proposed that a substantially complete application would have to clearly demonstrate and document an applicant's eligibility for waiver. We also proposed, at § 423.410(f)(3) to implement 1860D–12(c)(3) by establishing that if we determine that a State does not have a licensing process for PDP sponsors, we will approve a waiver for a PDP sponsor that meets our solvency and capital adequacy standards and that this waiver would not be time limited

Comments and our responses to these waiver requirements follow.

We received several comments questioning, in general, the requirement allowing State licensure to be waived when the State applies grounds for licensure other than those required by Federal law. Below, in the comment and responses section we discuss the specific bases of these comments concerning preemption by Federal law, as well as other comments we received on the proposed requirements.

Comments: Several commenters supported limiting our interpretation of the preemption authority under State licensure requirements. One of these, from a State insurance department, stated that only non-profit organizations were eligible to apply under its State HMO licensure law. The commenter expressed concern that State licensure waivers could interfere with this State licensure requirement, since for-profit entities might be able to receive licensure waivers from CMS. Another commenter from a State insurance department expressed its hope that Federal waiver authority of State licensure would not stop a State from devising its own State approach to funding and financial management of PDPs within its jurisdiction.

Response: In the issues raised by these commenters concerning general licensing requirements we would need to evaluate a licensure waiver request using the standards specified in § 423.410 and § 423.415 of the regulations. If an applicant met one of these standards for waiver, we would grant the waiver, as the Congress required. This could mean, for example, that a for-profit entity, operating under a Federal waiver, does business in a State that offer HMO licenses only to non-profit entities. We believe allowing qualified plans to participate in a State or States is essential for establishing the new program and, among other things, ensuring access for beneficiaries to benefits and other requirements central to the prescription drug benefit.

Concerning the comment about State solvency standards, our regulations at § 423.410(b)(3)(i) and (b)(3)(ii) allow a waiver of State solvency and information requirements if the State requirements concerning these go beyond those specified by Federal law. We are finalizing our language from the proposed rule concerning these requirements as we believe that the intent of the statute is to ensure that entities wishing to offer prescription drug program in a State or States not be subjected to requirements beyond those required by Federal law.

Comment: Another organization requested that we specifically identify those PDP sponsors which are State licensed and those which have received a Federal waiver.

Response: We concur with the comment in principle that an organization that is not State licensed but under a Federal waiver be identified as such. As we develop additional guidance for the requirements of Part D, we will consider how best to convey such an identification. We do not believe, however, that it is necessary to include the identification in the requirements of this final rule.

Comment: A PBM requested that we clarify the rules for States without PDP licensure processes. The PBM proposed that if a State does not have a specific insurance license for prescription drug-only insurance plans, then this should be sufficient grounds for approval of the waiver by us.

Response: The approach that we have in adopted in § 422.372(b)(4) requires that the State licensing authority give the organization written notice that it will not accept its licensure application. Following this standard, we would require an organization to approach the State licensing authority for review and receive their decision prior to filing a request for waiver of State licensure under the provisions of this section.

Comment: A managed care organization and an alliance of cost contractors requested that we apply the licensure waiver rules to Medicare cost plans as well as to PDPs.

Response: Section 1860D–12(c) of the Act specifically addresses the waivers for prescription drug plans. We believe it would exceed our authority to extend these waivers to cost plans, which are not mentioned in section 1860D–12(c) of the Act. In addition, cost plans are governed by the licensure requirements in Part C and in part 422 of the regulations. This final rule is primarily addressed to the regulations in the new part 423 of 42 CFR. Therefore, we do not believe this final rule would be an appropriate place to adopt rules that affect part 422 and not part 423 of the regulations.

Comment: A Native American council requested that State licensure not be imposed upon a PDP that might be sponsored by the Indian Health Service or a tribal health program.

Response: We do not have the authority to add to the waivers included in section 1860D–12(c) of the Act. If a PDP sponsored by an Indian Health Service or tribal health program meets one of the waiver requirements in § 423.410, the PDP applicant should receive a waiver.

With the clarifying language noted we are, then, adopting our regulations concerning eligibility for waivers largely as proposed for § 423.401 and § 423.410.

3. Temporary Waiver for Entities Seeking to Offer a Prescription Drug Plan in more than One State in a Region § 423.115.

We implemented the regional plan waiver rule provided at section 1860D–12(c)(1)(B) of the Act in the regulations at proposed § 423.410. (In this final rule, we have created a new § 423.415 to clarify that the regional plan waivers are distinct from the single-State waivers, and often subject to different standards (for example, they endure only until the end of the contract period and not for 36 months). As we stated, this would allow us to use the proposed waiver authority at section 1858(d) of the Act and the temporary waiver would be available in the event a prospective PDP sponsor proposed that its prescription drug plan would cover a multi-State region, but was not yet licensed in all of the States. (Under those circumstances, we stated we could waive the State licensure requirement until the State had completed processing of the application.) In the interim, the PDP sponsor would be

required to comply with the solvency standards established by us. In the event the State ultimately denied the application, we stated that we could extend the waiver through the contract year as we deemed appropriate to provide for transition.

In the final rule we have clarified, with the addition the distinctions between the temporary waiver (for regional plans) and the waiver for entities seeking to offer a plan in a single State, the timeline for processing the application for the waiver and the length of the waiver itself. Thus in new § 423.415(c) we clarify that Secretary will determine the time period appropriate for the processing of the application and in new § 423.415(d), we repeat the policy of the proposed rule that in no case will the temporary waiver extend beyond the end of the calendar year.

4. Solvency Standards for Non-Licensed Entities (§ 423.420)

In proposed § 423.420, we specified that sponsors that have been granted a waiver by us must maintain reasonable financial solvency and capital adequacy.

Solvency standards have been developed after statutorily required consultation with the National Association of Insurance Commissioners. These standards are undergoing internal CMS review. We anticipate that these standards, which are required to be published by January 1, 2005 will be published on the CMS website in the near future in conjunction with the initial application forms for PDP organizations. These solvency standards will include such items as required minimum net worth and liquidity requirements as well as reporting requirements for future PDPs who have received waiver of State licensure. We are adopting the policy we proposed for reasonable financial solvency and capital adequacy in this final rule.

5. Preemption of State Laws and Prohibition of Premium Taxes (§ 423.440)

In the August 4, 2004 proposed rule, we stated that we would implement section 1860D–12(g) of the Act at proposed § 423.440(a), by specifying that to the extent there are Federal standards, those standards supersede any State Law.

We proposed that for purposes of Part D, with the exceptions of State licensing laws or State laws related to plan solvency, State laws would not apply to prescription drug plans and PDP sponsors.

The proposed rule for the Medicare Advantage program also discussed preemption of State laws, and because Part D and Part C incorporate the same preemption laws at section 1856(b)(3) of the Act, we believe it is necessary to summarize those discussions in this final rule.

In the Medicare Advantage proposed rule, we noted that prior to enactment of the MMA, section 1856(b)(3) of the Act provided for two types of preemption: general and specific. The presumption was that a State law was not preempted if it did not conflict with an M+C requirement, and did not fall into one of the four specified categories where preemption was presumed. (These four categories were: benefit requirements, including cost-sharing rules; requirements relating to the inclusion or treatment of providers; requirements concerning coverage determinations and related appeals and grievance processes; and requirements relating to marketing materials and summaries and schedules of benefits concerning M+C plans.)

We concluded that the MMA reversed this presumption and provided that State laws are presumed to be preempted unless they relate to licensure or solvency. We also referenced the Congress' intent that the MA program, as a Federal program, operate under Federal rules, and referred to the Conference Report of the MMA as making clear the Congress' intent to broaden the scope of preemption through its change to section 1856(b)(3) of the Act. See 69 FR 46866, 46904. We believe that because the Congress incorporated the same preemption standard into the Part D program, and because the Congress required the preemption rules to apply consistently in Parts C and D, this same reasoning would apply to Part D.

In addition, in the proposed rule for Part D, we stated that although the Congress included broad preemption rules in section 1856(b)(3) of the Act, we did not believe that the Congress intended for each and every State requirement applying to PDP sponsors to become null and void. Specifically, we stated:

> In areas where we have neither the expertise nor the authority to regulate, we do not believe that State laws would be superseded or preempted. For example, State environmental laws, laws governing private contracting relationships, tort law, labor law, civil rights laws, and similar areas of law would, we believe, continue in effect and PDP sponsors in such States would continue to be subject to such State laws. Rather, our Federal standards would merely preempt the State laws in the areas where the Congress intended us to regulate—such as the rules governing pharmacy access, formulary requirements for prescription drug plans, and marketing standards governing the information disseminated to beneficiaries by PDP sponsors. We believe this interpretation of our preemption authority is in keeping with principles of Federalism, and Executive Order 13132 on Federalism, which requires us to construe preemption statutes narrowly. (69 FR 46696.)

We also recognized that while the Congress specifically stated that State licensure and solvency laws would not be preempted, this did not mean that States could condition licensure on a sponsor meeting requirements unrelated to what we would consider licensure requirements. We also addressed this issue in the Medicare Advantage proposed rule, explaining:

> We believe that the exception for State laws that relate to ''State licensing'' must be limited to State requirements for becoming State licensed, and would not extend to any requirement that the State might impose on licensed health plans that-absent Federal preemption-must be met as a condition for keeping a State license. If a State requirement could be considered to relate to State licensing simply because the State could revoke a health plan's license for a failure to meet the requirement, this would mean that States could impose virtually any requirement they wished to impose without the requirement being preempted. ... Because we believe that it is clear that the Congress intended to broaden the scope of Federal preemption, not to narrow it, we also believe that the exception for laws relating to State licensing must be limited to requirements for becoming State licensed (such as filing articles of incorporation with the appropriate State agency, or satisfying State governance requirements), and not extended to rules that apply to State licensed health plans. (69 FR 46904.)

We are adopting these preemption interpretations as our final policy. We also note that in the accompanying regulation text we have replaced PDP sponsor with Part D sponsor, as we believe that the preemption of State law and the prohibition against imposition of premium taxes should operate uniformly for all Part D sponsors. We note that licensure requirements in this Part continue to apply only to PDP sponsors, as other Part D sponsors (such as MA organizations and cost-based HMOs and CMPs) are subject to their own licensing laws.

Comment: One large insurer felt that our narrow interpretation of the statutory preemption authority was contrary to the language of section 1856(b)(3) of the Act. This insurer requested that CMS consider making clear that all State laws and regulations (with the exception of State licensing and solvency laws) are preempted with respect to MA and Part D plans.

Response: As noted in the proposed rule, we do not believe that either the

principles of Federalism or the statute justify such a broad preemption interpretation. We do not believe, for example, we could preempt all State environmental or civil rights laws, nor do we believe it was the Congress' intent to do so. The preemption in section 1860D–12(g) of the Act is a preemption that operates only when CMS actually creates standards in the area regulated. To the extent we do not create any standards whatsoever in a particular area, we do not believe preemption would be warranted.

Comment: A pharmaceutical manufacturer and a pharmaceutical manufacturing association requested clarification from us that it is not our intent to preempt any State pharmacy laws dealing with the practice of therapeutic substitution.

Response: In general, we do not think we have the authority to preempt State pharmacy licensing laws dealing with the practice of therapeutic substitution and we do not intend to establish standards in this area. However, it should be noted that the forthcoming electronic prescription standards do have the potential to impact State pharmacy practices and such standards could preempt State pharmacy practice laws and regulations that conflict with them.

We are adopting the requirements of the proposed rule with the technical and clarifying changes noted throughout this preamble. We are also adopting the premium tax prohibition included in the proposed without modification. Both rules are found at § 423.440

J. Coordination Under Part D Plans with Other Prescription Drug Coverage

Proposed subpart J set forth the application of Medicare Part D rules to Medicare Part C plans; established waivers for employer-sponsored group prescription drug plans, MA-PD plans, cost plans, and PACE organizations; and established requirements for coordination of benefits with State Pharmaceutical Assistance Programs (SPAPs) and other providers of prescription drug coverage.

Below we summarize the proposed provisions of subpart J and respond to public comments. (Please refer to the August 2004 proposed rule (69 FR 46696) for a detailed discussion of our proposals.)

1. Overview and Terminology (§ 423.454)

Subpart J implemented sections 1860D–2(a)(4), 1860D–2(b)(4)(D), 1860D–11(j), 1860D–21(c), 1860D–22(b), 1860D–23(a), 1860D 3(b), 1860D–23(c), 1860D–24(a), 1860D–24(b), and 1860D–24(c) of the Act, as added to the Act by section 101(a) of the MMA. We proposed that, in general, the requirements of Part D generally apply under Part C for prescription drug coverage offered by MA-PD plans, although certain waivers are available. In addition, we implemented section 1860D–22(b) of the Act at proposed § 423.458(c) providing us the authority to waive the requirements of this part for employer-sponsored group prescription drug plans.

a. Part D Plans

Unless otherwise indicated, references to ''Part D plans'' in the proposed rule referred to any or all of MA-PD plans, prescription drug plans (PDPs) and fallback prescription drug plans. Likewise, the term ''Part D plan sponsor'' referred to MA organizations offering MA-PD plans, PDP sponsors, and eligible fallback entities offering fallback plans. We have moved the definition of ''Part D plan'' to § 423.4 of our final rule and expanded the definition such that it includes cost plans and PACE organizations offering qualified prescription drug coverage. Similarly, we have revised the definition of ''Part D sponsor'' under § 423.4 of our final rule to include cost plans and PACE organizations offering qualified prescription drug coverage.

b. Employer-sponsored Group Prescription Drug Plan

We used the term ''employer-sponsored group prescription drug plan'' to mean a prescription drug plan under a contract between a PDP sponsor or MA organization offering an MA-PD plan and employers, labor organizations, or the trustees of funds established by one or more employers or labor organizations (or combination thereof) to furnish prescription drug benefits under employment-based retiree health coverage.

c. State Pharmaceutical Assistance Program (SPAP)

We defined an SPAP, for purposes of this part, as a program operated by or under contract with a State if it:

(1) Provides financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of Part D eligible individuals;

(2) Provides assistance to Part D eligible individuals in all Part D plans without discriminating based upon the Part D plan in which an individual enrolls;

(3) Meets the benefit coordination requirements specified in this part; and

(4) Does not change or affect the primary payer status of a Part D plan.

Comment: Although one commenter supported our proposed definition of the term ''SPAP,'' several commenters urged us to allow SPAPs to endorse one or more Part D plans for SPAP enrollees. They believe that the non-discrimination criteria contained in the definition of the term SPAP should be designed to maximize the efficiency and effectiveness of offering benefits that supplement the benefits available under Part D coverage to enrollees. Some of these commenters believe that a preferred plan approach, if accomplished via a competitive bid process, supports the competitive, market-based model that the Congress envisioned. One commenter stated that such an approach would help it to ''ratchet down'' administrative costs. Another commenter asserted that the statute does not prohibit a State from providing consumer advice to its SPAP enrollees regarding which Part D plan might work best with an SPAP or offer the best value.

Commenters believe that this interpretation is consistent with the intent to establish an effective coordination mechanism between SPAPs and Part D plans. Defining non-discrimination in a way that prohibits SPAPs from designating preferred Part D plans and prohibiting auto-enrollment of SPAP beneficiaries into preferred plans would not facilitate enrollment in Part D plans and would further complicate, rather than promote, coordination between Part D plans and SPAPs.

Response: Section 1860D–23(b)(2) of the Act defines an SPAP, in part, as a program that ''in determining eligibility and the amount of assistance to Part D enrollees, provides assistance to such individuals in all Part D plans and does not discriminate based upon the Part D plan in which the individual is enrolled.'' We are interpreting the non-discrimination language in section 1860D–23(b)(2) of the Act and § 423.464(e)(1)(ii) of our final rule to mean that SPAPs, if they offer premium assistance or supplemental assistance for Part D cost sharing, must not only offer equal assistance to beneficiaries enrolled in all Part D plans available in the State, but also may not steer beneficiaries to one plan or another through benefit design or otherwise. We believe that the law intends that all Part D plans in a State be given comparable opportunities. Requiring States to coordinate with all Part D plans, without discrimination, levels the playing field for Part D plans that want to provide benefits in a particular State.

We further interpret section 1860D–23(b)(2) of the Act as prohibiting SPAPs from automatically enrolling (''auto-enrolling'') beneficiaries into a preferred

plan because this would, in effect, allow the SPAP to choose a Part D plan for the beneficiary. The non-discrimination provision is part of the definition of an SPAP. Thus, even if under State law a State is the authorized representative of its SPAP enrollees for purposes of enrolling them in a Part D plan elected by the State, if it auto-enrolls beneficiaries into a select plan, the State program will no longer meet the statutory definition of SPAP under section 1860D–23(b) of the Act.

This will jeopardize the program's special status with respect to true out-of-pocket (TrOOP) costs. That is, if a State does not meet the definition of an SPAP, its contributions to beneficiary cost sharing under a Part D plan do not count toward the TrOOP limit, after which a beneficiary is eligible for catastrophic coverage.

Section 1860D–23(d) of the Act provides for grants to SPAPs for the purpose of educating their members who are Part D eligible individuals about the options available to them under the Medicare drug benefit, including information comparing Part D plans in the State so that SPAP enrollees they can choose the Part D plan that provides them with the best value. We will reach out to SPAPs and provide them with information they can use to help their enrollees who are Part D eligible individuals better understand their Part D plan options. We will also assist SPAPs in their efforts to ensure that their members understand the manner in which the Part D plans in their State coordinate with their SPAP benefit. Our outreach to SPAPs will also include guidance on the various educational, outreach, and assistance activities SPAPs may undertake in a manner that will not discriminate among Part D plans, for example: (1) SPAPs can provide beneficiaries with objective and comparative education on all available Part D plans offered in the State; and (2) SPAPs can advise members on:

- which plans have lower beneficiary premiums than others (after application of any low-income premium subsidy under 423.782 of our final rule or premium subsidy offered by the SPAP, which must be applied uniformly without respect to which Part D plan an individual enrolls in),
- which plan formularies include the drugs currently utilized by the beneficiary,
- which plans offer the beneficiary the most favorable combination of deductibles, coinsurance, and negotiated prices for the drugs currently utilized by the beneficiary, and
- which plans' network pharmacies include the same pharmacies participating in the SPAP, and which plans (if any) include an emblem or symbol on their ID cards indicating their coordination with the SPAP to facilitate secondary payment at the point of service.

The nondiscrimination requirement also bars SPAPs from recommending Part D plans based on the SPAP's financial interest in minimizing the cost of providing benefits under the SPAP that supplement the benefits available under Part D coverage. In addition, to the extent an SPAP assists the enrollment into Part D of its members who fail to elect a Part D plan during their initial enrollment period or upon joining the SPAP, we encourage SPAPs to mirror our procedures for auto-enrollment of full-benefit dual eligible individuals into Part D plans, which will be done on a random basis.

Comment: One commenter asked us to clarify whether a hybrid SPAP with multiple components, some of which meet our definition of SPAP, and some of which do not, would render an entire SPAP ''unqualified'' under our definition.

Response: We agree that components of State programs that provide pharmaceutical assistance, provided they meet the definition of the term ''SPAP'' in § 423.454(e)(1) of our final rule, may provide benefits that supplement the benefits available under Part D coverage, and that such supplemental assistance for covered Part D drugs will count toward Part D enrollees' TrOOP limit (as defined in § 423.104(d)(5)(iii) of our final rule). Thus, for example, if an SPAP receives Federal program funding for certain enrollees (for example, HIV/AIDS patients) or for certain drugs (for example, vaccines or HIV/AIDS drugs), while the State covers drug costs for other SPAP enrollees or for other drugs, only those components of the SPAP program that receive no Federal program funds may be considered an SPAP. We do not see any reason why the existence of both qualified and non-qualified components of a SPAP would interfere with our ability to count the spending of the qualified SPAP toward TrOOP, as long as operations and funding are appropriately segregated.

Comment: Several commenters asked for clarification regarding whether State Kidney Programs, which are structurally similar to SPAPs, can be defined as SPAPs so that their benefits supplementing the benefits available under Part D coverage count toward their enrollees' TrOOP limit.

Response: Section 1860D–23(b) of the Act provides that an SPAP is a State program that provides financial assistance for the purchase or provision of prescription drugs, and we interpret this to mean that it provides assistance with State funds. Therefore, to the extent that all sources of program funding for a State Kidney Program's financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of Part D enrollees are 100 percent non-Federal and provided a program that meets the other criteria included in the description of an SPAP in § 423.464(e)(1) of our final rule, the program will be considered an SPAP. Any benefits provided by such a program that supplement the benefits available under Part D coverage would therefore count as an incurred cost toward the calculation of a beneficiary's TrOOP threshold.

Comment: One commenter asked us to clarify that a State can use any source of funds available to it (other than Federal funds) to finance any form of assistance to SPAP enrollees.

Response: We have clarified in § 423.464(e)(1) of our final rule that the term ''SPAP'' excludes any program under which program funding is from Federal grants, awards, contracts, entitlement programs, or other Federal sources of funding. However, the statutory definition of the term SPAP does not address program funding sources. We believe that a State program may still be considered an SPAP if some or all of its program funding is from private sources (for example, from charities or independent foundations). We also clarify that the exclusion of Federal program funding does not exclude some Federal administrative funding or incidental Federal monies (for example, the Federal grants to SPAPs provided for in section 1860D–23(d) of the Act).

In addition, to ensure SPAPs are funded in a manner consistent with the Congress' intent in the statute, we clarify that a ''State program'' under § 423.454 of our final rule must provide assistance based on financial need, age, or medical condition, and cannot do so based on current or former employment status. Under section 1860D–23(b) of the MMA, an ''SPAP'' is defined as a State program which provides financial ''assistance'' for supplemental drug coverage or benefits. The term ''assistance'' is defined in Webster's II dictionary as ''help'' or ''aid.'' We therefore interpret the word ''assistance'' to mean financial help or aid provided to any individual in need of such support—specifically,

individuals in financial need, the aged, or those with certain medical conditions. Thus, as provided in § 423.454 of our final rule, a ''State program'' is one that provides financial assistance for supplemental drug coverage to individuals based on financial need, age, or medical condition, but not based on current or former employment status.

Comment: One commenter suggested that our interpretation of the MMA should allow for the continuation and renewal at State discretion of the Pharmacy Plus waivers.

Response: Pharmacy Plus programs can continue with Federal match after January 1, 2006, under certain circumstances. Any State that operates a Pharmacy Plus demonstration program must determine whether it is feasible to continue that Pharmacy Plus program by submitting a revised budget neutrality calculation for the demonstration. As required in section III (10) of the terms and conditions of approval for Pharmacy Plus programs, this calculation must account for the reduction in Medicaid drug costs and a lesser diversion of dual eligible beneficiaries into the Medicaid program due to the implementation of Part D. We will review the revised budget neutrality calculation and approve or disapprove the continuation of the demonstration for the period after Part D is implemented.

2. Application of Part D Rules to Certain Part D Plans on and after January 1, 2006 (§ 423.458)

In accordance with section 1860D–21(c)(1) of the Act, and proposed at § 423.458(a) of our notice of proposed rulemaking, the provisions of Part D pertaining to the provision of qualified prescription drug coverage apply under Part C to prescription drug coverage provided by an MA-PD plan in lieu of other Part C provisions that would apply to such coverage, unless otherwise provided. Thus, Part D requirements not related to the provision of drug coverage (for example, licensing requirements) do not apply to MA-PD plans.

We indicated that we would waive Part D provisions to the extent that we determine that they duplicate, or conflict with, provisions under Part C, or as necessary in order to improve coordination of Part D benefits with the Part C program. In addition, we indicated that we would apply our waiver authority to cost plans and PACE organizations as proposed at § 423.458(d).

Except as otherwise provided below, the final rule adopts the provisions related to the application of Part D rules to MA-PD plans, as well as waivers of Part D requirements for MA-PD plans and cost plans, set forth in § 423.458(a), (b), and (d) of the proposed rule.

Comment: Two commenters suggested that waivers of Part D rules related to formulary requirements and pharmacy and therapeutic (P&T) committee requirements should not be allowed for MA-PD plans under the waiver authority provided in section 1860D–21(c)(2) of the Act, since there are no comparable provisions under Part C with which the Part D rules could conflict. Another commenter believed that waivers of Part D rules regarding coverage determinations and appeals should not be allowed under the waiver authority provided in section 1860D–21(c)(2) of the Act. Another commenter said that Part D appeals and grievances requirements should be waived for MA-PD plans to the extent they are not identical with Part C appeals and grievances requirements.

Response: Section 1860D–21(c)(2) of the Act requires the Secretary to waive requirements under Part D to the extent the Secretary determines they duplicate or are in conflict with provisions otherwise applicable under Part C, or they are necessary to waive in order to promote coordination of Part C and Part D benefits. In our proposed rule, we proposed implementing this authority in § 423.458(b). The clear intent of this provision was to recognize that the delivery of health care services covered under the original Medicare program under Part C takes precedence over the delivery of a drug benefit under Part D. Although the Part D drug benefit will become a vital part of the health care services offered by an MA-PD plan, to the extent that the Part D rules make it impossible for an MA-PD plan to effectively deliver Part C benefits, we will exercise Part D waiver authority to ensure that Part C benefits continue to be effectively delivered under § 423.458(b) of the final rule. We agree with the commenter that the three waivers specifically mentioned related to formulary requirements, P&T committee requirements, and the Part D appeals process will not be waived for MA-PD plans insofar as there are no conflicting provisions or rules under Part C that will make these Part D requirements impossible for an MA-PD plan to implement.

Comment: One commenter requested two specific waivers related to the Part D benefit offered by MA-PD plans. Specifically, the commenter requested a waiver of the pharmacy access standards in § 423.120(a)(1) of our proposed rule under similar conditions to the waivers we have permitted for MA plans related to the Medicare Prescription Drug Discount Card and Transitional Assistance Program. The commenter also requested a waiver of the requirement that MA organizations post their negotiated prices on our website, again saying that we had approved a similar waiver for MA plans that are exclusive card sponsors under the drug discount card program.

Response: In our proposed rule, we signaled our intention to waive pharmacy network access requirements described at § 423.120(a)(3) in the case of an MA-PD plan that provides access (other than through mail order pharmacies) to qualified prescription drug coverage through pharmacies owned and operated by the MA organization to the extent we determine that the network is sufficient to provide comparable access for enrollees of the MA-PD plan. In the subpart B preamble of our proposed rule, we discussed the information resources available through the Internet at *www.medicare.gov*. Although we discussed information available to Medicare-approved discount drug cards in that section of the preamble, we did not specifically signal our intention to provide identical information related to Part D plans. Therefore, it remains unclear that the second waiver would be necessary. More importantly, to the extent we discuss the required written waiver process in § 423.458(b)(2), (c)(1) and (d)(2) of our final rule, it is more appropriate at this time to direct the commenter to those sections of the rule than it is to speculate as to what waivers would, and would not, theoretically be allowed, if they were requested by an appropriate party.

3. Application to PACE Organizations

Section 1860D–21(f) of the Act indicates that Part D provisions shall apply to PACE organizations electing to offer qualified prescription drug coverage in a manner that is similar to those of an MA-PD local plan and that a PACE organization may be deemed to be an MA-PD local plan. As discussed in detail in subpart T, PACE organizations will not be deemed as MA-PD local plans, but will be treated in a manner that is similar to MA-PD local plans for Part D requirements applicable to the offering of qualified prescription drug coverage. Proposed § 423.458(d) established regulatory authority for us to waive Part D provisions for PACE organizations to the extent the provisions duplicate or conflict with a requirement under PACE, or the waiver is necessary to promote coordination of benefits under

PACE and Part D, and indicates that PACE organizations may request waivers from us.

The final rule adopts the rules regarding waivers of Part D requirements for PACE organizations set forth in § 423.458(d) of the proposed rule.

Comment: We received various comments regarding waivers of Part D requirements for PACE organizations.

Response: Please refer to subpart T of this preamble for a detailed discussion of these comments and our responses to them.

4. Application to Employer Groups

Section 1860D–22(b) of the Act extends the waiver authority that is provided for MA organizations related to Part C under section 1857(i) of the Act and implemented at § 422.106(c) of our proposed MA rule to prescription drug plans. This waiver authority is intended to provide employment-based retiree health coverage an opportunity to furnish prescription drug benefits to its participants or beneficiaries through Part D in the most efficient and effective manner possible.

We invited comment on the process we proposed for authorizing waivers for employer-sponsored group prescription drug plans. We also asked for comment on the manner in which additional waivers should be permitted and what additional waivers, if any, we should not allow.

Except as otherwise provided below, the final rule adopts the provisions related waivers of Part D requirements for employer-sponsored group prescription drug plans set forth in § 423.458(c) of the proposed rule.

Comment: Most commenters indicated a strong desire to obtain clear non-regulatory guidance addressing key issues in the waiver process prior to the final regulations being published. Commenters also urged us to adopt a process for employer waivers that gives employers maximum flexibility while minimizing administrative burden. Several commenters stressed the importance of providing waivers to facilitate employers becoming their own PDP or MA-PD plan for their retiree population. Several employers commented that under ERISA, State licensure requirements would not apply. Commenters also suggested waivers for the areas of network access, service area, marketing, disclosure, and enrollment.

Response: We are adopting a streamlined approach for implementing employer group waivers that allows maximum flexibility for employers to retain retiree prescription drug coverage. Details on waivers that we will and will not consider will be included in separate guidance. Additional waiver requests will be addressed on a flow basis.

Comment: One commenter requested clarification as to whether we will extend to cost plans (as defined under section 1876 of the Act) its waiver authority under section 1860D–22(b) of the Act.

Response: Section 1860D–21(e)(1) of the Act provides that only those provisions of Part D (and related provisions of Part C) pertaining to the offering of qualified prescription drug coverage by a MA-PD local plan would apply to the offering of the coverage by a cost plan. Because the employer waiver authority under section 1860D–22(b) of the Act pertains to the offering of qualified prescription drug coverage, we believe section 1860D–21(e) of the Act extends this waiver authority to cost plans. This will facilitate the retention of employer sponsored retiree prescription drug coverage under cost plans. However, the provisions of Part C and D that do not relate to the offering of qualified prescription drug coverage by cost plans, including the employer waiver authority under section 1857(i) of the Act, would not apply to benefits offered under a cost plan other than any qualified prescription drug coverage. Accordingly, we do not interpret these statutory provisions as permitting us to apply our waiver authority for employer-sponsored group coverage to Part A and B benefits offered under cost plans.

Comment: One commenter stated that a PBM or other third party administrator supporting an employer should be able to elect to solely serve employer groups without also being required to open enrollment to beneficiaries also in the service area but unaffiliated with the employer.

Response: We will include details in separate guidance on waivers that we will and will not consider. Section 423.458(c) of our proposed rule did not propose interpreting section 1857(i)(2) of the Act as permitting entities other than PDP sponsors and MA organizations from requesting employer group waivers, or contracting with us to offer an employer-sponsored group prescription drug plan. However, given the commenter's request for clarification, we note that § 423.458(c) of our final rule provides that any entity seeking to offer, sponsor, or administer an employer-sponsored group prescription drug plan may request a waiver or modification of Part D requirements. We will provide separate guidance regarding what entities we will contract with, as well as how we will contract with them.

5. Medicare Secondary Payer Procedures (§ 423.462)

Section 1860D–2(a)(4) of the Act extends the Medicare secondary payer (MSP) procedures applicable to MA organizations under section 1852(a)(4) of the Act and 42 CFR 422.108 to Part D sponsors and their provision of qualified prescription drug coverage. Section 1852(a)(4) of the Act provides that an MA organization may charge or authorize a provider to seek reimbursement for services from a beneficiary or third parties to the extent that Medicare is made a secondary payer under section 1862(b)(2) of the Act. Accordingly, we proposed at § 423.462 of our proposed rule that Part D sponsors are required to follow the same rules as MA organizations regarding:

- Their responsibilities under MSP procedures;
- Collection of payment from insurers, group health plans and large group health plans, the enrollee, or other entities for covered Part D drugs; and
- The interaction of MSP rules with State laws.

Comment: One commenter notes that MSP rules will apply to Part D and that section 1860D–12(g) of the Act extends State law preemption to Part D sponsors. This commenter believes that the MSP provisions extended to Part D sponsors should also apply to cost plans offering qualified prescription drug coverage. They argue that Part D is a Federal program and should be implemented by all Part D plans in accord with the same Federal rules and without regard to any State laws except those governing licensure and solvency.

Response: Section 1860D–21(e)(1) of the Act provides that those provisions of Part D (and related provisions of Part C) pertaining to the offering of qualified prescription drug coverage by a MA-PD local plan would apply to the offering of such coverage by a cost plan. Accordingly, the MSP provisions under section 1860D–2(a)(4) of the Act and the preemption provisions under section 1860D–12(g) of the Act are extended to cost plans for offering of qualified prescription drug coverage under the plans. However, the MSP and preemption provisions of both Parts C and D would not apply to benefits offered under a cost plan providing other than any qualified prescription drug coverage. Accordingly, we do not interpret these statutory provisions as permitting us to apply these provisions to Part A and B benefits offered under

cost plans. Cost plans are thus still subject to the MSP and State law preemption provisions under § 411.172 for their Part A and B benefits.

6. Coordination of Benefits with Other Providers of Prescription Drug Coverage. (§ 423.464)

Section 1860D–23(a) of the Act authorizes us to establish procedures and requirements to promote the effective coordination of benefits between a Part D plan and an SPAP with respect to payment of premiums and coverage, and payment for supplemental prescription drug benefits. The elements to be coordinated include enrollment file sharing, claims processing, payment of premiums for both basic and supplemental drug benefits, third-party reimbursement of out-of-pocket costs, application of protection against high out-of-pocket expenditures (defined in section 1860D–2(b)(4) of the Act), and other administrative processes and requirements that we specify.

We will establish procedures and requirements for Part D plans no later than July 1, 2005, to ensure effective coordination. In addition, as specified at section 1860D–24(a) of the Act, we will apply the requirements for coordination of benefits with SPAPs to Part D plans when they coordinate with entities providing other prescription drug coverage, including Medicaid (including a plan operating under a waiver under section 1115 of the Act), insurers, group health plans, the Federal Employees Health Benefits Program (FEHBP), military coverage (including TRICARE), and other coverage that we specify.

Section 1860D–24(a)(3) of the Act permits us to impose user fees to defray the costs of Part D coordination of benefits, but not on SPAPs under any method of operation, for the transmittal of benefit coordination information under Part D. We are also provided authority to retain a portion of these user fees to offset costs we incur for determining whether enrollee out-of-pocket costs are being reimbursed by third parties and for alerting Part D plans when, in fact, they are being reimbursed. In the proposed rule, we noted that any user fees, if collected, would not be assessed until the implementation of the Part D benefit in 2006. We requested comments regarding the method we should use to impose user fees, especially concerning whether it would be advisable to impose user fees on a monthly or quarterly basis based on the volume of data exchanged and whether we should require electronic payment of user fees.

As provided in section 1860D–24(c)(1) of the Act, Part D plans may continue to use cost management tools (such as tiered or differential cost sharing) even if an SPAP or other drug plan provides benefits that supplement the benefits available under Part D coverage for individuals enrolled in the Part D plan. In the proposed rule, we requested comments on how we could ensure that supplemental benefits offered by SPAPs and plans providing other prescription drug coverage would not undermine or eliminate the cost management tools established by Part D plans. We also solicited comments on the most effective way to administer this provision without creating undue administrative burden on either Part D plans or other prescription drug coverage that supplements Part D benefits.

Except as otherwise provided below, the final rule adopts the coordination of benefit provisions set forth in § 423.464 of the proposed rule.

Comment: One commenter indicated that our policies regarding coordination of benefits should ensure that this process is as administratively simple as possible, and that coordination of benefits rules are structured in a way that does not create incentives for beneficiaries to switch Part D plans mid-year in order to obtain better basic benefits.

Response: We agree and will keep this in mind as we work to develop requirements for coordination of benefits between Part D plans and SPAPs and entities providing other prescription drug coverage. We note, as well, that Part D enrollees may only switch Part D plans mid-year under the limited circumstances triggering a Special Election Period (SEP) in accordance with § 423.38(c) of our final rule.

Comment: One commenter indicated that while section 1860D–23 of the Act requires us to establish requirements for coordination of benefits beyond the tracking of TrOOP expenditures and claims payment (for example, for premium payment with SPAPs), they believe that coordination of benefits responsibilities should be limited for now to the tracking of TrOOP expenditures and claims payment. This commenter believed that an incremental approach is in the best interests of all parties, particularly since it is still unclear how many entities will choose to participate in or provide supplemental coverage to Part D.

Response: Section 1860D–23(a)(2) of the Act requires that benefit coordination elements include, at a minimum, enrollment file sharing, processing of claims, claims payment, claims reconciliation reports, and application of the protection against high out of pocket expenditures. We must comply with these statutory requirements in establishing our coordination requirements for SPAPs and other providers of prescription drug coverage, and it is in the best interests of Part D enrollees and plans that coordination activities begin as soon as possible. We do not believe that an incremental approach will be necessary, and we will be issuing further information on our coordination requirements and processes soon.

Comment: One commenter recommended that we establish a technical advisory group with representatives from the industry, including pharmacy software vendors and switching services, to develop coordination of benefits requirements for Part D plans to ensure effective coordination with SPAPs and other providers of prescription drug coverage. Another commenter recommended that relevant stakeholders, including pharmaceutical benefit managers, be consulted as we develop our requirements.

Response: As discussed in our proposed rule, section 1823(a)(4) of the Act requires us to consult with SPAPs, MA organizations, States, pharmaceutical benefit managers, employers, representatives of Part D eligible individuals, data processing experts, pharmacists, pharmaceutical manufacturers, and other experts in establishing our coordination of benefits requirements. To date, we have not only encouraged comments on this issue in our proposed rule, but we have also held many consultation sessions with these various stakeholders and an Open Door Forum on TrOOP and coordination of benefits. We will continue to meet with these parties as we develop our coordination requirements and processes.

Comment: One commenter stated that an unintended consequence of requiring Part D plans to collect information on incurred costs for purposes of tracking of TrOOP expenditures is that confidential negotiated pricing information will be released. This commenter thought that we should require Part D plans to collect SPAP payment information on ''incurred costs'' on a monthly or other periodic basis, in an aggregate form broken out per beneficiary, or require SPAPs to report the utilization information for enrollees for whom the SPAPs make payments for benefits that supplement the benefits available under Part D coverage, and for the Part D plans to

apply the price that would have prevailed had the plan been responsible for payment.

Response: While we acknowledge the commenter's concern regarding disclosure of negotiated pricing in the sharing of claims data, we must point out that we will require Part D plans to submit point-of-sale pricing data to us for display on a Part D version of Price Compare, so this data will become publicly available information anyway. However, we emphasize that the cost and price concession information submitted on true acquisition costs in the allowable cost reconciliation processes will not be disclosed, and that cost and price concession information submitted as part of the bid submission process will be protected to the extent it is confidential commercial information.

We wish to clarify that given that section 1860D–2(b)(4)(C)(ii) of the Act allows SPAP assistance for covered Part D drugs to count toward TrOOP, we do not expect that SPAPs will need to report paid claims data. TrOOP calculation will work by counting all amounts not paid by the Part D plan, unless such amounts are paid through group health plans, insurance or otherwise, or third party payment arrangements. Financial assistance with covered Part D drug costs provided by SPAPs on behalf of beneficiaries is assumed to be equivalent to payments made by the beneficiary and automatically counts toward TrOOP.

For calculation of a beneficiary's TrOOP expenditures, the Part D plan will count the full amount left over after it pays a claim until it receives notice through the TrOOP/coordination of benefits process that some amount should not count (for example, because it was paid by a group health plan, insurance or otherwise, or a third party payment arrangement). The plan will then subtract that amount from the TrOOP total. Thus, for example, if a beneficiary with spending between the deductible and the initial coverage limit has a prescription for a covered Part D drug that costs $100, a Part D plan that offers defined standard coverage will pay $75 and count $25 toward the beneficiary's TrOOP total. If the beneficiary has insurance coverage that pays $20, the Part D plan will receive the information through the coordination of benefits process and subtract $20 from the TrOOP total. However, financial assistance provided by SPAPs will be treated as though the beneficiary paid that amount, so the Part D plan will not need to distinguish between how much an SPAP and the beneficiary paid, respectively. Thus, the entire $25 copay (even though the SPAP paid a portion of it) counts toward TrOOP, and it is not necessary for the Part D plan to know how much of it the SPAP paid.

Comment: Multiple commenters asked that we not charge user fees for Part D coordination of benefits. Their arguments were that supplemental payers, particularly employers, would be more likely to drop benefits that supplement the benefits available under Part D coverage because we would be imposing burdensome administrative costs on them. One commenter also added that Part D coordination of benefits, in particular the tracking of TrOOP expenditures, is a feature designed to lower costs to Medicare, and so the government (that is, the ultimate benefactor of the coordination of benefits) should bear the administrative cost of coordination of benefits under Part D.

Commenters varied in their responses to the methods for imposing user fees. One commenter noted that if we were to procure a TrOOP facilitation contractor but could not have it running beginning in 2006, we could charge higher user fees to offset our higher administrative costs until the contractor was up and running and then switch to a lower fee thereafter. Another commenter proposed that a flat fee be used instead of a transmission volume fee because if volume were the basis of fee amounts, the fees would be too variable and would be too complicated to audit properly.

Commenters had different ideas about how frequently user fees should be levied if indeed we charge them. One commenter said that because most health insurance fees are collected monthly, we should continue this trend and also collect its fees monthly. Another commentator preferred a quarterly collection in order to reduce overhead associated with the payment process.

Response: We appreciate all the feedback provided by commenters regarding whether, and how, to assess user fees. We believe that while third-party payers of drug claims, pharmacies, and Part D plans will all benefit from the use of a coordination of benefits system that supports the tracking of TrOOP expenditures, Part D plans are the ultimate benefactors of the TrOOP process. Therefore, we expect that we will charge a user fee of no more than $1 per beneficiary per year to Part D plans, and we may be able to charge considerably less. We will issue further guidance regarding the method we will employ for assessing such user fees on Part D plans in separate guidance.

Comment: One commenter argued that we should interpret the language in section 1860D–11(j) of the Act to mean that Part D plans may not impose unnecessary or unreasonable user fees on SPAPs even when the fees are related to coordination of benefits. This commenter added that plans should factor coordination of benefits costs into their bids and that we should bear these costs. The commenter wanted us to establish a ''nationwide baseline requirement of coordination'' and only make States bear coordination costs if the costs were ''extraordinary,'' beyond the baseline, and ''related to the State's unique situation.'' The commenter asked that in such situations we negotiate such costs with the SPAP in question before a contract with a Part D sponsor is executed.

One commenter wanted us to clarify whether the provision at section 1860D–24(a)(3)(B) of the Act—which specifies that the Secretary may not impose coordination of benefits user fees on SPAPs—meant that only we are prohibited from charging such fees, or if the prohibition extended to Part D plans as well. If Part D plans are allowed to charge coordination of benefits user fees under this provision, the commenter asked for clarification regarding the basis upon which we would allow plans to charge the fees. They specifically mentioned cost-based fees, enrollment-based fees, and flat fees. The commenter also wanted to know whether the SPAPs would be allowed to verify or audit the imposition of such fees. Another commenter asked if we would monitor Part D plans to ensure that the user fees they imposed on SPAPs were reasonable and accurate. One commenter argued that Part D plans should be required to substantiate their actual costs in determining what to charge, in order to avoid unreasonable charges. The commenter argued that Part D plans should not be able to impose unrestricted fees on SPAPs.

Response: Section 1860D–24(a)(3)(B) of the Act prohibits us from imposing user fees on SPAPs for the transmittal of third party reimbursement information necessary for the tracking of TrOOP expenditures. However, section 1860D–11(j) of the Act specifies that a Part D sponsor offering a Part D plan must allow SPAPs and other prescription drug coverage (described in sections 1860D–23 and 1860D–24, respectively) to coordinate benefits with the Part D plan. In connection with such coordination, Part D sponsors cannot impose any user fees that are unrelated to the cost of coordination on SPAPs or entities providing other prescription drug coverage. We interpret this

language to mean that Part D plans may charge user fees to SPAPs and entities providing other prescription drug coverage, but only for costs that are related to coordination of benefits between Part D plans and SPAPs or entities providing other prescription drug coverage. Any user fees imposed must be reasonable and related only to the Part D sponsor's actual coordination of benefits costs.

Comment: One commenter states that we should prevent entities providing coverage that supplements Part D benefits from removing enrollee incentives to choose cost-effective options under their Part D coverage. The commenter further stated that we should prohibit coverage that supplements the benefits available under Part D coverage from eliminating cost-sharing or otherwise reducing these to the extent that they lack any force to deter unnecessary drug expenditures. The commenter also thought that the supplemental benefits should also not be allowed to change or eliminate the tiering of drugs on a formulary.

Another commenter thought that unless we interpret section 1860D–24(c)(1) of the Act narrowly, plans could be allowed to veto many forms of cost-sharing assistance and benefits that supplement the benefits available under Part D coverage that employers, SPAPs, or others might want to provide for enrollees in order to ensure that they have at least as good drug coverage as they have today. They asked that we tightly define ''prohibited'' practices that might impair cost-management tools and make clear that plans are required to coordinate with SPAPs and other prescription drug coverage unless they utilize these prohibited practices as identified by us.

Response: Section 1860D–24(c)(1) of the Act provides that the coordination of benefits requirements contained in section 1860D–23 shall not impair a Part D plan's application of cost-management tools (such as tiered or differential cost sharing, prior authorization, step therapy, and generic substitution), even if an SPAP or other drug plan provides benefits that supplement the benefits available under Part D coverage for individuals enrolled in the Part D plan. We do not believe that section 1860D–24(c)(1) of the Act gives us the authority to override Part D enrollees' benefit rights under SPAPs and other prescription drug coverage. For example, we do not have the authority to override an employer's contractual obligation to provide its retirees generous supplemental drug benefits. Thus, while Part D plans may freely apply their cost-management tools, we cannot require these supplemental payers to modify their cost-sharing and other coverage rules in order to maximize the effectiveness of the Part D plan's cost management tools. However, we expect that supplemental payers may have some interest in applying utilization management tools as well.

a. Coordination with SPAPs

The statute envisions close coordination of benefits between SPAPs and Part D plans. SPAPs have filled a significant gap in prescription drug coverage for many Medicare beneficiaries in the absence of a Medicare drug benefit. With many States currently providing prescription drug coverage to a large number of Medicare beneficiaries, it is important to ensure that coordination between Part D plans and SPAPs occurs as efficiently and effectively as possible. However, section 1860D–23(c)(5) of the Act provides that nothing in the statute shall be construed to require that an SPAP coordinate with or provide financial assistance to beneficiaries enrolled in Part D plans.

We assume that some SPAPs will pay Part D plans' premiums on behalf of their SPAP enrollees. For SPAPs that choose to simply supplement the coverage provided under a Part D plan, and to forego subsidizing their enrollees' monthly beneficiary premiums, we expect to include SPAP enrollment information in the coordination of benefits system. In this way, pharmacies will know that a claim should be sent to the SPAP following adjudication by the Part D plan. We requested comment on this proposed approach, including the feasibility of the approach for SPAPs and the ease of administration for pharmacies. We also requested comment on whether or not SPAPs that choose to coordinate benefits on a wrap-around basis should be required to provide feedback on how much of the remainder of the claim they have actually paid.

Comment: Several commenters suggested that the information that Part D plans will be required to share with SPAPs as part of their coordination requirements needs to be specifically incorporated in our final regulations. In particular, several commenters asked for clarification regarding how we will assist States with receiving timely data exchanges from commercial insurance plans, employer-sponsored plans, Part D plans, and MA programs for cost-avoidance and recovery. Some commenters believe this information should include, among other things, the exchange of eligibility files, the exchange of claims payment files, and information concerning which drugs are on the plan formularies. Furthermore, they believed such information should be provided through a real-time point-of-sale process. One commenter provided extensive recommendations regarding the data and methods by which Part D plans should provide information to SPAPs.

Response: We appreciate the extensive number of comments we received on this issue. As specified in section 1860D–23(a)(1) of the Act, we will issue requirements by July 1, 2005, for Part D plans to ensure the effective coordination between the Part D plans and SPAPs and other entities providing prescription drug coverage for payment of premiums and coverage and payment for supplemental prescription drug benefits. These requirements will specify the specific coordination elements that Part D plans must share with SPAPs and other prescription drug coverage.

We note that, from a practical perspective, there may not be much need for coordination between Part D plans and SPAPs, since Part D plans will need information about supplemental payments that do not count toward TrOOP rather than those that do count toward TrOOP (for example, those made by SPAPs). To the extent that SPAPs are free-standing supplemental plans, there may not be much need for coordination activities that a Part D plan could charge for, since claims will be adjudicated at the point of sale. As we note elsewhere in this preamble, Part D enrollees will be required to provide their Part D plan with information about third-party coverage so that the Part D plan is aware that any supplemental coverage a beneficiary is receiving is from an SPAP and not, for example, from a group health plan, insurance or otherwise, or other third party payment arrangements.

However, we acknowledge that SPAPs and States have an interest in acquiring timely access to paid claims data on SPAP enrollees who are also enrollees of State medical assistance programs in order to use information on prescription drug utilization in their medical and case management activities. We are continuing to work on means to practically expedite the required data sharing with SPAPs. In addition, although we do not have the authority to require data exchanges between Part D plans and the States, we strongly encourage Part D plans to independently share data on these shared enrollees with State Medicaid plans, provided such disclosure is consistent with the HIPAA Privacy Rule provisions for the sharing of protected

health information with another covered entity. To the extent consistent with the applicable provisions of Title XIX, if there were a cost to the State for access to this data, we would match as an administrative cost at 50 percent.

Comment: One commenter believes that we should provide States with flexibility to provide benefits that supplement the benefits available under Part D coverage so as to ensure that SPAP beneficiaries have continuous access to covered Part D drugs, even during the coverage gap.

Response: As provided in § 423.464(a) of our final rule, Medicare Part D plans may coordinate with SPAPs in a number of ways, including coordinating on a claim-specific basis when Part D plan pays first and the SPAP is the secondary payer, and this may include providing assistance after the initial coverage limit. As provided in section 1860D–2(b)(4)(C)(ii) of the Act, SPAP payments for benefits that supplement the benefits available under Part D coverage will count toward an enrollee's TrOOP limit, which we believe provides SPAPs with an incentive to supplement Part D benefits on behalf of Part D enrollees, including paying part of a beneficiary's drug costs after the beneficiary has met the initial coverage limit (as defined at § 423.104(d)(3) of our final rule) under their Part D plan.

Comment: Several commenters were concerned that the coordination of prescription drug coverage between Part D plans and SPAPs and other prescription drug coverage will fall onto pharmacists. Pharmacists would have to file multiple claims to bill both the primary and secondary payers. They urged us to address these concerns when developing the coordination of benefits system.

Response: In consultation sessions we held with various groups, including pharmacies and companies that run pharmacies, they expressed a willingness to perform multiple transactions in order to bill both the primary and any secondary payers as necessary in order to get billing and payment right the first time. Furthermore, if the pharmacy does not perform a secondary transaction with the SPAP, the beneficiary must pay everything left after the Part D plan pays. Beneficiaries who qualify for SPAP coverage generally do so because they are low-income; thus, being required to pay up front themselves and bill the SPAP for later reimbursement is likely to be a heavy financial burden that may make it impossible for some of these enrollees to purchase their prescription drugs.

b. Coordination with Other Prescription Drug Coverage

As provided under section 1860D–24(a)(1) of the Act, Part D plans must also coordinate with the following entities providing other prescription drug coverage: (1) Medicaid programs (including a State plan operated under a waiver under section 1115 of the Act, such as a Pharmacy Plus waiver); (2) group health plans, as defined in 29 U.S.C. 1167(1); (3) the Federal Employee Health Benefits Program (FEHBP) under chapter 89 of title 5 of the United States Code, (4) Military Coverage (including TRICARE) under chapter 55 of title 10 of the United States Code; and (5) other prescription drug coverage as we specify.

In the proposed rule, we requested comments regarding situations that might involve coordination of benefits between States and Part D plans (other than situations in which a State is acting as an employer). We also invited comments on the other administrative processes and requirements that we might identify in order to facilitate coordination of benefits between Part D plans and entities offering other prescription drug coverage.

Comment: Two commenters requested that we clarify that States are prohibited from requiring pharmaceutical manufacturers to pay rebates on medications delivered to beneficiaries through Part D plans. Several other commenters thought that States should continue to be able to benefit from drug rebates related to drugs purchased by the SPAP as a supplemental benefit to SPAP enrollees enrolled in Part D plans.

Response: Given that the Medicaid rebate program does not apply to SPAPs, we do not have the authority under the MMA to regulate or impose prohibitions on drug rebate or drug pricing negotiations between SPAPs and manufacturers.

c. Coordination of Benefits

Sections 1860D–23(a)(1) and 1860D–24(a)(1) of the Act require that by July 1, 2005, we establish requirements for coordination of benefits between Part D plans and SPAPs and other insurers providing prescription drug coverage. The elements that are to be coordinated must include: enrollment file sharing; claims processing and payment; claims reconciliation reports; application of the protection against high out-of-pocket expenditures (by tracking TrOOP expenditures); and other processes we specify.

We considered whether a drug denied Part B coverage because the beneficiary fills the prescription at a pharmacy that does not have a Medicare supplier number should be considered a Part D drug (provided such drug otherwise meets the definition of a Part D drug), and requested comments on the relative likelihood of such an occurrence and on alternative means of addressing such circumstances.

For drugs potentially covered by Part B that are dispensed by a pharmacy that is not a Medicare supplier, we considered the development of automatic cross-over procedures. (Similar cross-over procedures are used today in connection with dual-eligible individuals entitled to both Medicare and Medicaid and related to coordination between Medicare and supplemental insurers.) We also mentioned a potential need for similar cross-over procedures for any physician-administered drugs that may be covered under Part B or Part D. Our proposed rule invited comments on both these issues.

Comment: Several commenters suggested that we allow drugs and biologicals that would otherwise be covered under Part B to be covered under Part D when a beneficiary obtains the drug at a pharmacy that has no Medicare supplier number. One commenter believed that our failure to do so could greatly hinder enrollee access to therapies for which Part D benefits should be available. In addition, allowing coverage of such drugs under Part D would facilitate the coordination of benefits process we have proposed. Another commenter asserted that these drugs and supplies are necessary for vulnerable populations at high risk. One commenter believed it would circumvent the Medicare statute to cover drugs only under Part B or Part D and would also impose a penalty in the form of higher out-of-pocket expenses on beneficiaries.

Response: While we understand the impact this could have on some beneficiaries, we do not believe that commenters have provided a compelling rationale for automatically covering drugs under Part D that are denied coverage under Part B because a beneficiary fills the prescription at the wrong pharmacy. Under section 1860D–2(e)(2)(B) of the Act, a drug is excluded from coverage under Part D to the extent that coverage for that drug is available to an individual under Parts A or B. In this case, coverage would have been available under Part B had the enrollee obtained the drug at a participating Medicare pharmacy.

To reduce the risk that beneficiaries do not lose Part B coverage by filling a prescription at a pharmacy that does not have a Medicare supplier number, we will: (1) encourage Part D plans to enroll pharmacies with Medicare supplier

numbers in their networks; (2) encourage Part D plans to inform beneficiaries whether their network pharmacies have a Medicare supplier number, and explain why this is important when filling prescriptions for drugs potentially covered by Part B; and (3) develop educational materials reminding pharmacies without Medicare supplier numbers that they must refund any payments collected from beneficiaries enrolled in Part B for Part B drugs unless they first notify the beneficiary (through an advanced beneficiary notice (ABN)) that Medicare likely will deny the claim.

Statutory ''refund requirements'' apply to claims for ''medical equipment and supplies'' that Medicare denies because the supplier lacked a supplier number (unless the beneficiary signed an ABN notifying him or her that Medicare will deny payment, and agreed to be personally responsible for payment), or the supplier did not know and could not reasonably have known that Medicare would deny payment. For this purpose, coverage of medical equipment and supplies includes durable medical equipment (DME), certain drugs and other supplies necessary for use of an infusion pump, oral immunosuppressive drugs and anti cancer drugs, and ''such other items as the Secretary may determine.'' (See the Medicare Claims Processing Manual, Chapter 30, sections 150.1.3 and 150.1.5.) Suppliers are presumed to know that Medicare will not pay for medical equipment and supplies furnished by a supplier that lacks a supplier number. (See section § 150.5.4 of Chapter 30 of the Medicare Claims Processing Manual.)

Comment: Several commenters urged us to provide guidance regarding how vaccines not covered under Part B will be covered under Part D, including reimbursement for their administration. One commenter encouraged us to arrange for Part B carriers to serve as the point of contact with physicians for purpose of payment by Part D plans for vaccine administration.

Response: As discussed in subpart C, vaccines (and other covered Part D drugs that are appropriately dispensed and administered in a physician's office) administered in a physician's office will be covered under our out-of-network access rules at § 423.124(a)(2) of our final rule, since Part D plan networks are defined as pharmacy networks only. A scenario under which a Part D enrollee must obtain a Part D-covered vaccine in a physician's office constitutes a situation in which out-of-network access would be permitted because a beneficiary could not reasonably be expected to obtain that vaccine at a network pharmacy.

Below, we use vaccines as an example of how out-of-network access to covered Part D drugs dispensed and administered in physician offices will work under Part D. However, it is worth noting that other covered Part D drugs that are appropriately dispensed and administered in a physician's office will be subject to the same treatment under our out-of-network access rules. As mentioned in subpart C, we expect the application of our out-of-network access rules to covered Part D drugs dispensed and administered in physician offices to be limited.

Costs directly related to vaccine administration may be included in the physician fees under Part B, since Part B pays for the medically necessary administration of non-Part B covered drugs and biologicals. However, there is currently no ready mechanism for physicians to bill Part D plans for vaccine costs. Requiring physicians who administer such Part D-covered vaccines to submit a claim to the appropriate Part B carrier would involve developing automatic cross-over procedures such that, if the carrier denies the claim under Part B, it would submit the claim to the TrOOP facilitation contractor, discussed elsewhere in this preamble, which would in turn create an electronic claim that it would send automatically to the Part D plan (or its claims processing agent) through which the enrollee has Part D coverage. The Part D plan would then pay the physician for the plan allowance for that vaccine.

While it is possible that we could eventually develop automatic cross-over procedures, we are concerned that establishing the cross-over procedures by January 1, 2006, will be onerous given many other systems and implementation challenges that must be addressed by then. Therefore, we believe that a two-step approach is the most appropriate policy. In the short-term, a Part D enrollee may self-pay the physician for the vaccine cost and submit a paper claim for reimbursement to his or her Part D plan. We note that this will not be necessary for enrollees of MA-PD plans, since medical and pharmacy benefits will be integrated. This approach is consistent with how beneficiaries accessing covered Part D drugs at an out-of-network pharmacy will be reimbursed by Part D plans for costs associated with those drugs. Once Part D is implemented, we will get a better sense for the actual volume of Part D-covered vaccines and other physician-dispensed and administered Part D drugs, and the need and most appropriate mechanisms for such automatic cross-over procedures.

We note that, to the extent that the amount charged by a physician for a Part D-covered vaccine and the plan's allowable cost for that vaccine vary, a beneficiary may be responsible (depending on the plan's out-of-network payment policy) for any out-of-network differential, as is the case with other covered Part D drugs obtained out-of-network.

d. Collection of Data on Third Party Coverage

Section 1860D–2(b)(4)(D)(ii) of the Act permits Part D plans to request information on third party insurance from beneficiaries. We expect Part D plans to update Medicare records based on the information provided by beneficiaries to reflect changes in coverage, including the primary or secondary status of the coverage relative to Medicare. Beneficiaries who materially misrepresent information about third party coverage may be disenrolled from any Part D plan for a period specified by us and may also be subject to late enrollment penalties upon subsequent enrollment in another Part D plan.

Section 1860D–2(b)(4)(D)(i) of the Act authorizes us to establish procedures for determining if costs for Part D enrollees are reimbursed by other payers, and for alerting Part D plans about such arrangements. In our proposed rule, we also considered mandating that beneficiaries enrolling in Part D plans provide third-party payment information and consent for release of data held by third parties as part of their enrollment application and which could be validated through a HIPAA-compliant beneficiary ''release'' or authorization. We clarify, however, that a HIPAA authorization to disclose protected health information to Part D plans for purposes of coordination of benefits related to reimbursement for health care for an individual is not required for third party payers that are covered entities under HIPAA, since such disclosures are considered ''payment'' disclosures under the HIPAA Privacy Rule.

Comment: One commenter believes that we should impose mandatory reporting requirements on third-party payers regarding the payment of out-of-pocket costs and that, as an incentive, the user fees charged to third-party payers could be adjusted depending on their degree of cooperation in providing TrOOP cost data. This commenter also thought we should require enrollees to provide third-party payment information in a standardized way as part of the enrollment process. Another

commenter suggested that the collection of third party enrollment data be incorporated into the application process as it is with the Medicaid eligibility determination, which requires a mandatory release of information by the beneficiary. One commenter agreed that beneficiaries must provide third-party payment information and consent to release of data held by third parties, which could be validated through a HIPAA-compliant beneficiary release or authorization.

Response: The Act does not give us an enforcement mechanism in the statute to impose mandatory reporting by third-party payers. However, as provided in § 423.32(b)(ii) of our final rule, we will require beneficiaries enrolling in or enrolled in a Part D plan to provide, in a form and manner that we will specify in separate guidance, third-party coverage information. Part D enrollees must also consent to the release of such information collected or obtained from other sources. Failure of beneficiaries to provide such information may be cause for termination of Part D coverage, as discussed in greater detail in subpart B.

We would like to clarify that in the event that a beneficiary does not disclose alternative coverage payments to the Part D plan, that plan has the authority to recover any payments made in error on the basis of incorrect assumptions about the level of TrOOP expenditures. The plan may recover these payments directly from the beneficiary on whose behalf the payments were made. We have modified § 423.464(f)(2) of our final rule and added paragraph (f)(4) to clarify this authority.

e. Tracking True Out-of-Pocket (TrOOP) Costs

In the proposed rule we considered a number of options for facilitating the exchange of data needed in order for Part D plans to track a beneficiary's TrOOP costs, and discussed alternatives around both mandatory versus voluntary reporting of claims and out-of-pocket costs, and centralized versus distributed responsibility for tracking the information in the. We considered two options for operationalizing the data exchange related to the Part D coordination of benefits system and TROOP accounting:

Option 1: The Part D plans will be solely responsible for tracking TrOOP costs.

Option 2: We will procure a TrOOP facilitation contractor to establish a single point of contact between payers, primary or secondary.

Additionally, to foster proper billing and coordination of benefits we also considered the establishment of the Medicare beneficiary eligibility and other coverage query system using the HIPAA 270/271 eligibility query and requested comments concerning the development of this system.

Comment: An overwhelming majority of commenters on the issue of tracking TrOOP costs supported Option 2—having us procure a TrOOP facilitation contractor to establish a single point of contact between primary and secondary payers. Generally, commenters thought that a single point of contact option would lead to standardization and compatible formats among payers, as well as a cost-efficient and effective means for providing accurate, consistently interpreted, and timely information to all parties involved in operationalizing Part D. One commenter stated that PBMs do not calculate this data and would therefore be forced to build a new system for performing coordination of benefits functions and tracking multiple payers. One commenter thought that exchange of data between payers and us must be administered efficiently and timely, and using technology and standard processing already well established in the pharmacy industry to promote online pharmacy benefit management. This commenter also urged us to require Part D plans to routinely provide enrollment updates to the TrOOP facilitator, including all data needed by payers to coordinate benefits, as well as to develop an oversight task force consisting of all parties involved in developing user requirements for the data system. Another commenter urged us to include community retail pharmacies in its single point of contact system, thereby considerably increasing the efficiency and effectiveness of this option for tracking TrOOP expenditures. One commenter supported our establishing a central clearinghouse similar to that used for Medicare Parts A and B, and another recommended that we streamline current coordination of benefits procedures so that they can be accommodated in a new TrOOP/coordination of benefits system.

Several commenters thought that tracking TrOOP expenditures in real time might not be feasible immediately after implementation of the Part D but should be a long or medium-range goal. One commenter thought we should limit our coordination of benefits responsibilities to tracking TrOOP and claims payment and reevaluate our options at a later date when it becomes clearer how different parties will participate in or interact with Part D. Another commenter urged us to establish interim rules that are administratively workable and do not impose compliance burdens or risks. Only one commenter thought that we should rely on Part D plans to track and report TrOOP amounts rather than involve an intermediary or TrOOP facilitation contractor.

Response: PDP and MA/PDs will be responsible for calculating TrOOP for all individuals enrolled in their plan. When a beneficiary has no supplemental coverage, TrOOP can be easily calculated. This is because the plan has all the necessary data within the claims it processes to calculate TrOOP. TrOOP is more complicated to compute when the supplemental coverage is through a ''free standing'' plan that wraps around Part D.

The overwhelming majority of responders felt that CMS must have some facilitation role in terms of TrOOP. We are considering facilitating the tracking of TrOOP in many ways, including: through the establishment of a TrOOP facilitation contractor, contractors, or blends of other suggested methods. Our goal is to facilitate the tracking of TrOOP by leveraging the existing coordination of benefit processes for Part D COB and TrOOP. This will include the collection of other payer information that can be used by Part D plans as part of the ongoing Medicare Secondary Payer processes. This process will be modified to include information as to whether these alternative payers that are primary to Medicare include coverage for prescription drugs. We will also expand the existing trading partner processes for Parts A and B supplemental wrap-around agreements to provide for the collection of supplemental drug plan information. In situations where an employer retiree wrap-around plan is currently wrapping around Medicare Part Parts A and B, this will require that a small amount of additional information be collected as part of the trading partner agreement to ensure coordination with the primary Part D plan. Under this strategy only one enrollment file would be required. (Employers, plans or payers may choose to submit separate enrollment files for Parts A and B crossover and Part D.) Only one file is required because this data will be maintained in the CMS Medicare beneficiary database.

SPAPs can choose this method of enrollment file sharing as well. Under this strategy an SPAP or employer will not have to create a separate enrollment file for each Part D plan. Data collected through these processes will be shared with the Part D plans. In addition to our data collection efforts, the Part D plan will also request information from beneficiaries on the presence of other

coverage that is primary or secondary to Part D, and will then have the ability to add, change, or delete information about other coverage in plan and CMS files.

We will also work with pharmacy providers, payers, PBMs and other affected parties to create an acceptable solution to facilitate situations where the pharmacy is lacking information in order to bill the appropriate payer. It is our hope that our solution will include, among other capabilities, an online eligibility file query function so the pharmacy may obtain information sufficient to direct a claim to the payer responsible for payment of a beneficiaries' claim.

We continue to work with industry on a solution to facilitate the TrOOP tracking process. A final decision on how best to address TrOOP process challenges will be released well before the July 1, 2005 statutory deadline. We are looking for a solution that will allow TrOOP to be calculated in as close to real time as possible.

Comment: One commenter recommended that we establish a standard for the transmission of TrOOP information since there is currently no HIPAA standard for the transmission of coordination of benefits information between payers in connection with pharmacy transactions. In addition, this commenter recommends that we establish a national identifier for payers and, with the help of the Congress, for patients as soon as possible in order for coordination of benefits to function most effectively.

Response: We intend to establish an efficient and effective process for handling coordination of benefits and tracking of TrOOP expenditures by the Part D plans in accordance with Federal laws and CMS guidelines.

Comment: Several commenters thought that Part D sponsors should be responsible for tracking TrOOP and that enrollees should not be held accountable to the extent that another plan providing prescription drug coverage does not act. Another commenter suggested that in circumstances in which the information maintained by the TrOOP facilitation contractor is not consistent with what an enrollee claims to be the case at a pharmacy, benefits should be administered based on data in the system at that time. The Part D plan should correct the errors afterwards, as it is the plan's ultimate responsibility to administer the benefit. The Part D plan could, for example, create a flag in the system noting that the enrollee believes his or her payment obligation is in error because of incorrect data; this flag would result in notification to a plan so that the potential error can be investigated and resolved. Another commenter thought that Part D plans should not be responsible for tracking TrOOP costs when the plan is not aware of a third party payer.

Response: Part D plans will always be responsible for correctly calculating TrOOP for their Part D enrollees. In the event that enrollees fail to provide information about other prescription drug coverage to their Part D plans, and the Part D plan later discovers that payments were made by a third-party payer, it must recalculate TrOOP and, if necessary, recover overpayments. We agree that, at the point-of-sale, the Part D plan's current information will always be the basis for its payment; a beneficiary's disagreement with such information can only be resolved by contacting the plan. At the pharmacy, the beneficiary must either pay the amount specified or decline to purchase the prescription until after the dispute is resolved. We note that in the course of normal operations, the status of beneficiary liability will fluctuate due to events such as failure to pick up prescriptions or corrected transactions, and that current pharmacy benefit management systems will automatically recalculate beneficiary liability after the updating of information in their systems. Consequently, any over- or under calculation of TrOOP will automatically be adjusted on the next claim once correct information has been received.

K. Application Procedures and Contracts with Part D Sponsors

1. Overview

Subpart K of part 423 implements section 1860D 12(b) of the Act. This subpart sets forth requirements for contracts with Part D plans, including application procedures, contract terms, procedures for termination of contracts, and reporting. We note that while Medicare Advantage (MA) organizations offering Part D plans are Part D plans, they follow the requirements of part 422 for MA organizations, except in cases where the requirements for the qualified prescription drug coverage involve additional requirements (for example, the fraud and abuse requirements specified in § 423.504(b)(4)(vi)(H) and the certification requirements in § 423.505(k). Although in the proposed rule we included the requirements of section 1860D–12(b)(2) prohibiting a fallback from acting as a PDP sponsor or a subcontractor to a PDP sponsor in subpart F of the regulations, we believe these requirements are more appropriately viewed as contract requirements, and not as bid requirements; therefore, we have moved those regulations to this subpart.

As in the proposed rule, this subpart sets forth the conditions necessary for an applicant to be considered qualified to contract with Medicare as a Part D sponsor, as well as contract requirements and termination procedures that would apply to Medicare-contracting Part D sponsors. The final rule specifies those procedures and requirements. Additionally, as we stated in the proposed rule, the applicable requirements and standards included in Part D of Title XVIII of the Act and our provisions under part 423, as well as the terms and conditions for payments described in regulation and in the statute, also apply to ''fallback plans'' found under subpart Q.

In this final rule, we clarify that any entity offering a Part D plan under the Medicare program is considered a Part D plan sponsor for the purposes of this subpart. In addition to PDPs that offer fallback plans, Part D plan sponsors can also include MA organizations that offer MA-PD plans, cost plans, and competitive medical plans (CMPs), as well as PACE organizations that offer Part D plans.

We clarify that entities offering Part D plans under Medicare must follow the provisions of this subpart unless requirements specifically pertaining to these entities in this final regulation include or allow for a waiver of these requirements. Similarly, we also clarify, as is the case with MA organizations and cost plans offering prescription drug plans, that these organizations follow the requirements of part 422 for MA organizations except when there are additional requirements in part 423 related solely to the prescription drug benefit component of the MA plan (In these cases, MA organizations offering the prescription drug benefit are directed by part 422 to any additional requirements in part 423.).

As further clarification of the exceptions to, or waiver of, requirements of this subpart, please note, for example, that PACE programs, though subject to part 423 if offering a prescription drug benefit, may waive several of the contract requirements under part 423. PACE programs are unique in that they have a Medicaid component and have been offering a prescription drug benefit for some time. As a result, some of the part 423 requirements are duplicative or not applicable. (Please see subpart T for discussion of the PACE program and the prescription drug benefit under Part D.)

In our definitions section at § 423.4 we include, as clarification, the entities

identified above in our definition of ''Part D plan sponsor.''

The proposed rule discussed at § 423.153(e) requirements for a program to control fraud, waste and abuse as required by Section 1860D–4(c)(1)(D) of the Act. In an effort to consolidate the requirements, we are moving them to this subpart at § 423.504(b)(4)(vi)(H) as a component of a Part D sponsor's or MA organization offering a MA-PD plan's overall compliance plan. In the preamble to this subpart, we will discuss our final provisions and the comments we received on the proposed requirements concerning fraud, waste, and abuse. For easier reference, we discuss this section at the conclusion of this preamble.

Further, as stated in the proposed rule, the MMA requires that the MA contracting provisions incorporated through section 1860D–12(b)(3) of the Act be applied to contracts with PDP sponsors in the same manner as those provisions apply to contracts with MA organizations under Part C of Title XVIII of the Act. Our overarching intent in the proposed rule, and our intent in the final rule, is to achieve a high degree of uniformity in the contract and application processes for both Part C and Part D. The maintenance of a single application and evaluation procedure, and a single set of contract requirements for both the Part C and Part D programs, brings simplicity, consistency, and reduced administrative burden for those entities managing both programs. Towards that end, the requirements under § 423.501 through § 423.516 are similar to the requirements in § 422.500 through § 422.524. We made every effort to keep the requirements in this subpart the same as those requirements for MA organizations; this effort was received without objection by any of the commenters; however, we did receive some comments asking us to clarify if certain sections were exclusive to PDP sponsors and inclusive of MA plans. In this preamble we address those and other comments.

2. Definitions (§ 423.501)

We proposed that the definitions pertaining to PDP sponsors and MA organizations offering MA-PD plans would be the same as those found in § 422.500, except in cases where the Part C definition is inapplicable (for example, in definitions that reference hospitals or hospital services). In addition, as mentioned above, we have added the definition of ''Part D plan sponsor'' to § 423.4 to clarify that we consider any entity offering a Part D benefit to be a Part D sponsor and, with the exception of requirements that may be waived. We have made nomenclature changes throughout the regulations text for this subpart as well, revising ''PDP sponsors'' in most cases to ''Part D plan sponsors'' to bring this language into line with our definition at § 423.4 and to indicate more clearly that a Part D sponsor includes any entity offering a Part D plan.

The majority of the subpart K regulations would also apply to fallback entities, since fallback entities are included in the definition of Part D sponsor. In addition, under § 423.871(a), fallback contracts are required to include the same terms of conditions as risk contracts, except as appropriate to carry out the provisions of subpart Q. We have also clarified the provisions that would not apply to fallback entities. For example, because fallback entities do not renew their 3-year contracts on a yearly basis, we have clarified that the renewal and non-renewal provisions would not apply to fallback entities. Fallback entities are also not required to be risk-bearing entities, and at this time we are not requiring that the licensure or solvency requirements of subparts I and K apply to fallback entities, although we may reconsider this issue in the future and we may use holding applicable licenses as a preferred, but not required selection criterion. We have clarified these provisions in the accompanying regulation text in § 423.504(b)(2).

We did not receive any comments regarding the proposed definitions for this subpart and will be adopting the policies proposed in the proposed rule.

3. Application Requirements (§ 423.502)

We proposed application procedures based on those included for the Part C program. Interested applicants would need to complete and submit a certified application in the form and manner required by CMS. In addition, we proposed that applicants must: (1) submit documentation of appropriate State licensure; (2) submit documentation of State certification that the entity is able to offer health insurance or health benefits coverage that meets State specified standards as discussed in the proposed subpart I; or (3) submit a Federal waiver as described in the proposed subpart I of the proposed rule. An individual authorized to act on behalf of the entity applying to become a Part D sponsor must describe thoroughly how the entity meets the requirements of the rule. We will determine if the applicant is qualified to contract with CMS as a Part D sponsor and if that entity meets the requirements of part 423. Also, we proposed that, as in the Part C program, an applicant submitting material that the applicant believes would be protected from disclosure under the Freedom of Information Act (FOIA) (5 U.S.C. § 522), or because of exceptions provided in 45 CFR Part 5 (the Department's regulations providing exceptions to disclosure), would have to label the material ''privileged'' and include an explanation of the applicability of an exception described in 45 CFR Part 5.

Comment: We received one comment stating that we were silent on the transition application requirements for current MA organizations wishing to add a prescription drug component to their MA plans.

Response: The application requirements for current MA organizations, and potential MA organizations wishing to offer MA-PD plans, will basically mirror those listed here for other Part D sponsors. In other words, MA organizations offering MA-PD plans and other entities offering Part D plans will, subject to any specified exceptions, follow the same requirements. Technically, MA organizations are following these requirements as specified at part 422, while other Part D plans are following these requirements at part 423. One difference between the requirements at part 422 and those at part 423 is the provisions for fraud and abuse which apply only to entities offering Part D benefits. In this case, the MA organization offering Part D benefits is directed at part 422 to follow the additional requirements specified in part 423 regarding its prescription drug benefits. In general, however, the application and contracting provisions in part 422 and part 423 are identical. Thus, while the MA-PD contract is separate from the PDP contract under Part 423, the requirements of this part will be incorporated, with any exceptions specified, into the contract of the MA organization offering an MA-PD plan. Specific transition guideline procedures will appear on the CMS Web site and through other CMS guidance to ensure that the transition to the prescription drug benefit under Part D works as smoothly as possible. Similar guidance will given to M+C organizations wishing to make the transitions to MA organizations.

To clarify further the transition to the MA-PD plan, for organizations interested in offering a MA-PD plan, we are, whenever practicable, keeping the contracting application and process the same for PDP sponsors and MA organizations. Medicare Advantage contractors will be required to apply for qualification to offer a Part D plan as

part of their MA application if their organization is a new participant in the MA program. If the MA organization is transitioning from a previous Medicare managed care contract, the Part D application will simply be a stand-alone submittal. MA organizations can expect the Part D portion of the MA application to be an abbreviated version of the PDP sponsor application, as the regulation and the Act at section 1860D–21(c)(2) of the Act, allow CMS to waive provisions that are duplicative of, or in conflict with, MA requirements or where a waiver would be necessary to improve coordination of Part C and Part D benefits.

Comments: In the application process under § 423.502(d), we proposed that a PDP sponsor applicant may request to have submitted material protected from public view under the Disclosure of Application Information under the Freedom of Information Act. A commenter recommended that we make it clear that an entire application of a potential PDP sponsor may not be protected in this manner. Also, the commenter requested that we set standards for when and why exemptions would be approved or provide a list of what is, and is not, protected from disclosure.

Response: The final rule, while not specifying 'how little' or 'how much' of an application may be protected, does require the applicant submitting material under FOIA to include an explanation of the applicability of an exemption specified in 45 CFR Part 5. The exemptions specified here serve as the standard for 'when' and 'why' an application in part, or whole, would be protected. Price and cost information provided by the bidders marked as ''confidential'' or ''proprietary'' will generally be protected by the Trade Secrets Act. However, FOIA requires the agency to disclose data to a requester if the information does not fall within any of the FOIA's exemptions. We would need to consider whether the pricing and cost data are covered by FOIA Exemption 4, which protects trade secrets and commercial or financial information obtained from a person that is privileged or confidential. See 5 U.S.C. § 552(b)(4). To facilitate this process, submitters of information to the Department may designate part or all of the information as exempt under FOIA Exemption 4 at the time the records are submitted or within a reasonable time thereafter. See 45 CFR 5.65(c). When there is a request for information that is designated by the submitter as confidential or that could reasonably be considered exempt under Exemption 4, the Department is required by its FOIA regulation at 45 CFR 5.65(d) and by Executive Order 12,600 to give the submitter notice before the information is disclosed. When notice is given, in order to determine whether a submitter's information is protected by Exemption 4, the submitter must show that: (1) disclosure of the information is likely to impair the government's ability to obtain necessary information in the future; (2) disclosure of the information is likely to cause substantial harm to the competitive position of the submitter; or, (3) the records are considered valuable commodities in the marketplace which, once released through the FOIA, would result in a substantial loss of their market value. (This is the general Exemption 4 legal standard used for required submissions to the government.) A submission may be ''required'' if it is necessary to get the benefits of a voluntary program (for example, applying to be a Part D plan sponsor).

4. Evaluation and Determination Procedures for Applications to Be Determined Qualified to Act as a Sponsor (§ 423.503)

Under proposed § 423.503, we established procedures to evaluate and determine an entity's application for a contract as a Part D plan sponsor. These provisions mostly mirrored the provisions applicable to MA specified at § 422.502 of our proposed requirements for MA organizations. We stated that the evaluation and determination of the application would be done on the basis of information contained in the application itself, as well as any additional information we obtained through on-site visits, publicly available information, and any other appropriate procedures. We also proposed rules regarding the timing of the application process, as well as the window for applicants to cure an incomplete or faulty application. See 69 FR 46709. Comments on these provisions are discussed below.

Comment: Several comments were received asking us to produce the final regulations as early as possible in January 2005 and to streamline our application process in a way that that does not increase administrative burden for MA organizations wishing to apply to offer MA-PD plans or for other Part D plan sponsor applicants. A commenter stated that the timing of the contracting (and bidding) and appeal process would afford too short a time frame for applicants to make the June 6 bidding deadline specified in subpart F. One commenter pointed out that the timelines for appeals by other Part D sponsors and MA organizations (that is, the timelines specified in parts 422 and 423) varied widely, and would cause unnecessary confusion and administrative burden. Two comments were received asking that we allow the contract determination process and the bid application process to run concurrently.

Response: We thank commenters for these comments and, in response, we are specifying in the final rule that we will be allowing applicants to enter into the bid process without an executed contract, and that the application and bid processes will run concurrently. Note that the bid application process will include both new bids to initially participate as a sponsor, as well as renewal bids. The contract will be pre-qualified and left unsigned until a successful bid negotiation has been approved by CMS. We will not award a Part D contract to an applicant until the applicant's bid is approved.

The contract application process and the bidding process as detailed under subpart F are separate but dependent processes. We view the bid application process as a negotiation and the contract process as a determination of an entity's qualifications to provide the Part D benefit. We have revised this final rule to make clear that the application process under subpart K determines only whether an applicant is qualified to contract as a Part D plan sponsor. However, actually signing the contract will require a successful bid negotiation as described under subpart F. Thus, although an entity may be pre-qualified to enter into a contract, a contract may not be signed if CMS and the entity cannot reach agreement on the bid.

We believe distinguishing between the bidding and the contract application processes carries out the intent of the Congress in section 1860D–11(d)(2) of the Act, under which the Congress provided the Secretary with the authority to ''negotiate the terms and conditions of the proposed bid . . . and other terms and conditions of a proposed plan'' and to exercise authority similar to that provided to the Office of Personnel Management under 5 U.S.C. Chapter 89. The bid negotiation will focus on the aspects of the bid and the benefit package to be provided by the Part D plan sponsor, while the contract application process will determine whether the entity offering the benefit package has the capability to contract with us under Part D. In addition, because the bid process is envisioned as a negotiation, only the contracting process under subpart K will be subject to the determinations and appeals process described in subpart N of these regulations. In order

to clarify the language concerning this distinction, we have revised our proposed rule to include new § 423.503(c)(2). Whether or not the entity and CMS are able to reach agreement on the bid and the benefit package will not be subject to subpart N. Indeed, we do not believe that the Congress intended for the bid to be appealable under these administrative provisions, because subjecting the bid to these appeals would frustrate our ability to calculate a national average premium in time for the annual enrollment period starting November 15 of each year. (We expect to have calculated the national average premium by at least August so that the beneficiary premiums, which are based on the national benchmark, can be published in time for open enrollment.)

Furthermore, taking bid negotiations out of the subpart N reconsideration process encourages plans to negotiate in good faith, as plans will realize that failure to negotiate will not lead to an opportunity to appeal, thereby maintaining the integrity of the negotiation process. We believe these changes to the contracting application and determination process will allow qualified candidates more time to prepare for CY 2006.

Additionally, we will be making the various timelines for appeals of determinations under subpart N of part 422 (Part C) and subpart N of part 423 (Part D) equivalent to eliminate any confusion and to shorten the contract application process.

Comment: In the proposed rule, we asked for comment on allowing 10 days for an incomplete application to be cured by an applicant from the date of the incomplete notice, and noted that the MA provision in § 422.502(a)(2)) currently provides a 30-day window for the MA program to furnish missing information. We also proposed a 10-day time frame for responding to an intent to deny. We received comments suggesting that the differing timelines between the Part D plan and MA organization appeal timelines (that is, the requirements specified in parts 422 and 423) were confusing in general and expressing concern with the relatively short timeline for the contract application process.

Response: We remain committed to providing successful applicants a reasonable time to be prepared to begin operations by the first of the year in their selected service area(s). However, we also wish to ensure all potential applicants are given every chance to contract with CMS.

In the event that we determine that an application is incomplete, we afford a means for the applicant to cure the contract application. However, the bidding process required under the MMA makes the use of the 'rolling application' system previously used under the Medicare Advantage and Medicare+Choice programs impracticable. As a result of the new bid calculation requirements for Part C and Part D, we need to process all final bids by a certain deadline each year. Therefore, we needed to apply a similar deadline to the application review process.

In order to respond to concerns that the determination application process as it was proposed could compromise a Part D plan sponsor's ability to effectively prepare for the beginning of a contract period, we are making the following modifications: We are no longer considering § 423.503(a)(2) as a separate and distinct step in the review process. If an applicant's contract is submitted and found to be both incomplete, as well as unqualified, (resulting in an intent to deny notice) the period to remedy the application will be 10 days from the date of the notice. Additionally, if after the initial review of applications, we determine that an application is missing information necessary for us to make a determination, we will make all reasonable efforts to notify the applicant that this is the case. This is not a requirement, however, and we are stating in the final rule that our procedural rule will be that applicants receiving notification that their application is incomplete, but who have not yet received an intent to deny notice, respond back to CMS with a cured application within two days of receiving the notice (instead of the ten days originally proposed). The two days are, thus, a guide; however, we are ultimately constrained by the total amount of time it will have to review applications. As a result, an applicant that takes longer than two days to remedy its incomplete application risks our issuing a notice of intent to deny before the Applicant submits the requested information. In cases where an Intent to deny notice has been issued, either as a result of missing information, information that would lead us to deny the application, or both, the applicant has ten days from the date of the notice to remedy the application. We believe that the amount of time given to applicants to furnish information is a procedural rule that is not subject to notice and comment. In addition, applicants will still receive the same 10 days included in the proposed rule to revise their applications if they fail to respond within 2 days, and then receive an intent to deny notice from us.

These changes to the application timelines mirror the changes we have included in the final rule for MA organizations. We believe that maintaining a single application and evaluation procedure and a single set of contract requirements for both the Part C and Part D programs brings simplicity, consistency, and reduced administrative burden for those entities that are managing both programs.

5. General Provisions (§ 423.504)

In the proposed rule, we stated that the requirements of § 423.504 would specify the general provisions that apply to Part D sponsor contracts. For more details on those proposals please see 69 FR 46709–11. For the most part, we stated that we planned to adopt the provisions that already applied to MA organizations through the Part 422 regulations. As part of these general provisions, we proposed mandatory self-reporting requirements and asked for comments on the provisions. Finally, we noted that we would annually audit the financial records (including, but not limited to, Medicare utilization, costs, reinsurance cost, low-income subsidy payments, and risk corridor costs) of at least one-third of the Part D plan sponsors, including fallback plans. We asked for comments on the best approach to audit fallback plans and whether they would require more frequent auditing because of their different payment arrangements. In the proposed rule, we also specified that we would use the authority of section 1857(c)(5) of the Act (incorporated through section 1860D–12(b)(3)(B) of the Act) to enter into Part D plan sponsor contracts without regard to the Federal and Departmental acquisition regulations set forth in title 48 of the CFR. We did not receive any comments regarding fallback plans audit methods, but did receive some comments on auditing in general, which are discussed in more detail below.

Comment: One commenter thought that PBMs should be prohibited from charging pharmacists a fee for submitting claims, as this has become customary in the private sector, and some PBMs have increased their fees for claims submission substantially. Some commenters said plans should not be allowed to tie Medicare business to other commercial business through an existing ''all products'' clause or passively enroll pharmacies in Medicare drug plan networks; rather, plans should be required to sign a Medicare-specific contract with each pharmacy, or at least get a written response from each

pharmacy confirming its participation. One commenter suggested that plans be allowed to set a limited sign-up period in which pharmacies can take advantage of the standard contract.

Response: Concerning the comment that PBMs not be allowed to charge pharmacists a fee for submitting claims, we believe that the intent of the statute is to let market forces prevail within the regulatory provisions outlined in the MMA and this final rule. In other words, if a PBM charges a relatively high fee to participating pharmacies to process claims, then it follows that a PBM would have difficulty securing contractual arrangements with a sufficient number of pharmacies to meet ''access'' requirements under Part D.

As to the comments concerning Medicare-specific contracts, our primary goal is to ensure access to Part D drugs for Medicare beneficiaries. To the extent a contract is reasonably construed by both parties to ensure access to Part D by Medicare beneficiaries, the contract is deemed sufficient.

Comment: As noted in the proposed rule, we proposed changing the compliance program requirements for MA organizations at § 422.501(b)(3)(vi)(G) to include provisions that would require MA organizations to report misconduct it believes may violate various criminal, civil or administrative authorities. We based the compliance program requirements for Part D plan sponsors on these new and recently proposed MA requirements. Numerous comments, both for and against, were received regarding these requirements of mandatory self-reporting of misconduct. The very large majority of the comments, however, objected that the rule as written was vague and broad, with no basis in statute. Other comments directed us to eliminate the proposal, stating that current compliance requirements were sufficient.

Response: In response to these comments, we are eliminating from this regulation an explicit requirement that Part D plan sponsors report to CMS violations of law, regulation, or other wrongdoing on the part of the organization or its employees/officers. While we are not requiring Part D plan sponsors to engage in mandatory self-reporting, we continue to believe that self-reporting of fraud and abuse is a critical element to an effective compliance plan; and we strongly encourage Part D plan sponsors to alert CMS, the OIG, or law enforcement of any potential fraud or misconduct relating to the Part D program. If after reasonable inquiry, the Part D plan sponsor has determined that the misconduct has violated or may violate criminal, civil or administrative law, the Part D plan sponsor should report the existence of the misconduct to the appropriate Government authority within a reasonable period, that is, within 60 days after the determination that a violation may have occurred.

The failure to disclose such conduct may result in adverse consequences for PDP sponsors, including criminal prosecution. For example, Title 42 U.S.C. Section 1320a–7b(a)(3) punishes as a felony the knowing failure to disclose an event affecting the initial or continued right to a benefit or payment under the Medicare program. The Federal civil False Claims Act, 31 U.S.C. Section 3729(a)(7) states that any person who knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government, is liable to the United States for a civil penalty plus trebled restitution for the damages sustained by the government. In addition, both DOJ and the OIG have longstanding policies favoring self-disclosure.

In summary, we have elected to recommend reporting fraud and abuse as part of the compliance plan required as a condition of contracting as a Part D plan sponsor. Plans that self-report violations will continue to receive the benefits of voluntary self-reporting found in the False Claims Act and Federal sentencing guidelines. In the future, we will examine mandatory self-reporting of health care fraud and abuse across all Medicare providers and contractors.

Comment: A commenter questioned the need for proposed § 423.505(h), which would require Part D plan sponsors to comply with certain specific Federal laws and rules, other laws applicable to recipients of Federal funds, and all other applicable laws and rules. The commenter argued that these requirements were on their face seemingly inconsistent with our regulatory provisions exempting Federal plans from procurement standards and preempting State laws other than those relating to licensure. Furthermore, nothing suggests a rationale for naming some laws and not others. The commenter also suggested that the provisions might more appropriately be replaced with one focused on plans committing themselves to compliance with Federal standards aimed at preventing or ameliorating waste, fraud, and abuse.

Response: We agree that our efforts are best focused on requirements to prevent fraud, waste, and abuse in the Part D program and on issues for which we are responsible to enforce (for example, the HIPAA Administrative Simplification rules).. We have, therefore, made the suggested changes to reflect this focus. These changes are in no way meant to imply that Part D plan sponsors need not comply with other Federal laws and regulations as applicable, but rather only that the enforcement of these Federal laws and regulations is the responsibility of Federal agencies other than CMS. We have made a similar change in the Medicare Advantage regulation.

Comments: We received four comments asking that we add an annual audit to proposed § 423.504(d) (protection against fraud and beneficiary protections). Commenters requested stronger language to clarify that we will perform an annual audit as part standard oversight procedures. One commenter referred to a $1.1 million penalty imposed on a company found to be switching patients from lower priced generics to more expensive brands. Two comments requested that we add language to the final rule that reads: ''CMS must audit annually...'' (as opposed to reading ''CMS may audit annually.''). (emphasis added), not 'may.'''

Response: Section 1860D–12(b)(3)(C) of the Act requires CMS to implement the provisions of section 1857(d) in the same manner as those provisions that apply to contracts under Part C of the Medicare program. Section 1857(d)(1) of the Act specifies that the Secretary will audit ''at least one-third'' of organizations. Therefore, in this final rule, we will continue to adopt the regulations used in the MA program under which we would expect to audit one-third of contracted plans each year. If additional audits are necessary, we would have the discretionary authority to perform them as well under § 423.505(e)(2)(iii).

Comment: A commenter asked that we require plans to contract with, and provide service through, long-term care pharmacies and Indian Health Service, Tribal or Urban Indian pharmacies. Additionally, we should carefully monitor and report on access to drugs for nursing home residents and ensure equal access to prescription drugs for those residents.

Response: We are including this issue here because some readers might look for clarification in this subpart. However, we believe that this issue is more appropriately discussed in the context of pharmacy networks and therefore refer interested readers to a

discussion of this comment in subpart C of this final regulation.

Other than the above changes, we are adopting the substance of proposed § 423.504.

6. Contract Provisions (§ 423.505)

In the proposed rule we stated that, for the most part, we would be adopting the additional contract provisions for the MA program with modifications as necessary to accommodate differences between the MA program and the prescription drug program. For a full discussion of our proposals, please see 69 FR 46711–713. We noted that elsewhere in the proposed rule, we identified additional contract terms that would apply uniformly to MA organizations offering MA-PD plans and other Part D plan sponsors (for example, the requirement to support e-prescribing). These rules continue to be included in the final rule at subpart D.

Comments: In § 423.505(d), we proposed requiring record maintenance and retention for six years, stating that records should be kept ''for the current year and 6 prior years.'' This requirement mirrored the record retention requirements from the MA program. A commenter stated that this should be changed to read, ''6 prior contract periods,'' stating that this would better clarify that the retention requirements do not precede the execution of the contract. An additional request was made to clarify whether the retention periods also refer to MA-PD plans. Another commenter asked that we clarify our retention of records to include all pertinent documents (whether in paper or electronic form). That commenter also asked that our records retention policy parallel the statute of limitations that applies to False Claims Act (that is, a maximum of 10 years from the time of the violation).

Response: We agree with the commenter that our retention requirements should more closely follow the statute of limitations that applies to the False Claims Act. As a result, in the final rule at § 423.505(e)(4), we are requiring that records be maintained for 10 years from the last contracting period or audit, whichever is latest, to conform to the statute of limitations for the discovery of violations under the False Claims Act.

We recognize that 10 years is the upper limit under the False Claims Act, but we believe that this period will best enable us to have access to pertinent records should this be necessary. Also, the 10-year retention policy is in line with requirements concerning the prescription drug rebates under the Medicaid program (§ 447.534(h)). We believe, as is the case with the Medicaid rule, that in order to ensure that we have the proper oversight for investigating the complex payment and other relationships associated with the delivery of prescription drugs under a program like Part D, the 10-year retention requirement is necessary. In order to maintain uniformity between requirements for MA organizations and other Part D sponsors, we are making a similar change to the final MA regulations.

We do not agree with the commenter, however, that we specify the particular medium of records (paper or electronic, for example)that must be retained. Specifying the type of record could lead to a requirement that is unnecessary, lengthy, and confusing with CMS attempting to list every type of medium (past, present, and future) that could contain any information. We do believe, however, that all pertinent information should be maintained, including any and all electronic records.

In response to the comment requesting that ''6 prior contract periods'' be specifically identified as opposed to ''6 years'' for the record retention requirement, we continue to specify years in this final rule (though 10 years, now, to parallel the statute of limitation for the False Claims Act) as we believe there may be occasions when a Part D sponsor during a prior period was under contract with us, ceased operation, and, at a later time, contracted again with Medicare. Specifying contract periods in these cases could make for a partial record of information and prevent us from having full access to the information over the period in question.

Comment: In § 423.505(l), we proposed six certifications that would be required of PDP sponsors. Although we refer readers to the regulations for a full discussion of these certifications, generally stated, they include certifying that—

(1) All data related to payment is accurate, complete and true;

(2) Each enrollee is validly enrolled in the prescription drug plan;

(3) The claims data submitted is accurate, complete and truthful;

(4) The information in the bid submission and assumptions related to projected reinsurance and the low income subsidy is accurate, complete, truthful, and conforms with the regulations;

(5) The information provided for purposes of supporting allowable costs for purposes of calculating risk corridor and reinsurance payments is accurate, complete, truthful, and fully conforms to the regulations; and

(6) The data submitted for price comparison is accurate, complete, and truthful. These certifications were based on the certifications required under the MA program, but were modified to reflect the different payment mechanisms under the Part D program. A commenter requested that we revise these six certifications and provide general authority for requiring the certifications. The commenter requested that we remove the specific language related to the content of the certifications in order to provide CMS with flexibility in the start-up phase of MMA, and to make it easier to integrate the Part D certifications with the Part C certifications.

Response: As we have done elsewhere, we largely based the certification process for Part D on the Part C requirements for MA organizations. We do this because of the similarity in scope of both programs, as well as the familiarity many will have with the MA process. However, the Part D program differs in some payment respects from the Part C program. Thus, while the MA regulations currently require a certification of data included in the ACR, the Part D regulations similarly require a certification of the information included in the bid submission. Also, because there are additional payment mechanisms under Part D (for example, risk corridors and reinsurance) that do not exist for Part C, we believe it is appropriate to require certifications for these separate types of payment. If at the time it is found that additional, or alternate, certifications are required we have the discretion to change them through notice and comment rulemaking. The final rule requires that the CEO or CFO of a Part D sponsor, or an authorized individual, request payment of claims on a document that certifies (based on best knowledge information and belief) the accuracy, completeness and truthfulness of all data related to payment. We highly recommend that Part D sponsors collect certification from their downstream partners as well. Further, if claim data is generated by a related entity, contractor, or subcontractor of a PDP sponsor, the entity, contractor, or subcontractor would be required to similarly certify (based on best knowledge, information, and belief) that the information provided for purposes of supporting allowable costs, as defined in § 423.308, is accurate, complete and truthful, and fully conforms to the requirements in § 423.336(c) and § 423.343(c).

Comment: A commenter recommended that we explicitly state that the certification provisions of

§ 423.505(l) apply not exclusively to PDPs, but also to MA organizations offering MA-PD plans as well.

Response: We note that the certification provisions under § 423.505(l) apply to all Part D plan sponsors as defined earlier in this section and in the definitions section at § 423.4.

In § 423.505(f)(2)(vii) we have added examples of other matters where CMS may require statistical data and information from PDP sponsors to further clarify these ''other matters that CMS may require.'' For an effective oversight program, for example, CMS may require PDP sponsors to submit statistics and information regarding performance of operations in the following areas:

(a) Experience and capabilities.
(b) Licensure and solvency.
(c) Business integrity.
(d) Benefit design.
(e) Service area and regions.
(f) Pharmacy network.
(g) Enrollment and eligibility.
(h) Exceptions, appeals, and grievances.
(i) Quality assurance and utilization management.
(j) Medication Therapy Management Programs.
(k) HIPAA.
(l) Customer service and satisfaction.
(m) Coordination of Benefits (COB).
(n) Tracking Out-of-Pocket Costs (TrOOP).
(o) Marketing and beneficiary communications.
(p) Provider communications.
(q) Control of fraud, abuse, and waste.
(r) Claims processing.
(s) Other performance measures as specified in guidelines provided by CMS.

7. *Effective Date and Term of Contract (§ 423.506)*

In the proposed rule, we specified the term of non-fallback contracts (12 months) and specified that contracts could be renewed from year to year, but only in the event that we inform the Part D plan sponsor that a renewal is authorized, and only if the Part D plan sponsor does not provide us with a notice of intent not to renew. We stated that we would not require an application process for renewals, and that because of the need to establish a national average monthly bid amount from the approved bids, PDP contracts could not be effective at any time other than the first of the year. We received no comments on these provisions and are adopting the policies as stated in the proposed rule on this section. We have changed the regulations to clarify the distinction between the bidding and the application processes. As discussed previously in this subpart, the revisions indicate that the renewal process leads only to a determination that a sponsor is qualified to renew its contract and that the actual renewal of the contract will depend upon whether CMS and the sponsor are able to reach agreement on the bid.

8. Nonrenewal of Contract (§ 423.507)

In the proposed rule, we indicated provisions concerning the non-renewal of a Part D plan sponsor's contract. Under proposed § 423.507, we required that a Part D plan sponsor not renewing its contract provide us with notification in writing by the first Monday of June in the year in which the contract ends. The Part D plan sponsor would also have to notify each Medicare enrollee at least 90 days before the date on which the nonrenewal is effective. This notice would have to include a written description of alternatives available for obtaining Medicare prescription drug services within the PDP region, including MA-PD plans, and other Part D plans, and would have to receive our approval. The general public would also have to be notified at least 90 days before the end of the current calendar year by publishing a notice in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.

We proposed that if a Part D plan sponsor chose to non-renew a contract as described in § 423.507(a)(3), we would not enter into a contract with the organization for 2 years unless circumstances warranted special consideration, as determined by CMS. For purposes of this section, we stated that we may elect not to authorize renewal of a contract for any of the reasons listed in § 423.509(a)(conditions for terminating a contract) or in subpart O (including § 423.752 (bases for imposing intermediate sanctions or civil money penalties.))

We proposed providing notice of our decision whether to authorize renewal of the contract to the PDP sponsor by May 1 of the contract year. In the event we found after May 1st that a plan for whatever reason should not be renewed the following year, we stated that we retained the right to terminate the Part D plan sponsor contract at any time based on any of the reasons stated in § 423.509, regardless of whether we renewed a Part D plan sponsor contract. If we decided not to authorize a renewal of the contract, we stated we would provide notice to the Part D plan sponsor's Medicare enrollees by mail at least 90 days before the end of the current calendar year. We also stated we would notify the general public at least 90 days before the end of the current calendar year by publishing a notice in one or more newspapers of general circulation in each community or county located in the PDP sponsor's service area. We stated that we would give the Part D plan sponsor written notice of its right to appeal the decision that it was not qualified to renew its contract in accordance with proposed § 423.642(b).

We received a few comments on this section which we discuss below. In the final rule we are adopting the provisions of the proposed rule with some minor modifications (in particular to clarify that a decision to non-renew a contract constitutes a determination that a contractor is not qualified to renew its contract).

Comment: One commenter indicated that allowing for only four months (January 1st—May 1st) for us to decide whether or not to renew a Part D plan contract provides an inadequate amount of time for us to make an informed decision.

Response: We must make the determination that a contractor is not qualified to renew its contract by May so that we can know if an organization will be entering a bid, and also so that we may calculate the benchmarks for that particular area. If, after the deadline for CMS non-renewal passes, we uncover additional information causing us to question the qualifications of the contractor to continue serving as a Part D plan sponsor, we have a range of options available under this subpart, as well as under subpart O. (For example, we could impose an enrollment freeze, a termination of marketing, or terminate the contract if necessary.) In addition, even if we determine an entity is qualified to renew its contract, this does not mean the contract will necessarily be renewed. If we and the contractor cannot reach agreement on the terms of the bid, then the contract will not be renewed.

Comment: Concern was expressed by a commenter that it was unclear how a Part D plan sponsor not renewing its contract could fulfill the requirement to inform consumers of other Part D plan options in the same service area, especially if other plans are changing or leaving the area at the same time.

Response: The plan is also required to notify the public 90 days before the end of the current calendar year. If 90 days is October 1, at that point, the plan should know (or should be able to find out from CMS) what plans are likely to offer prescription drug coverage for the

upcoming annual enrollment period in the service area.

9. Modification or termination of contract by mutual consent (§ 423.508).

In proposed § 423.508, we specified that a contract could be modified or terminated at any time by written mutual consent. If the contract were terminated by mutual consent, the PDP sponsor would have to provide notice to its Medicare enrollees and the general public using a timeframe we determine is appropriate. If the contract were modified by mutual consent, the PDP sponsor would be required to notify its Medicare enrollees of any changes that we determine are appropriate for notification within timeframes specified by CMS. We received two comments concerning this section on the proposed rule.

Comment: A Part D plan sponsor not intending to renew its contract with CMS is required to provide notice by the first Monday in June in the year in which the contract ends. Several commenters believed that this was not enough lead-time to ensure a complete transfer of files. They suggested that, as a condition of participating in the Part D program or recovery of surety bonds, Part D sponsors be required to cooperate in a timely manner with regard to all file and data transfers, including in cases where the Part D sponsor is leaving the market.

Response: We agree with the commenters that we should specify that data and files must be transferred timely and are adding language at § 423.507(a)(4), § 423.508(d), § 423.509(b)(1)(iv), and § 423.510(f) to clarify that these transfers must take place in cases of non-renewal, as well as in cases where the plan is ended for other reasons..

10. Termination of Contracts by CMS (§ 423.509)

This section discusses reasons for termination by CMS of a Part D sponsor. In the proposed rule, we asked for comments on § 423.509(a)(14), which allows us to immediately terminate a plan's contract without making corrective action available. This authority would be used if we have credible evidence of false, fraudulent, or abusive activities affecting the Medicare program. For the remainder of our proposals under this section, please see 69 FR 46714–715. We received one comment on this section as discussed below and are adopting the proposed policies in this final rule.

Comment: A commenter stated that our requirements allowing plans to cease operations 90 days after a CMS termination decision, and then requiring that the terminated Part D sponsor notify enrollees at least 30 days before the termination, is an unacceptable 60-day delay in notifying beneficiaries, and may cause gaps in coverage. Additionally, the commenter asked that the regulations stipulate that plans be immediately barred from any further marketing as soon as they are notified by CMS of their termination.

Response: We must allow some time between when a termination notice is given to an entity and when enrollees are notified of the termination so that we can alert other plans in the same service area that they are going to have to be open for enrollment and so that we can determine which plans have the capacity to accept new enrollees. In the event that only one other plan is in the area, we must make every effort in a short amount of time to contract with a qualified Part D sponsor to preserve beneficiary choice.

Regarding the comment about ending marketing immediately upon termination, sponsors are afforded appeal rights. Terminated sponsors have 15 days to file a notice of appeal.

11. Termination of Contract by the Part D Plan Sponsor (§ 423.510)

The proposed requirements for termination of a contract by a Part D plan sponsor were discussed at 69 FR 46715. These proposed requirements were unchanged from the MA program. We received one comment on notifying the States of PDP sponsors that have their contract terminated. We expect to adopt this suggestion in other guidance. In this final rule, we are adopting the provisions of the proposed rule.

12. Minimum Enrollment Requirements (§ 423.512)

We discussed the minimum enrollment requirements for potential Part D plan sponsors at 69 FR 46715 in the preamble of the proposed rule. We asked for comments on whether we should retain the minimum enrollment requirements from the MA program. We received one comment, discussed below, addressing that proposal. In this final rule, we are adopting the policies of the proposed rule.

Comment: Three commenters asked that we raise the minimum enrollment amounts from the current levels of at least 5,000 individuals enrolled for the purpose of receiving prescription drug benefits, and at least 1,500 enrollees for those plans serving rural areas. Their rationale was that at these low levels, a Part D plan sponsor could not be expected to negotiate and receive adequate prescription drug discounts or provide quality customer services to its beneficiaries.

Response: Although we have the authority under section 1860D–12(b)(3)(A)(i) of the Act to increase the minimum number of enrollees for PDP sponsors, given that we are in the first phase of the new drug benefit, we believe it would be reasonable to maintain the minimum enrollment numbers that were proposed. We may, in the future, need to adjust these thresholds based on our early experience. For now, however, we believe it would be prudent to adopt the minimum enrollment thresholds already used in the MA context, as we have greater experience with that program. Given that MA organizations offer a broader range of services than will be offered by PDP sponsors, and given that the minimum enrollment requirements have not seemed to stifle negotiation in that context, we believe it is reasonable to maintain these minimum enrollment numbers for potential PDP sponsors. Additionally, it should be noted that during the first contract year for a PDP sponsor in a region, the minimum enrollment requirements are waived. In addition, our intention for the final rule is to attract as many plans as possible to contract with us, thereby ensuring beneficiary choice and price competition. If, in the future, we find that the minimum enrollment numbers are too low for plans to garner high enough discounts or to provide quality customer service, we may increase the number through another round of rulemaking.

13. Reporting Requirements (§ 423.514)

Proposed reporting requirements were discussed at pages 46715 and 46716 of the proposed rule. We received no comments on this section and will be adopting the policies proposed.

14. Prohibition of midyear implementation of significant new regulatory requirements. (§ 423.516)

Under proposed § 423.516, we stated that we could not implement, other than at the beginning of a calendar year, provisions under this section that would impose new, significant regulatory requirements on a Part D plan sponsor or a prescription drug plan. We did not receive any comments on the provision, and the policy will be adopted in the final rule.

15. Fraud, Waste and Abuse.

Section 423.153(e) of the proposed rule discussed requirements for a program to control fraud, waste and abuse as required by Section 1860D–4(c)(1)(D) of the Act. In an effort to

consolidate the various compliance requirements in the rule, the requirements (and preamble discussion) pertaining to fraud, waste, and abuse programs have been moved from subpart D to subpart K, and included at § 423.504(b)(4)(vi)(H) as a component of a Part D plan sponsor's overall compliance plan.

Fraud and abuse compliance plans (referred to in this subpart as fraud and abuse programs) have been a part of private business practices since the early 1990's with the implementation of the Federal Sentencing Guidelines for Organizations of 1991. The Guidelines provide that a corporation can mitigate its sentencing when convicted of a Federal crime if its compliance plan is effective. Additionally, prosecutors may use their discretion in pursuing potential criminal conduct for those organizations that have an effective compliance plan. The Guidelines require an organization to exercise due diligence to detect and prevent violations of law (not just criminal law), and to promote an organizational culture that encourages compliance. They also require that businesses periodically assess the risk that criminal conduct might occur notwithstanding the organization's compliance and ethics program.

With these Guidelines in mind, we developed a set of elements for Part D plans to consider including in the fraud and abuse program component of their Compliance Plan so that they may benefit from an effective plan. These elements are similar to what many companies are doing in the private industry, including what is being done in the Federal Employee Health Benefits Program (FEHBP).

The Office of Personnel Management (OPM) requires the FEHBP plans to have a fraud and abuse program that contains at a minimum these components: an anti-fraud policy statement, written plan and procedures, formal training, fraud hotlines, education, use of technology to combat fraud and abuse, security safeguards to protect member and provider information, and a mechanism to address fraud and abuse practices that become patient safety issues.

States are also beginning to develop standards that pharmaceutical companies must follow before doing business in their State. For example, on September 29, 2004 Governor Arnold Schwarzenegger of California signed a new law that requires pharmaceutical companies to implement a Comprehensive Compliance Program (CCP). This CCP requires companies that sell pharmaceuticals in the State of California to comply with the tenets of the Code on Interactions with Health Care Professionals of the Pharmaceutical Manufacturers and Researchers of America (PhRMA) and the HHS Office of Inspector General's Compliance Program Guidelines for Pharmaceutical Manufacturers. In addition, the companies must declare in writing compliance with the plan, make its CCP and written attestation accessible to the public on its Web site, and provide a toll-free number where copies of the CCP and written attestation may be obtained.

Similarly, the current M+C organizations, under § 422.501(b)(3)(vi), must have a compliance plan that consists of the following:

- Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable Federal and State standards related to fraud and abuse.
- The designation of a compliance officer and compliance committee who are accountable to senior management.
- Effective training and education between the compliance officer and organization employees.
- Effective lines of communication between the compliance officer and the organization's employees.
- Enforcement of standards through well-publicized disciplinary guidelines.
- Provision for internal monitoring and auditing.
- Procedures for ensuring prompt response to detected offenses and development of corrective action initiatives relating to the organization's M+C contract.

With the emergence of organized criminal groups that have become involved in healthcare fraud across the country, the defrauding of Medicare and Medicaid has increased program vulnerabilities for CMS. For example, prescription drug expenditures constitute one of the fastest growing components of all Medicaid programs and amount to more than $1 billion a year in Medicaid expenditures on pharmaceuticals. Preventing inappropriate expenditures from occurring is preferable to recouping inappropriately paid claims. States have been very aggressive in responding to many of the fraud schemes used by individuals and groups to defraud Medicaid programs. States have addressed fraud and abuse by developing systems, processes, and procedures to identify and prevent fraudulent providers from entering their programs, thus avoiding patterns of payment and recovery.

As the Medicare Prescription Drug Benefit is implemented, it is crucial to the success of the Medicare program to have a fraud detection and prevention model in place. The identification and analysis of inappropriate activities that are essential aspects of the model will help Medicare to proactively combat fraudulent drug schemes.

After researching best practices currently utilized in the industry, we recommend that Part D plan sponsors consider adopting a program similar to the one used in FEHBP by including in the fraud, waste and abuse component of their overall compliance plan the following elements:

1) Written policies and procedures for detecting and preventing fraud, waste, and abuse among Part D plan sponsors, any Pharmacy Benefit Managers, pharmacies, drug manufacturers and physicians and providers with whom the sponsors and MA organizations do business. In developing these policies and procedures, sponsors and MA-PDs may also consider requiring pharmacies to adhere to the Code of Ethics of the American Pharmaceutical Association as a best practice for its standard of conduct.

2) Designation of a compliance officer and compliance committee with responsibility for developing, operating, and monitoring the Fraud and Abuse program and with authority to report directly to the board of directors, the president, or the CEO. The Part D plan sponsor or MA-PD should consider the compliance officer's scope of responsibilities, the organization's size and resources, and the complexity of the task in determining whether this compliance officer needs to be a different individual than the one required in the overall compliance plan.

3) Effective training and education on fraud, waste, and abuse, which would address pertinent laws related to fraud and abuse (for example, anti-kickback provisions and False Claims Act provisions) and include training for Part D plan sponsor staff and contracted entities on common fraudulent schemes in the pharmaceutical industry, identified by CMS, the Office of Inspector General or Department of Justice.

4) Effective lines of communication between the sponsor and the following entities: CMS and its contractors; law enforcement; Pharmaceutical Benefit Managers; pharmacies; and physicians and providers with whom the Part D plan sponsors do business, including an effective line of communication between the Part D plan's compliance officer and all employees using a process (for example, a hotline or other reporting system) to receive complaints or questions. There should also be procedures in place to protect the

anonymity of complainants and protect whistleblowers from retaliation.

5) Internal monitoring and auditing to protect the Medicare Trust Fund from Part D fraud and abuse, including regular monitoring and auditing by the Part D plan to ensure that they are in fact taking the steps necessary to comply with all Federal and State regulations related to fraud and abuse and are following their compliance plan to mitigate the potential for fraud, waste, and abuse within their organization.

6) Enforcement of standards through guidelines that are widely disseminated to employees, contractors, agents, and directors.

7) Procedures to ensure prompt responses to detected problems and to undertaking corrective action. We recommend these procedures include: (a)referral of any abusive or potentially fraudulent conduct or inappropriate utilization activities, once identified via proactive data analysis or other processes, for further investigation to CMS or its contractors; (b) procedures to cooperate with law enforcement; (c) reporting of potential violations of Federal law to the HHS Office of Inspector General or, alternatively, to appropriate law enforcement authorities; and (d) the conduct of appropriate corrective actions, including repayment of any overpayments due to the fraud or abuse and disciplinary actions against responsible employees.

The guidelines discussed above will help ensure that the Medicare Trust Fund is protected against fraud, waste, and abuse in the Part D program. These guidelines should not be misconstrued to mean that Part D plans should undertake law enforcement activities. Rather, Part D plan sponsors should implement effective fraud and abuse programs, consistent with industry standards, to detect problems, make referrals to CMS or the appropriate program integrity contractor for further investigation and follow-up, and undertake corrective action. These provisions are crucial to the success of the Medicare Part D program and to the millions of beneficiaries who rely on these benefits.

As noted in the proposed rule, we proposed changing the compliance program requirements for MA organizations at § 422.503(b)(4)(vi)(G) to include provisions that would require a MA organization to report misconduct it believes may violate various criminal, civil, or administrative authorities. We also proposed basing the compliance program requirements for Part D plan sponsors on these proposed new MA requirements. Numerous comments, both for and against, were received regarding these mandatory self-reporting of misconduct requirements. The very large majority of the comments, however, objected that the rule as written was vague and overbroad, with no basis in statute. Other comments mentioned that imposing a self-reporting requirement on only specific health providers contracting with Medicare was patently unfair, and other comments directed us to eliminate the proposal, stating that current compliance requirements were sufficient.

In response to these comments, we have eliminated the mandatory self-reporting requirements that were proposed, but we expect all Part D plan sponsors to comply with the requirement for a comprehensive fraud and abuse plan as found under § 423.504(b)(4)(vi)(H). We continue to believe that self-reporting of fraud and abuse is a critical element to an effective compliance plan, and that organizations contracting with CMS will find it in their best interests to alert CMS, the OIG, or law enforcement to any potential financial fraud or misconduct. Part D plan sponsors must continue to have a compliance plan as found under § 423.504(b)(4)(vi).

The potential for fraud, waste, and abuse exists not only in Part D plan sponsors offering prescription drug coverage, but also in the PBMs, pharmacies, physicians, and other providers with whom Part D sponsors do business. Therefore, we recommend that, as part of their ongoing screening for abusive or fraudulent activity, one of the many fraud and abuse activities that Part D sponsors should screen for is the illegal prescribing of narcotics by physicians.

We recognize that there are many possible approaches to implementing a successful waste, fraud, and abuse program, and we have given Part D plans sponsors discretion in developing this program as part of their overall compliance plan. In developing its fraud and abuse program, we recommend that Part D plan sponsors consider the previously outlined set of elements as well as other industry best practice (for example, compliance guidelines published by the Office of the Inspector General).

Comment: Commenters cautioned CMS against imposing additional administrative requirements (for example, periodic reports summarizing data analysis activities or reports on illegal prescribing practices) unless it has been proven effective in reducing fraud and abuse.

Response: Based on the comments received, respondents felt that these additional reports would be too burdensome to submit. We will not be imposing these additional reporting requirements at this time. However, while we expect that Part D plan sponsors will have policies and procedures in place to effectively screen for wasteful, fraudulent, and abusive activity, they should also be expected to produce evidence (for example, a summary of data analysis activities, tools used, resources employed, or trend analyses performed) of this activity upon CMS request.

Comment: Commenters expressed concern that we were expecting plans to be law enforcement-like entities who would take decisive action if fraud was identified. Commenters did not believe that plans or their contracted entities were in a position to take enforcement action regarding physician or patient abuse, and that they did not have the medical information necessary to track physician or patient abuse. Commenters did not believe that plans or PBMs should be tasked with taking, or judged for failing to take, enforcement actions against providers or patients.

Response: We recognize that Part D plan sponsors are not law enforcement entities and will not expect these entities to pursue fraudulent activity in the same manner that law enforcement would. However, just as other contractors who administer Medicare benefits are responsible for monitoring for wasteful, abusive, and fraudulent activities in their organizations, we have the same expectations for Part D plan sponsors. We therefore recommend that Part D plan sponsors offering prescription drug plans detect and prevent potentially fraudulent or abusive activity. For assistance in identifying what constitutes abusive or fraudulent activity, Part D plan sponsors may consult a variety of sources including relevant statutes, regulations, and case law, as well as media reports, DOJ litigation history, HHS-OIG published guidance and CMS policy manuals. Once identified, we encourage referrals be made to CMS or appropriate CMS contractors. CMS and its contractors will investigate all cases referred as potentially fraudulent and then refer them to the appropriate law enforcement agency as warranted. Likewise, we encourage Part D sponsors offering prescription drug plans to fully cooperate in any investigation that we or our law enforcement partners pursue related to fraud identified in a particular plan's area.

Comment: We give no assurance that the proposed rule provides those giving

price concessions protection from liability under fraud and abuse laws. CMS should strongly endorse the offering of price concessions as entirely consistent with the anti-kickback statute for all manufacturers or providers who: (1) identify the price concessions as such in the applicable contract; (2) do not interfere with the reporting obligations of Part D plans; and (3) contractually obligate the plan at issue to accurately report all price concessions provided.

Response: The anti-kickback statute is enforced by the OIG and the Department of Justice. Therefore we cannot respond directly to this comment. Interested entities may wish to submit a request to the OIG for an advisory opinion on these kinds of questions.

Comment: We should make clear in the final rule that Part D plan sponsors that engage in illegal practices may be subject to sanction under the False Claims Act and certify on an annual basis that sponsors will meet all of the requirements imposed.

Response: Part D plan sponsors should devise their compliance programs so that their policies and procedures are consistent with the False Claims Act. With regard to the issue of annual certification, we are not requiring Part D plan sponsors at this time to certify that they are in compliance with their fraud and abuse programs.

Comment: In responding to the proposed rule, commenters questioned whether we would develop uniform standards for all Part D plan sponsors or if each Part D plan sponsor would develop its own criteria. Additionally, commenters wanted to know whether these compliance programs would be compared against one another.

Response: Understanding that there are many approaches to a successful fraud, waste, and abuse program, we have developed a set of suggested elements for Part D plan sponsors to consider as they develop a plan for identifying and reporting fraud and abuse activity within the overall compliance plan. We will not compare fraud and abuse plans to each other, but expect Part D plan sponsors to follow through with the monitoring and compliance initiatives that are identified in their own fraud and abuse control plans.

In addition to plan efforts to control waste, fraud and abuse, we will work to develop program level performance measures using our oversight data related to costs, benefit structure, and other factors to make comparisons with the non-Medicare prescription drug benefit market and with Medicare prescription drug baseline data. We will review these comparisons as part of our normal, continual review of the Part D program. When divergent trends between the Medicare and non-Medicare markets are identified, we will take appropriate action, as necessary. In this way, we can work to ensure that the Medicare continues to reflect private sector best practices in the efficient delivery of drug benefits and that we can remove unnecessary barriers to efficient care delivery.''

Comment: Commenters expressed concern that the proposed rule identified illicit prescribing of narcotics by physicians as a primary responsibility for Part D plan sponsors.

Response: Illegal narcotic prescribing is one of many ongoing vulnerabilities we recommend that Part D sponsors should screen for in implementing a successful fraud and abuse program. As noted in the suggested guidance on developing a fraud and abuse plan, we recommend Part D plan sponsors have in place procedures to detect and prevent abusive or fraudulent activity in their organization.

Comment: Several respondents were concerned with the illegal switching of medications and drug substitution for financial gain. For instance, switching from brand to generic may be appropriate, but switching brands, for example, Lipitor to Zocor, may not be appropriate without consultation with the prescribing physician.

Response: We agree that the potential for fraud and abuse surrounding drug substitutions programs is of grave concern. We have no intention of restricting or targeting providers who are acting in the genuine best interests of the patient, but rather are concerned that such switching practices could be abused for financial gain. Therefore, we recommend that Part D plan sponsors monitor for aberrant or abusive behavior related to drug switching both within its own organization (through its fraud and abuse component of its compliance program) and with its pharmacy network (through proactive data analysis and trending capability).

Comment: Several commenters asked CMS how they should forecast fraud and abuse detection and prevention into their solicitation proposal to be a Part D plan sponsor.

Response: Part D plan sponsors should bid these costs in the same way they cost-out their current compliance and utilization control activity, as fraud and abuse is inherently a utilization control.

Comment: Some commenters asked that safe harbors be developed for Part D plans under the Anti-kickback and physician self-referral laws.

Response: The anti-kickback statute is enforced by the OIG and the Department of Justice. Therefore, we cannot respond with specific guidance to comments asking for exceptions to the anti-kickback laws. While the physician self-referral rules are under CMS jurisdiction, this final rule does not create any exceptions to these rules at this time, as nothing on this topic was proposed. However, law concerning physician self-referral is generally not implicated in many arrangements involving PDPs and MA organizations, unless the arrangement involves a referring physician.

Comment: Some commenters were concerned about unfair extrapolation policies in the Part D plan auditing process of pharmacies. It was recommended that the same standard required for Part D auditors be required of CMS; that is, ''a statistically valid random sample.''

Response: We recommend that Part D plan sponsors utilize ''a statistically valid random sample'' when auditing pharmacies; however, Part D plan sponsors and pharmacies should agree on auditing procedures in their network contracts.

Comment: Several commenters expressed concern about unfair ''bounty hunting'' practices in the Part D plan auditing process of pharmacies. It is recommended that Part D plan sponsors be prohibited from paying auditors based on the denial of reimbursement claims. Instead, they should be paid based on an objective analysis of reimbursement claims.

Response: We do not expect Part D plan sponsors to pay auditors based on the number of reimbursement claims that auditors deny; rather, Part D auditing processes should be based on an objective analysis of reimbursement claims. Specific instructions regarding Part D auditing practices will be outlined in subsequent policy guidance.

Comment: One commenter recommended that the Agency utilize the regular auditing of plans and pharmacy benefit managers (PBMs) to help control fraud, waste, and abuse.

Response: As a part of our mandated oversight responsibilities, we will regularly audit all drug sponsors involved in the Part D program as stated under § 423.504(d).

Comment: Commenters wanted to ensure that providers and pharmacies who were on State sanction lists could not participate in Part D.

Response: Part D entities such as providers, pharmacies, PBMs, and plans may be excluded from participating in

Part D under certain circumstances. The Office of the Inspector General maintains the authority to exclude individuals and entities from participating in Federal health care programs, including Medicare. Therefore, we cannot respond with specific guidance to comments asking under what circumstances providers might be excluded from participating in Part D.

Comment: The provider community indicated that they wanted to review proposed fraud and abuse plan to ensure the consistent use of fraud and abuse tools to mitigate illegal actions.

Response: Compliance plans are the property of the Part D plan sponsors and for their internal use; consequently, we do not expect plans to publish these documents for public access. Compliance plans will only be available to government and oversight entities upon request. However, CMS manuals that outline program integrity expectations are available for public access. As for the consistent application of fraud and abuse processes and procedures, we have suggested in the final rule a set of elements for a fraud and abuse control plan for Part D sponsors to consider in developing the fraud, waste and abuse component of their overall compliance plans. Any requirements in addition to this set of elements are encouraged by CMS and are at the discretion of the Part D plan sponsors.

L. Effect of Change of Ownership or Leasing of Facilities During the Term of Contract

Subpart L of part 423 describes the impact that a change of ownership (CHOW) or the lease of facilities during the term of a PDP sponsor's contract would have on the status of the organization's contractual relationship with us, as well as the procedures the Prescription Drug Plan sponsor is required to follow when a CHOW occurs. The provisions of this subpart apply to PDP sponsor organizations and are almost identical to the provisions that apply to MA organizations at subpart L of part 422. We proposed making the requirements essentially the same since we believe a single set of CHOW requirements for both MA organizations and PDP sponsors will simplify management, assure consistency, and reduce administrative burden. The requirements in § 423.551, § 423.552, and § 423.553 of this rule, which apply to PDP sponsors, are, therefore, substantially the same as the requirements found in § 422.550, § 422.552, and § 422.553, which apply to MA organizations. We received no comment on this proposal and will adopt these provisions without modification (with the exception of a slight change in wording which we will describe below).

We also sought comments regarding the potential modification of the CHOW rules. In particular, we sought comments regarding—

- The situations which constitute a CHOW;
- How these provisions should be applied to large companies with multiple business units;
- The notification requirements related to a CHOW and the novation agreement provisions; and
- The provision related to the leasing of a PDP sponsor's facilities.

We received only favorable comments on our proposal to consider that, under § 423.551(a)(2), an asset sale only occurs when there is a transfer of substantially all the assets of the sponsor to another party. We requested comments on situations where a sponsor transfers substantial assets to another party, but less than substantially all of its assets. We received a few comments describing different scenarios that commenters believe should not constitute a CHOW. The intent of the proposals under subpart L was to fashion requirements that would not unfairly burden an organization when something less than substantially all of an organization's assets were sold or transferred. When reviewing the comments, however, it became apparent that for some organizations selling or transferring their entire PDP line of business could constitute something less than substantially all of their assets. We note that we interpret the sale or transfer of an entire PDP line of business as an asset transfer. We recognize that we cannot define all possible existing business arrangements and transactions, we are, therefore, issuing these rules as a framework and will provide guidance as needed via interpretive documents (for example, FAQs,) and on a case by case basis. Contracting organizations should be aware that we will be alert to situations where organizations may be looking to avoid compliance with the CHOW provisions to evade Medicare liabilities and obligations.

In this final rule, we note that contracted PDP sponsors must adhere to the Privacy Rule on sharing protected patient health information in the course of a CHOW and the preparation of a novation agreement. PDP sponsors are not permitted to share protected health information, absent authorization from an enrollee, with a new owner that is not, or will not, become a covered entity.

We also proposed a definition of a novation agreement. A novation agreement is an agreement among the current PDP sponsor, the prospective new owner, and CMS. This agreement would have to be signed by all three parties and, to be effective, contain the provisions at § 423.552. In the agreement, we will recognize the new owner as the successor in interest to the current owner's Medicare contract. This definition has been adopted without modification.

1. General Provisions

We are adopting the provisions we proposed for this Subpart with one slight modification to § 423.551(a)(2). This paragraph is now entitled, Asset transfer rather than Asset sale.

2. Change of Ownership (§ 423.551)

We asked for comments on the various arrangements between and within companies that may, or may not, constitute a CHOW.

Comment: Commenters requested that we clarify that a CHOW does not occur when a change in the structure of an entity's business units occurs, but the same entity continues to be the PDP sponsor.

Response: The commenter did not provide, or otherwise define, what was meant by ''change of structure.'' Assuming the entity here is a unit of a multi-unit business with the PDP sponsor contract, and that the change of structure is within the company, and the same entity continues to hold, and be responsible for, the PDP sponsor contract, we would agree that a CHOW would not appear to occur in this instance. However, as mentioned above, we will be alert for any attempts by any Medicare contracted organizations to evade their responsibility to the Medicare program and its enrollees by avoiding compliance with the CHOW requirements.

Comment: We sought comments regarding how the CHOW provisions and provisions regarding the lease of a PDP sponsor's facilities should be applied to large companies with multiple business units. We received a number of similar comments regarding this issue. Commenters questioned whether the transfer of functions within a multi-State operation that centralizes functions within one entity would constitute a CHOW. One commenter recommends that the final regulation clarify that the transfer of functions within a multi-State company to an entity in another State does not constitute a CHOW.

Response: We believe that the transferring of functions within a

company consisting of multiple business units is a common practice and will in most cases be free of CHOW obligations, regardless of whether or not the transfer of functions was from one State to another, and was done in compliance with all applicable State licensure laws. What is pertinent in this instance is whether the transfer of functions does not represent substantially all assets of the organization and is truly an intra-company transfer—that is, that the same party, or parties, continues to be responsible for the PDP contract. As discussed in a previous response we will be scrupulous in ensuring that organizations contracting with the Medicare program do not evade their Medicare contract obligations. Any transfer of functions, or assets cannot result in a change of the entity responsible for the PDP contract without complying with all the CHOW provisions at § 423.551, § 423.552, and § 423.553.

Comment: A commenter requested that, given the impact a CHOW might have on SPAPs and State retirees, the final regulation provide for States to be notified of any CHOW.

Response: We will adopt the commenter's suggestion to notify States in the event of a CHOW. We will likely handle this internally and notify the appropriate State agencies.

3. Novation Agreement Requirements § 423.552

In the proposed rule, we identified the three conditions that would have to be met for approval of a novation agreement. A novation agreement is an agreement among the current PDP sponsor, the prospective owner and CMS. All three parties must sign the novation agreement for it to be in effect. Consistent with the requirements that apply to the MA program, at § 423.552(a) we proposed that three conditions would need to be met in order to obtain our approval of a novation agreement. First, the PDP sponsor would be required to give us notice at least 60 days before the effective date of a CHOW. That notice would include updated financial information and a discussion of the financial and solvency impact of the CHOW on the surviving organization. If notice were not timely, the contractor would continue to be liable for payments that we make to it on behalf of Medicare enrollees after the date of the CHOW, as described in § 423.551(c)(2). Second, the PDP sponsor would be required to submit three signed copies of the novation agreement (that contains the provisions specified in § 423.552(b)) at least 30 days before the proposed CHOW date, and submit one copy of other required documents. Third, the PDP sponsor would have to obtain our determination that—

- The new owner is in fact a successor in interest to the contract;
- Recognition of the new owner as a successor in interest is in the best interest of the Medicare program; and
- The successor organization meets the requirements to qualify as a PDP sponsor under proposed subpart K.

At § 423.552(b) we proposed that a valid novation agreement would include the following provisions:

- The new owner would assume all obligations under the Medicare contract.
- The previous owner would waive its right to reimbursement for covered services furnished during the rest of the current contract period.
- The previous owner would guarantee performance of the contract by the new owner during the contract period, or post a performance bond that is satisfactory to us;
- The previous owner would agree to make its books, records, and other necessary information available to the new owner and to us to permit an accurate determination of costs for the final settlement of the contract period.

We proposed that the new owner would become the successor in interest to the current owner's Medicare contract if the novation agreement meets all the requirements of § 423.552 and is signed by us (and the parties to that agreement).

Comment: One commenter requested that we require that enrollees of the PDP undergoing a CHOW receive detailed notification about any change, including any impact the CHOW may have on the ability of the new PDP sponsor to provide for enrollees' healthcare. This commenter also notes that we do not seem to provide for a special enrollment period to ensure continuity of care for beneficiaries in the event a novation agreement is not reached between the prior owner of the Medicare contact and the new owners, and the commenter requests that a special enrollment period be provided to ensure continuity of care.

Response: If a CHOW takes place that we believe would not be in the best interest of the beneficiaries then we will not enter into a novation agreement with the parties. Under § 423.551(3)(e), if a novation agreement is not reached, the existing contract will become invalid. However, before this occurs, we will send out notification of the pending CHOW, and will make every effort to ensure that beneficiaries are made aware of the alternate PDPs in the same service area. In the event that a novation agreement is not executed, an enrollee will be allowed to enroll during a Special Enrollment period, as provided for at § 423.36(c).

Comment: A commenter noted that it does not believe the proposed requirements are administratively burdensome. However, the commenter points to the advance notice requirement under § 423.551(c), which requires a PDP sponsor that is considering a CHOW to provide updated financial information and a discussion of the financial and solvency impact of the CHOW on the surviving organization. With respect to that requirement, the commenter suggests that administrative burden could be further reduced if the information required be equivalent to the documentation routinely submitted to State departments of insurance or similar entities.

Response: We appreciate the commenter's suggestion, but, in order to maintain uniformity, we will retain the advance notice requirement as proposed. Given that different States require different financial solvency information we believe that the advance notice requirement will best serve both our interests and the interests of our beneficiaries without being unduly burdensome for the PDP sponsors.

M. Grievances, Coverage Determinations, and Appeals

1. Introduction

Subpart M of part 423 implements sections 1860D–4(f), 1860D–4(g), and 1860D–4(h) of the Act, which sets forth the procedures PDP sponsors and MA-PDs must follow with regard to grievances, coverage determinations, and appeals. The MMA amended the Act to provide the following:

- A PDP sponsor or MA-PD must provide meaningful procedures for hearing and resolving grievances between the PDP sponsor or MA-PD (including any entity or individual through which the PDP sponsor or MA-PD provides covered benefits) and enrollees.
- A PDP sponsor's or MA-PD's procedures must meet the same requirements as those that apply to MA organizations for organization determinations and redeterminations.
- If a PDP sponsor or MA-PD has tiered cost sharing for formulary drugs, it must establish an exceptions process.
- PDP sponsors or MA-PDs must follow appeals requirements that are similar to those applicable to MA organizations regarding independent

review entity (IRE) review Administrative Law Judge (ALJ) hearings, Medicare Appeals Council (MAC) review, and judicial review, respectively.

- Appeals involving coverage of a covered part D drug that is not on a PDP's or MA-PD's formulary are permissible only if the prescribing physician determines that all covered Part D drugs, on any tier of the formulary for treatment of the same condition, will not be as effective for the individual as the non-formulary drug, would have adverse effects on the individual, or both.

We received 192 comments on subpart M in response to the August 2004 proposed rule. Below we summarize the major proposed provisions in this subpart and respond to public comments. (For a detailed discussion of our proposals, please refer to our proposed rule (69 FR 46,632).) Please note that, for the convenience of the reader, we use the term ''plan'' to connote a PDP sponsor, MA-PD, or other Part D plan sponsor throughout the discussion in this subpart.

Comment: We received several comments that we need to clarify whether all of the subpart M provisions apply to PDPs, Medicare Advantage plans that offer prescription drug benefits (MA-PDs), and Section 1876 of the Act cost plans that offer qualifying Part D coverage. Two commenters argued that we should determine which provisions in subpart M of Part 423 apply to MA organizations and cost plans and incorporate those provisions in Part 422 and Part 417 by cross-reference. Alternatively, the commenters suggested that we add language to the corresponding sections in Parts 422 and 417.

Response: We agree with the commenters, and wish to clarify that the Part D appeal provisions do apply to PDPs (including fallback plans), Medicare Advantage plans that offer prescription drug benefits (MA-PDs), and Section 1876 of the Act, cost HMOs that offer qualifying Part D coverage. Therefore, this final rule replaces all ''PDP sponsor'' references in subpart M with ''Part D plan sponsor,'' which is defined in § 423.4 as PDP sponsors (including fallback entities), MA organizations offering MA-PD plans, PACE plans offering qualified prescription drug coverage, and cost-based HMOs and CMPs.

We recognize that MA-PDs and cost-based HMOs and CMPs will be required to follow two different processes depending on whether a claim involves a request for benefits under Part 422 or Part 423. (Note that cost-based HMOs and CMPs will be required to follow Part 422 procedures no later than January 1, 2006). However, we do not believe that it is unduly burdensome for MA-PDs and cost-based HMOs and CMPs to follow two sets of rules instead of one. To the contrary, we believe that if we adopted the commenters' suggestions, the Part 422 provisions would be difficult to follow.

2. General Provisions (§ 423.560 through § 423.562)

We proposed, at § 423.560, several definitions for terms used in the subpart. These definitions were generally self-explanatory and mirror those used in subpart M of part 422 for MA, but were modified to reflect applicability to Part D drug benefits.

Proposed § 423.562, General Provisions, provided an overview of the responsibilities of plans and the rights of enrollees for grievances, coverage determinations, and appeals. In general, plans are responsible for establishing and maintaining procedures for grievances, coverage determinations, exceptions to tiered cost-sharing formulary structures, requests for formulary exceptions, and appeals. Enrollees must receive written information about the grievance and appeal procedures available to them through the plan, and about the QIO complaint process available to enrollees. If the plan delegates this task, it is still ultimately its responsibility to ensure that the requirements are met.

Section 423.562(b) of our proposed rule explained the basic rights of enrollees in relation to plans under subpart M and referenced the regulations that explain the rights.

Proposed § 423.562(c) specified that an enrollee has no appeal right when there is no payment liability, or when benefits have been provided by a non-network provider, except in those situations in which, under subpart C, the plan is obligated to cover such drugs. Finally, § 423.562(d) explained that, unless otherwise noted, the general Medicare appeals rule under part 422, subpart M, is applicable for appeals to an ALJ or the MAC. We note that since new § 423.562(c) will incorporate part 422, and since part 422 incorporates part 405, the provisions of part 405 apply to the extent that they are appropriate. This means, for example, that the provisions to implement the time and place for a hearing before an ALJ under section 1869 of the Act would apply to Part D appeals. Thus, we have added a reference to § 423.612(b) that the time and place for a hearing before an ALJ will be set in accordance with section 405.1020. Although that section has not yet been published in final form, we expect that it will be published prior to the effective date of this rule. Readers may refer to 67 FR 69311, 69331 (Nov. 15, 2002) for an explanation of the proposals and a discussion of the possibility of using video-teleconferencing in ALJ hearings. On the other hand, the ALJ and MAC provisions that are dependent upon qualified independent contractors would not apply since an independent review entity will conduct reconsiderations for Part D appeals.

Comment: We received a comment suggesting that we modify the definition of appeal in § 423.560 from ''when a delay would adversely affect the health of the enrollee'' to ''when a delay could adversely affect the health of the enrollee.'' The same commenter suggested that we must define ''delay'' in order for it to have functional meaning.

Response: We disagree with the commenter. The ''would adversely affect the health of the enrollee'' standard we proposed in the proposed rule is consistent with the language governing MA procedures, which were incorporated in the Part D regulations. In addition, we do not think the term ''delay'' needs to be defined in the regulations. The term ''delay'' simply refers to the plan not providing benefits within the applicable adjudication timeframe.

Comment: We received several comments requesting that we not prohibit an enrollee's appeal rights when the enrollee has no further financial liability for a Part D benefit. The commenters' underlying concern is, by prohibiting enrollees who have no financial liability for a medication from filing a request for appeal, we are also prohibiting State Pharmaceutical Assistance Programs (SPAPs) or other secondary payors from acting on behalf of enrollees in the appeals process.

Response: Under our proposal, an enrollee's appointed or authorized representative (which could include SPAPs or secondary payors) are able to act on behalf of enrollees in the appeals process. However, in the proposed rule we took the position that if an enrollee has no further financial liability for a medication because the secondary payor (that is also the enrollee's appointed or authorized representative) covered the enrollee's additional cost-sharing amount, neither the enrollee nor the secondary payor would be able to request an appeal. We did not intend to preclude SPAPs or other secondary payors from filing appeals with Part D plans on behalf of enrollees. Therefore, we agree with the commenters and have

deleted the proposed provision that would prohibit an enrollee's appeal rights when he or she has no further liability to pay for prescription drugs furnished through a Part D plan.

Comment: We received one comment requesting that the definition of enrollee be revised to include people who are automatically enrolled in a PDP or MA-PD.

Response: We agree with the commenter and have revised the definition of enrollee in this final rule to mean a Part D eligible individual who has elected or has been enrolled in a Part D plan.

3. Grievance Procedures (§ 423.564)

As defined in § 423.560 of our proposed rule, a grievance means any complaint or dispute, other than one that constitutes a coverage determination, expressing dissatisfaction with any aspect of a plan's operations, activities, or behavior, regardless of whether remedial action is requested. Our proposed regulations (at § 423.564) required that each plan have procedures to ensure that grievances are heard and resolved in a timely manner, but the regulations did not include prescriptive details on the procedures. The only exception to this approach was proposed under § 423.564(d) and involved certain limited situations where a plan must respond to a grievance within 24 hours.

Section 423.564(c) explained the distinction between the grievance procedures of the plan and the quality improvement organization (QIO) complaint process. This section further established that when an enrollee submits a quality of care complaint to a QIO, the plan must cooperate with the QIO in resolving the complaint.

Proposed § 423.564(e) completed the grievance procedures by proposing minimum record keeping requirements for a plan, which included recording the receipt date of a grievance, its final disposition, and the date the enrollee is notified of the disposition.

Comment: We received one comment suggesting that the QIO be utilized to respond to expedited external appeals related to drug benefits, and all complaints regarding quality of care should be forwarded to the QIO.

Response: We thank the commenter for the suggestion, and will take it into consideration when determining the entity that will perform the IRE workload. In addition, we believe that a complaint involving a quality of care issue must be processed by the QIOs since they are statutorily required to perform such reviews under section 1154(a)(14) of the Act. Although QIOs are required to review complaints involving quality of care issues, by statute, plans must establish an internal grievance procedure to resolve these types of issues as well. An enrollee may choose to file a quality of care complaint with either the plan, QIO, or both. Therefore, quality of care complaints will not be automatically forwarded to QIOs. In addition, even if the quality of care complaints were voluntarily forwarded by a plan, QIOs do not have a statutory responsibility to review such complaints. QIOs are responsible for reviewing quality of care complaints only when the complaint has been filed directly with the QIO, in writing, and by an individual (or his or her representative) who is entitled to Medicare benefits.

Comment: We received several comments indicating that the grievance procedures should be modeled after MA and include better record-keeping requirements for grievances. Other commenters suggested that we allow enrollees to appeal grievances directly to the IRE. Commenters also requested that we clarify what types of issues can be adjudicated in the grievance process, and what types of issues are subject to the appeals process. Another commenter recommended allowing enrollees to choose whether they want their complaint to be filed as an appeal or a grievance.

Response: We agree with the commenters who suggested that the Part D grievance procedures be modeled after the MA grievance procedures. Therefore, as proposed, the same grievance requirements (including who may request a grievance, the filing procedures and record-keeping procedures) that are applicable under MA are applicable under Part D. In the MA final rule, we are adopting revised grievance provisions similar to those from a January 24, 2001 Medicare+Choice proposed rule. See 66 FR 7,593. This is in response to comments we received on the August 3, 2004 proposed rule to establish the MA program. See 69 FR 46,866, 46,913. There, in response to statutory changes in the MA Federal rules governing preemption of State requirements, commenters recommended that we adopt the January 2001 proposed grievance provisions in an effort to establish uniform Federal procedures under MA. Once these regulations are in effect, MA organizations will be required to notify enrollees of their decisions as expeditiously as the case requires, but no later than 30 calendar days after receiving a complaint. An extension by up to 14 calendar days may be permitted if the enrollee requests the extension, or if the organization justifies a need for additional information and the delay is in the best interest of the enrollee. Also, grievances that are made orally may be responded to orally or in writing, unless the enrollee specifically requests a written response. Quality of care issues and written complaints must be responded to in writing. An enrollee must file a grievance no later than 60 days after the event or incident that precipitates the grievance. Because the MMA dictates that the grievance provisions of the MA program also apply to the Part D program, the final MA requirements have been included under § 423.564, and thus will apply to PDP sponsors and MA-PDs as well.

In the proposed rule, we specified the differences between grievances, coverage determinations, and appeals in proposed § 423.564, paragraphs (b) and (c). Nothing in the proposed rule prohibits an enrollee from requesting that his or her complaint be adjudicated under the process applicable for appeals or grievances. However, plans are required to maintain different processes for each and must determine which process applies when a request is received. As stated in the proposed rule, any complaint that does not involve a coverage determination or quality of care issue may be filed under the grievance process. However, if the complaint involves a coverage determination issue, plans must process it under its appeals procedures. If the complaint involves a quality of care issue, an enrollee may request the quality improvement organization or the plan to review the complaint using its procedures. When a plan makes a decision on a grievance, its resolution is final and is not subject to an appeal. We have retained these proposals in the final rule.

4. Coverage Determinations (§ 423.566 through § 423.576)

Proposed § 423.566 through § 423.576 implemented the MMA requirement that plans establish procedures for making coverage determinations and redeterminations regarding covered drug benefits that are essentially the same as those in effect for MA organizations under part 422, subpart M for MA. Therefore, for the drug benefits under Part D, we continued standard and expedited requirements for coverage determinations and redeterminations.

Section 423.566(a) of our proposed rule specified that each plan must have a procedure for making timely coverage determinations regarding the drug benefits an enrollee is entitled to receive

and the amount, if any, that an enrollee is required to pay for a benefit. The plan would be required to establish both a standard procedure for making coverage determinations and an expedited procedure for situations in which applying the standard procedure could seriously jeopardize the enrollee's life, health, or ability to regain maximum function.

As proposed in § 423.566(b), actions that constitute coverage determinations include: a plan's decision not to provide or pay for a Part D drug (including a decision not to pay because the drug is not on the plan's formulary, the drug is determined not to be medically necessary, the drug is furnished by an out-of-network pharmacy, or because the plan determines that the drug otherwise would be excluded under section 1862(a) of the Act); failure to provide a coverage determination in a timely manner that would adversely affect the health of the enrollee; decisions on the amount of cost sharing; or decisions on whether the preferred drug is appropriate for an enrollee. As proposed at § 423.566(c), only the enrollee (including his or her authorized representative) and the prescribing physician on behalf of the enrollee could request a standard coverage determination.

Similarly, those individuals who could request an expedited determination or an expedited redetermination were an enrollee (including his or her authorized representative), or the prescribing physician on behalf of the enrollee. In these situations we proposed that a prescribing physician need not be an appointed representative of the enrollee in order to assist in obtaining either a standard or an expedited coverage determination. We welcomed comments on any additional individuals or entities that should be able to request a coverage determination.

The standard timeframes and notice requirements for coverage determinations were proposed in § 423.568. These requirements, which are consistent with MA requirements and were incorporated in Part D, included making a determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after receipt of the request if the request was for prescription drug benefits. An extension of the timeframe by up to 14 calendar days would be allowed if the enrollee requests the extension, or if the plan can justify how a delay is in the interest of the enrollee. An enrollee must be notified of the reasons for the delay, and informed of the right to file an expedited grievance if the enrollee disagrees with the plan's decision to invoke an extension.

As specified at proposed § 423.568(b), which is consistent with MA requirements and was incorporated in Part D, if the request is for payment, the determination would need to be made no later than 30 calendar days after receipt of the request. This section also established, at proposed § 423.568(c), the requirement for written notice for plan denials and the form and content of the denial notices, including that the notices must explain the reason for the denial and the availability of appeal rights.

Section 423.570 and § 423.572 proposed the requirements regarding expedited coverage determinations, including how an enrollee or an enrollee's prescribing physician could make an oral or written request (§ 423.570(b)), and how the plan must process requests (§ 423.570(c)). We clarified in § 423.570(a) that requests for payment of prescription drugs already furnished for an enrollee could not be expedited.

Section 423.570(b)(2) specified that a prescribing physician may provide written or oral support for a request for expedition, and under § 423.570(c)(3)(ii), we clarified that when requests for expedition were made or supported by an enrollee's prescribing physician, the plan would grant the request if the physician indicated that applying the standard timeframe could seriously jeopardize the enrollee's life, health, or the ability to regain maximum function. Section 423.570(d) proposed actions following a denial of a request and explained that when a plan denies a request for an expedited determination, the request would be automatically transferred and processed under the standard determination procedures.

Proposed § 423.572 outlined the timeframe and notice requirements for expedited determinations. Specifically, this section proposed the following:

- The plan must make its expedited determination and notify the enrollee and the prescribing physician of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request.
- The enrollee has the right to file an expedited grievance if he or she disagreed with the plan's decision to invoke an extension.
- If the plan first notified an enrollee of an adverse expedited determination orally, then it must mail written confirmation to the enrollee within 3 calendar days.
- Notice of expedited determination must contain specific information outlined by us.
- Failure to provide a timely notice would constitute an adverse coverage determination, which may be appealed.

Similar to the expedited requirements for MA under Part C, these sections proposed requiring that drug coverage determinations be made as expeditiously as the enrollee's health condition requires. Note that given the requirement that the timing of determinations (and redeterminations) be based on an enrollee's health condition, the plan would have a responsibility to ensure that an enrollee's health situation and needs are fully considered in reviewing any request (for example, if an enrollee has a chronic condition that has necessitated ongoing use of the drug in question).

Comment: Several commenters were unclear about the differences between the processes for coverage determinations, exceptions for non-formulary and non-preferred drugs, and appeals. Some commenters believed that the procedures were too complex for enrollees to navigate.

Response: We believe that it is important to clarify the process for coverage determinations, including exceptions, and appeals to ensure that enrollees, prescribing physicians, and plans understand the procedures that apply to disputes involving drug benefits. Section 1860D–4(g) of the Act addresses the procedures for coverage determinations and redeterminations of plans. In general, the MMA requires that a plan's procedures meet the same requirements as those that apply to MA organizations (under paragraphs (1) through (3) of section 1852(g) of the Act) for organization determinations and redeterminations. This includes the same requirements for expedited procedures when the standard timeframes could seriously jeopardize an enrollee's life, health, or ability to regain maximum function. In addition, section 1860D–4(g)(2) of the Act specifies that if a plan has tiered cost sharing for formulary drugs, it must establish an exceptions process. Under the exceptions process, consistent with guidelines established by the Secretary, a non-preferred drug could be covered under the terms applicable for preferred drugs if the prescribing physician determines that the preferred drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual, or both.

Section 1860D–4(h) of the Act addresses appeals of a plan's coverage

determinations and redeterminations. Here, the MMA requires that the plans follow appeal requirements that are similar to those applicable to MA organizations under paragraphs (4) and (5) of section 1852(g) of the Act (regarding IRE review and ALJ hearings, respectively). In addition, section 1860D–4(h)(2) of the Act specifies that appeals, involving coverage of a covered part D drug that is not on a plan's formulary, are permissible only if the prescribing physician determines that all covered Part D drugs, on any tier of the formulary for treatment of the same condition, would not be as effective for the individual as the non-formulary drug, would have adverse effects on the individual, or both.

In light of the MMA requirements mentioned above, our final regulations at § 423.566 through § 423.630 establish a process for addressing coverage determinations and appeals that largely mirror the procedures under the MA program. The primary structural difference between the Part D requirements and the MA rules involves the unique feature whereby enrollees may request exceptions to a plan's formulary and tiered cost-sharing structure. (Note that requests for non-formulary drugs are of course part of the MA program today, but they are not addressed separately in either the statute of regulations.) We treat these exception requests as requests for coverage determinations. Put another way, requests for tiering and formulary exceptions are forms of coverage determinations. We have made several technical changes to the proposed regulations to help clarify this point.

Section 423.566(b) of this final rule specifies the actions that we consider coverage determinations. They include a plan's decision not to provide or pay for a Part D drug (including a decision not to pay because the drug is not on the plan's formulary, because the drug is determined not to be medically necessary, because the drug is furnished by an out-of-network pharmacy, or because the plan determines that the drug is otherwise excluded under section 1862(a) of the Act) that the enrollee believes may be furnished by the plan; failure to provide a coverage determination in a timely manner when a delay would adversely affect the health of the enrollee; a decision on the amount of cost sharing for a drug; and a decision on whether a drug is a preferred drug for an enrollee. Although a plan's decision to pay for or provide a Part D drug is a coverage determination, these types of determinations are not appealable and therefore are not included in the definition of a coverage determination for purposes of subpart M. We anticipate that only a fraction of all Part D claims will involve disputes subject to the appeals and grievance procedures

Cost-utilization tools employed by plans may also result in coverage determinations. For instance, a plan's denial of a request for a specific drug based on an enrollee's failure to complete step-therapy requirements constitutes a coverage determination. Similarly, a denial based on an enrollee's exceeding a plan's quantity limitation also constitutes a coverage determination. Although enrollees may appeal such determinations if they believe that the cost-utilization requirements have been satisfied or the requirements cannot be satisfied for reasons of medical necessity, enrollees may not challenge the fact that a plan has cost-utilization tools. These tools are essentially part of a plan's benefit design, which is reviewed by us as part of the plan approval process, and like other parts of the benefit design may not discourage enrollment by certain Part D eligible individuals as described in § 423.272.

Only adverse coverage determinations are subject to the appeals process. Therefore, if a plan denies an enrollee's request for an exception, this action constitutes an adverse coverage determination that may be appealed. If we did not treat a plan's decision regarding an exceptions request as a coverage determination, then any adverse decision by a plan regarding an exceptions request would not be subject to the appeals process.

All of the enrollee filing deadlines; plan decision-making timeframes, including rules on when to apply the expedited versus the standard procedures; and notice requirements apply to exceptions requests in the same manner as they apply to other coverage determinations. Thus, § 423.578(c) specifies that a plan's decision concerning an exceptions request constitutes a coverage determination under § 423.566.

Consistent with MA appeal procedures, the entity that makes the coverage determination has an opportunity to take a second look at its original determination. Thus, the first level of the appeals process is a redetermination by the plan. One or more individuals who were not involved in making the coverage determination must make the redetermination. If a lack of medical necessity formed the basis for the coverage denial, then a physician with expertise in the field of medicine appropriate for the services at issue must make the redetermination. The redetermination procedures are set forth under § 423.580 through § 423.590.

Plan redeterminations are subject to reconsideration by an IRE under § 423.600 through § 423.604. Further appeals may be made to an ALJ under § 423.610 through § 423.612, the MAC under § 423.620, and to Federal court under § 423.630. An enrollee must meet an amount in controversy threshold, as determined by the Secretary on an annual basis, for appeals at the ALJ and Federal court levels.

Comment: We received a significant number of comments indicating that the adjudication timeframes were unreasonably long. The commenters argued that if we shortened the timeframes for coverage determinations, including exceptions, and appeals, the process would be less complex. Some commenters recommended designing an expedited exceptions process for enrollees with immediate needs such as mental health issues or chronic or debilitating conditions, which requires a response within 24 hours. Many others suggested shortening the proposed 14-day deadline for exception requests to 72 hours, or 24 hours for emergencies. One commenter stated that requiring plans to respond to all exceptions requests within 72 hours would be consistent with the practice typical in private plans and would allow enrollees better access to the therapies they need. The commenter maintained that the adjudication timeframes under Part D should be shorter than the MA adjudication timeframes because the majority of Part D claims will involve prescription drugs that have not been received by enrollees, while MA claims typically relate to payment for physician and hospital benefits that enrollees have received. A few commenters supported allowing for immediate online point of sale adjudication.

Response: We agree with the commenters that the proposed adjudication timeframes are too long for making decisions involving an enrollee's access to drugs. Therefore, we have amended the adjudication timeframes for coverage determinations (which includes exception requests), redeterminations by the plan, and reconsiderations by the IRE. The NAIC created and adopted the Health Carrier Prescription Drug Benefit Management Model Act, which has been used by many States to develop laws that regulate prescription drug formularies and Pharmacy Benefit Managers (PBMs). The NAIC Model Act requires plans to make determinations within 72 hours after the date of the receipt of the request, or if required by the health

carrier, the date of the receipt of the physician's supporting statement. Many of the States that have created laws requiring plans and PBMs to make determinations within a specified time-period have adopted adjudication timeframes that are shorted than the 72-hour timeframe adopted in the NAIC Model Act. For instance, Michigan, New Jersey, Oklahoma, and Virginia requires plans and PBMs to make a determination on an exceptions request within 24 hours of receipt, while New Hampshire requires determinations on exceptions requests to be made within 48 hours of receipt. Like many States, we have relied on the adjudication timeframes adopted in the NAIC's Model Act as a benchmark for developing the Part D adjudication timeframes. We continue to maintain the requirement that all determinations be made as expeditiously as the enrollee's health condition requires, but will shorten the maximum amount of time that a plan or the IRE can take to make a determination. A plan will have 24 hours for expedited coverage determinations (including exception requests) and 72 hours for expedited redeterminations. The expedited procedures will continue to apply to situations where an enrollee's life, health, or ability to regain maximum function could be seriously jeopardized by waiting for a determination within the standard timeframe. For non-expedited matters, plans will have up to 72 hours to make standard coverage determinations (including acting on an exceptions request) and no later than 7 days for standard redeterminations. In this final rule, the adjudication timeframes begin after receipt of the request, or in the case of an exceptions request, after receipt of the physician's supporting statement. The timeframes of 72 hours for expedited cases and 7 days for non-expedited cases used for redeterminations also apply to reconsiderations by the IRE.

Although the MMA requires plans to meet the requirements for plan determinations and redeterminations for Part D in the same manner as such requirements apply to MA organizations under sections 1852(g)(1) through (3) of the Act, we believe that we have the authority under the Act to shorten the adjudication timeframes. Section 1852(g)(1)(A) of the Act does not require us to mandate a specific amount of time for MA plans to make standard coverage determinations. The Act requires only that such coverage determinations be made on a ''timely basis.'' Under MA, we interpreted ''timely basis'' to mean no more than 14 days from the date the request is received. However, we agree with many of the commenters that 14 days is not timely for determinations that involve prescription drugs. There is too much risk for an enrollee's health if determinations are not made sooner than 14 days from the date the request is received, since an enrollee often will not be able to pay out-of-pocket for a prescribed medication and thus must forgo necessary therapy until a determination is made. We agree with the commenter that the MA adjudication timeframes do not offer an appropriate standard for Part D. We anticipate that the majority of Part D requests for exceptions and appeals will involve prescription drugs that have not yet been provided to enrollees, in contrast with MA requests, which typically involve services that have already been received or are not immediately needed, such as procedures that are often scheduled weeks in advance of being performed. (Expedited determinations are the exception to this general rule.) Clearly, Part D enrollees are likely to suffer significant adverse consequences if medications are not received quickly.

Section 1852(g)(2)(A) of the Act gives the Secretary the authority to require MA organizations to make standard reconsiderations in a time period that is no later than 60 days from the date the request is received. In MA, we require MA organizations to complete standard reconsiderations in 30 days from the date it receives a request. However, in this final rule, we have established adjudication timeframes that are shorter than the 60-day maximum imposed by the Act. Under our final regulations at § 423.590(a), plans must make standard redeterminations within 7 days from the date a request is received.

Because section 1860D–4(h)(1) of the Act only requires plans to meet the requirements that apply to Part D IRE reconsiderations or higher appeals in a similar manner as they apply to MA organizations, we have the authority to revise the adjudication deadlines as appropriate. As mentioned previously, we will hold the IRE to the same timeframes as Part D plans (that is, as quickly as the beneficiary's health requires but no later than 72 hours for expedited reconsiderations and 7 days for standard reconsiderations). However, ALJ hearings and Departmental Appeals Board (DAB) reviews will follow the same timeframes and procedures under MA. The complexities associated with in-person hearings and appellate reviews make it impossible for an ALJ or the DAB to complete a decision in an abbreviated timeframe.

Section 1852(g)(3)(B)(iii) of the Act requires MA organizations to process expedited coverage determinations and reconsiderations ''under time limitations established by the Secretary, but no later than 72 hours of the time of receipt of the request or the information necessary to make the determination or reconsideration, or such longer period as the Secretary may permit in expedited cases.'' Under MA, health plans and the IRE must process expedited reviews no later than 72 hours. However, given that the final rule reduces the timeframe for making a standard coverage determination (including an exceptions request) under Part D from 14 calendar days to 72 hours, the 72-hour decision-making timeframe we initially proposed for expedited determination is unreasonable. We believe that a 24-hour deadline for expedited initial coverage determinations (including expedited exceptions requests) is more meaningful. This change is reflected under § 423.572(a). Expedited redeterminations and reconsiderations will be processed no later than 72 hours, as proposed. We note that we have removed references to 14-day extensions of the adjudication timeframes. We believe that allowing extensions is inconsistent with our rationale for shortening the adjudication timeframes.

Comment: We received many comments from the public suggesting that we require plans to provide continued coverage of a prescription drug during part or all of the coverage determination and appeals process, or provide an emergency supply in limited circumstances. Several of the commenters were concerned that the proposed timeframes for making coverage determinations were too long, which would result in lapses of coverage for enrollees.

The commenters' recommendations varied on the length of time a drug should be supplied, as well as who should bear the burden of cost. Some commenters recommended providing enrollees with a 72-hour emergency supply of the prescription, while others suggested that enrollees be provided with coverage for 45 days. A number of commenters suggested that enrollees be permitted to continue receiving a requested drug at no cost until the appeal is resolved, while others recommended providing enrollees with the requested drug at the preferred cost-sharing amount until final resolution.

Response: Although the commenters suggested different solutions, each has requested some degree of continued coverage as a means of addressing a larger concern—whether and how

enrollees can continue receiving a prescribed medication until the coverage issue is properly adjudicated. We do not believe we have the statutory authority to require plans to continue covering a drug that has been removed from the plan's formulary, or placed on a different tier during the plan year, pending the outcome of an appeal. Nevertheless, we believe that we can address the commenters' concern in this final rule by minimizing the adjudication timeframes as discussed above, and by modifying the proposed provisions related to the timelines for notices and coverage and appeals decisions. As required under subpart C of this regulation, plans must either provide notice to affected enrollees 60 days in advance of a change to its formulary or tiering structure, or provide notice regarding the change along with a 60-day supply after an enrollee's request for a refill of the drug affected by a change. As mentioned above, we have also significantly reduced the adjudication timeframes for coverage determinations, redeterminations, and reconsiderations. As a result, when a formulary changes, enrollees will have sufficient time to obtain a determination, including an independent review, before their medication runs out. Finally, beneficiaries always have the option of paying out of pocket for an initially non-covered Part D drug and then appealing to seek reimbursement.

Comment: Some commenters also suggested that we incorporate a fast-track appeals process for Part D similar to the fast-track appeals process provided in the Medicare appeals regulations as a result of the Grijalva v. Shalala settlement.

Response: The MA provisions at § 422.624 and § 422.626 apply to situations where an MA organization intends to terminate an enrollee's services in a skilled nursing facility, home health agency, or a comprehensive outpatient rehabilitation facility. The provider must deliver a notice two days in advance of the services ending, thereby affording an enrollee the ability to request an appeal by an IRE before the services end. As noted above, we have created a similar concept in Part D by shortening the maximum amount of time that a plan or the IRE can take to make a determination and requiring plans to either provide notice to affected enrollees 60 days in advance of a change to its formulary or tiering structure, or provide notice regarding the change along with a 60-day supply after an enrollee's request for a refill of the drug affected by a change. Thus, enrollees will receive notice in advance of a change to a plan's formulary, thereby affording an enrollee the ability to request an appeal by an IRE before a lapse in coverage occurs.

Comment: We received several comments from organizations arguing that the regulations proposed in subpart M fail to meet the Due Process Clause of the Fifth Amendment of the United States Constitution. Specifically, the commenters believe that the proposed rules do not afford enrollees with adequate notice explaining the reasons for a denial and right to appeal, and an adequate opportunity to a hearing with an impartial trier of fact. The commenters also noted that Medicaid enrollees whose prescription requests are not being honored currently receive a 72-hour supply of medication pending a resolution of the initial coverage request, and Medicaid appeals are completed more expeditiously than Medicare appeals. The commenters recognize that although the most efficient means of protecting enrollees, amending the MMA to provide for an appeals process similar to Medicaid, is beyond our authority, we can take steps to improve notice and the opportunity for a speedy review.

Response: As noted above, we have addressed the commenters' concerns by significantly reducing the adjudication timeframes for coverage determinations, redeterminations, and reconsiderations, and requiring plans to either deliver notice to affected enrollees 60 days in advance of a change to its formulary or tiering structure or provide notice regarding the change along with a 60-day supply after an enrollee's request for a refill of the drug affected by a change. Under § 423.568(d) and § 423.572(c), we require plans to provide enrollees with detailed written notices explaining the reason(s) for the denial, and the enrollee's right to, and conditions for, obtaining a redetermination and the rest of the appeals process. In addition, under § 423.590(g), we require plans to provide enrollees with the same type of written notices required in § 423.568(d) and § 423.572(c) when a redetermination is made. Finally, § 423.602 contains provisions governing the notice issued by an IRE upon a reconsideration. Thus, we believe that the Part D process affords enrollees with appropriate notice explaining their rights to an exceptions process, reasons for any coverage denials, and the opportunity to appeal to an independent review entity.

Comment: We received many comments that we need to clarify whether the point-of-sale transaction at the pharmacy counter constitutes a coverage determination. Some commenters suggested that the transaction should not be considered a coverage determination on the basis that it would be unrealistic to treat a pharmacy as an agent of a plan for the purpose of accepting and processing appeals, and providing information about a plan's benefit design does not constitute a denial triggering notice. Others commented that point-of-sale transactions should be considered coverage determinations because those transactions result in enrollees receiving a decision that a drug is either covered or not, and pharmacies receive real-time claims adjudication information from plans and deliver that information to enrollees.

Response: We agree with the commenters who suggested that transactions that occur at the pharmacy counter should not be considered coverage determinations. Although pharmacists will receive information from plans regarding whether to provide or pay for a covered Part D drug, the amount of cost sharing, or whether a drug is a preferred drug for the enrollee, we do not believe as a policy or practical matter that such information by itself should be considered a coverage determination. Instead, the pharmacist is conveying information regarding the plan's benefit design as it pertains to all enrollees, and is exercising no discretion on behalf of a plan. The same type of information is provided in writing by the plan to enrollees at the beginning of a new plan year, and is often made available to enrollees in other formats, for example, online.

Like MA organizations under Part C, plans must issue written notices to enrollees whenever the plans deny a drug benefit in whole or in part. The written notice must state the specific reason(s) for the denial and explain the enrollee's right to an appeal. It would be difficult for pharmacists to create and issue written notices that satisfy the coverage determination requirements given the number of customers (likely from various plans) that pharmacists assist each day. In addition, not all pharmacies have systems capable of receiving information specific enough to explain that a prescription is not on a plan's formulary or why the level of cost-sharing is higher than the enrollee expected to pay.

The DOL considered a similar issue under 29 CFR 2560.503–1, which generally applies to all claims for benefits under plans subject to the Employee Retirement Income Security Act (ERISA). Specifically, the DOL

considered whether, when a group health plan participant presents a prescription to a pharmacy to be filled at a cost to the participant determined by reference to a formula or schedule established in accordance with the terms of such plan and for which the pharmacy exercises no discretion on behalf of the plan, the regulation under § 2560.503–1 requires that the presentation of the prescription be treated as ''claim for benefits.'' The DOL is of the view that neither ERISA nor the regulation under § 2560.503–1 requires that a group health plan treat interactions between participants and preferred or network providers under such circumstances as a ''claim for benefits'' governed under § 2560.503–1. See DOL, EBSA, Benefit Claims Procedure Regulation Frequently Asked Questions and Answers, A–11, at *http://www.dol.gov/ebsa/faqs/faq__claims__proc__reg.html*. We agree with the approach taken by DOL. Under this final rule, therefore, a plan is not required to treat the presentation of a prescription as a claim for benefits; instead, enrollees must contact their plans to formally request coverage determinations. However, consistent with the DOL approach, nothing in this rule prohibits a plan from treating the presentation of the prescription as a claim for benefits if it chooses to. As under Part C, we will require PDP sponsors and MA-PDs to provide information in the enrollee's Evidence of Coverage explaining how to contact the plan to obtain a coverage determination and an appeal. We will also develop standardized notices and require plans under § 423.562(a)(3) to arrange that their pharmacy networks utilize the standardized notices to notify enrollees of the right to receive, upon request, a detailed written notice from the Part D plan sponsor regarding the enrollee's prescription drug coverage, including information about the exceptions process. The standardized notices may, for example, be posted in or disseminated by a plan's network pharmacies.

Comment: One commenter requested that we clarify § 423.566(b)(4), which specifies that a decision on whether a drug is a preferred drug for an enrollee is a coverage determination. The commenter is concerned that, as proposed, the provision allows an enrollee to challenge a plan's formulary development process, without regard to whether the enrollee actually received the drug. To remedy this problem, the commenter suggested that we ''limit the coverage determination in this case to the scope of the exception.''

Response: We agree that enrollees may not challenge a plan's formulary. The intent of § 423.566(b)(4) was to ensure that a plan's determination regarding an enrollee's request for an exception involving a non-formulary drug is considered a coverage determination. To clarify our intent, we have amended § 423.566 (b)(3) and (4) to state that a decision concerning an exceptions request under § 423.578(a), or a decision concerning an exceptions request under § 423.578(b), is a coverage determination.

Comment: One commenter requested clarification as to whether a decision made by a plan not to pay for drugs obtained at an out-of-network pharmacy is subject to appeal.

Response: If a plan decides not to pay for a drug that an enrollee obtained at out-of-network pharmacy in accordance with § 423.124(a), this action constitutes a coverage determination that is subject to appeal. Therefore, § 423.566(b)(1) requires that a plan's decision not to provide or pay for a Part D drug because the drug is furnished by an out-of-network pharmacy is a coverage determination. To avoid confusion, we deleted the limitation proposed in § 423.562(c)(2), which gave the impression that such determinations are not appealable. When a plan denies coverage for a drug obtained at an out-of-network pharmacy on the grounds that the provisions of § 423.124(a) were not satisfied, but the enrollee believes that the denial was unreasonable, for example, the enrollee obtained a drug at an out-of-network pharmacy because he or she needed the drug at midnight and the only pharmacy open at that time within a reasonable driving distance was an out-of-network pharmacy, then the enrollee can appeal the plan's determination. However, the policies that plans develop to encourage enrollees to use network pharmacies are not subject to appeal.

Comment: We received several comments expressing concern regarding the notification procedures when a plan denies a prescribed medication. Some commenters suggested that both the physician and enrollee be provided with immediate written notification, while others recommended providing the prescribing physician and the enrollee with notification within 24 hours from the time the determination is made. Several commenters requested that denials and approved requests be reported to the pharmacists, and a significant number of commenters suggested that we require pharmacists to distribute notices to enrollees at the pharmacy counter.

Response: Most commenters who suggested that the point-of-sale transaction is a coverage determination also argued that pharmacists should deliver written notification of the coverage determination to enrollees when they are not able to obtain a prescription at the pharmacy counter. Although plans are required under the regulations to deliver written notice to enrollees when plans make a coverage determination, plans are not required to deliver a notice as a result of the transaction that occurs at the pharmacy counter. As mentioned above, point-of-sale transactions are not coverage determinations and thus do not trigger the notice requirements associated with adverse determinations. However, we recognize that it would be helpful for enrollees to receive some information at the pharmacy explaining how to obtain a coverage determination or request an exception. Therefore, we will require plans under § 423.562(a)(3) to arrange that their network pharmacies notify enrollees of their right to receive, upon request, a detailed written notice from the Part D plan sponsor regarding the enrollee's prescription drug coverage, including information about the exceptions process. Plans may, for instance, require their network pharmacies to post or distribute notices that instruct enrollees on how to contact their plans to obtain a coverage determination or request an exception when enrollees disagree with the information provided by the pharmacist.

Another concern raised by the commenters involved who would receive notices from the entities offering Part D plans. Entities offering Part D plans must send written notification to enrollees whenever the plan makes any adverse coverage determination. Plans also must notify prescribing physicians of any adverse coverage determination when the physician requests standard or expedited coverage determinations, and expedited redeterminations on behalf of enrollees. Plans must notify enrollees and prescribing physicians, if the physician requested the determination, for all favorable coverage determinations. Also, when a plan denies a request that a determination or redetermination be expedited, renders an unfavorable expedited coverage determination, or affirms its unfavorable expedited coverage determination, the plan must provide oral notification within the applicable timeframe and follow-up with a written notice within three days.

A written notice of any determination must be sent to enrollees, or any individual or entity appointed by an enrollee or authorized under State or

other applicable law to act on behalf of an enrollee. We also wish to point out in this final rule that we believe it is unnecessary to require plans to provide pharmacists with formal written notice of plans' coverage determinations or appeals. Plans have established customary practices for communicating their benefit determinations with pharmacists, and we see no reason to interfere with that relationship.

Comment: We received many comments expressing concern regarding who should be considered an authorized representative. Commenters suggested that we modify the definition of authorized representative to include any licensed healthcare and social service provider caring for the beneficiary, a practitioner's agent who may act on behalf of the physician caring for the enrollee, pharmacists where State Pharmacy Acts empower collaborative practice agreements, and secondary payors, including employers, SPAPs, Medicaid agencies, and charities that provide wrap-around coverage or otherwise may pay for a drug when the plan denies coverage. One commenter suggested that we limit representatives to authorized family members and physicians.

Response: We considered the comments provided and believe that the commenters' concerns are already addressed. We do not need to add to the list of individuals or entities permitted to act on behalf of enrollees because they have the ability to appoint anyone to be their representative under this rule. In addition, individuals or entities authorized under State law may also act on behalf of enrollees. Therefore, we removed the definition of an ''authorized representative'' under § 423.560 and replaced it with ''appointed representative'' to clarify that a representative is an authorized representative, or is an individual appointed by an enrollee, or authorized under State or other applicable law, to act on behalf of the enrollee in obtaining a coverage determination or in dealing with any of the levels of the appeals process. Thus, any individual or entity (including prescribing physicians, secondary payors, charities, and pharmacists) appointed by an enrollee, or authorized under State law, may file a grievance, request a coverage determination, or appeal on behalf of enrollees. We also have clarified that the appointed representative will have all of the rights and responsibilities of an enrollee in obtaining a coverage determination or in dealing with any of the levels of the appeals process.

In proposed § 423.560, we proposed to define ''enrollee'' as a part D eligible individual or his or authorized representative. Instead, in our final rule we clarify that an enrollee is a Part D eligible individual who has elected or has been enrolled in a prescription drug plan offered by a PDP sponsor, MA organization, or other Part D plan sponsor. Although we have now clarified that an appointed representative is not an enrollee, a plan, nevertheless, has an obligation to the appointed representative to fulfill the requirements under this subpart in the same manner that it is required to do so for the enrollee.

We also disagree with the commenter who suggested that we limit authorized representatives to authorized family members and physicians. We have always provided Medicare beneficiaries with the ability to choose who may act on their behalf, and we see no reason to deviate from this practice in Part D.

Comment: We received several comments addressing permissible filing methods and locations for grievances, appeals, and exceptions. Some commenters suggested that we require enrollees to submit requests in writing only. Other commenters suggested that we require plans to accept requests electronically, or by telephone, fax, or mail. One commenter stated that accepting oral requests would be unduly burdensome, and another argued that requests only be submitted directly to the plans.

Response: As noted above, an enrollee may file a grievance either orally or in writing. Also, as previously mentioned, the MMA requires plans to meet the requirements for coverage determinations and redeterminations under Part D in the same manner as they apply to organization determinations and plan-level reconsiderations in MA. The regulations applicable to MA do not specify the method by which enrollees must file requests for standard organization determinations. However, the MA regulations require MA organizations to have procedures for accepting oral or written requests for expedited organization determinations. The MA regulations also require requests for reconsideration to be filed in writing, but permit requests for expedited reconsiderations to be filed orally or in writing. Therefore, plans must also have procedures for accepting oral or written requests for expedited coverage determinations (including exceptions) and requests for expedited redeterminations. However, plans need only accept standard requests for redetermination when they are made in writing.

Similar to the MA proposed rule, we proposed to require plans to have procedures for accepting oral (including by telephone) or written (including by fax or mail) requests for standard redeterminations. However, consistent with the MA final rule, Part D enrollees must make standard requests for redetermination in writing, unless the plan accepts oral requests. Therefore, we deleted the provision in § 423.582(a) that would have permitted enrollees to file oral requests for redetermination with plans. Although the process currently cannot accommodate electronic appeal requests, we intend to explore this as another filing option for Medicare appeals.

Comment: We received several comments related to the consequences that should apply when a plan fails to meet its adjudication deadlines or provide timely notice. Some commenters suggested that this failure should be considered a favorable determination because, under the proposed rule, plans have no incentive for making coverage determinations or redeterminations since the failure to meet the adjudication deadlines result in de facto denials. The commenters argue that, to ensure enrollee protection, there must be meaningful consequences when plans fail to meet adjudication deadlines. Still others believed that it should result in an adverse determination that may be appealed.

Response: In the proposed rule, we indicated that the failure to provide timely notice of a coverage determination or redetermination would constitute an adverse determination that may be appealed. We also proposed in § 423.578(c)(2) that when the plan fails to make a determination on an exceptions request when a drug is being removed from a formulary, the enrollee would be entitled to receive the medication in dispute until the plan notified the enrollee of its determination. We agree with the commenters who suggested that this provision provides little incentive for plans to make determinations any sooner than by the end of the adjudication deadline, especially if the plan expects to issue an unfavorable determination. Our intent, in part, was to require plans to make timely determinations as mandated by section 1852(g) of the Act. However, we also wanted to remove any barriers for enrollees to accessing needed medications as quickly as possible. We now believe that the provisions, as proposed, fall short of that policy goal. Under MA, if a plan does not provide the enrollee with timely notice of an organization determination, this failure constitutes an adverse determination that may be appealed. However, if the

MA plan fails to issue its reconsideration within the appropriate timeframe, this failure constitutes an adverse determination that must be automatically forwarded to the IRE within 24 hours of the expiration of the timeframe. Unlike under MA, however, we did not propose that Part D plans be required to automatically forward all adverse determinations to the IRE. Instead, we believe that a more effective policy under Part D is to require plans to automatically forward enrollees' requests for determination or redetermination to the IRE only when the plans fail to meet the adjudicatory timeframes for making determinations and redeterminations. As under MA, plans must forward the enrollees' requests to the IRE within 24 hours of the expiration of the adjudication timeframe.

Comment: Several commenters maintained that enrollees should be able to pursue an expedited appeal regardless of whether they already paid for the drug in dispute. Commenters believed that low income beneficiaries, in particular, would be harmed by having to wait 30 days for a plan to make a coverage determination or 60 days to render a redetermination.

Response: A determination regarding benefits is expedited when the application of the normal time frame for making a decision could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function. As proposed in Part D and like Part C, such a determination would not involve a payment request since a medical emergency does not exist for an enrollee who already obtained the medication in dispute. Nevertheless, the concern raised by the commenters regarding the length of time it takes for an enrollee to be reimbursed has been remedied by our decision to no longer distinguish between payment and service-related disputes. As a result, we have reduced the timeframe for plans to make standard coverage determinations to 72 hours in § 423.568(a), and redeterminations to 7 days in § 423.590(a). In addition to shortening the adjudication timeframes, we also reduced the effectuation timeframes for requests involving payment issues to 30 days. Thus, while plans must make a decision on whether to pay for a prescription drug within 72 hours, they must effectuate the decision within 30 days. Likewise, although a plan must make a redetermination within 7 days, it must effectuate no later than 30 days. The effectuation timeframes for requests involving payment issues are longer than the effectuation timeframes for requests for benefits because our experience is plans normally process claims in 30-day cycles. Therefore, plans must effectuate claims for payment no later than 30 days after making a favorable coverage determination or redetermination, or receiving notice of a reversal by the IRE, ALJ, MAC, or Federal court.

Comment: One commenter suggested that we delete the term ''seriously'' and add ''or maintain'' to the last sentence of § 423.566(a) so that it states ''may jeopardize the enrollee's life, health, or ability to regain or maintain maximum function, in accordance with § 423.570.'' The commenter maintained that such a modification is necessary because any amount of jeopardy to an enrollee's health or life is serious enough to warrant an expedited review, and maintenance of maximum function is just as important as regaining maximum function.

Response: The MMA requires entities that offer Part D plans to meet the requirements that apply to Part D coverage determinations and redeterminations in the same manner as they apply to MA organizations for organization determinations and reconsiderations. Section 1852(g)(3)(B) of the Act requires MA organizations to establish procedures for expediting organization determinations and reconsiderations when ''the application of the normal timeframe for making a determination...could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.'' Therefore, we are not adopting the commenter's suggestion.

Comment: We received one comment suggesting that the prescribing physician should make the determination whether to expedite an enrollee's request for a coverage determination or redetermination. The commenter maintained that the physician, not the plan, is in the best position to determine how quickly an enrollee needs a prescribed medication.

Response: We agree with the commenter. Therefore, like under MA, we require plans to automatically provide an expedited determination or redetermination when the prescribing physician indicates that applying the standard timeframe would seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

Comment: Two commenters suggested that prior authorization decisions should be included in the list of actions that constitute a coverage determination under § 423.566(b). The commenters maintain that placing a medication on a prior authorization list has the effect of limiting access to such a medication since the administrative cost and burden associated with obtaining a prior authorization may cause physicians to cease prescribing drugs that require that a prior authorization requirement be satisfied.

Response: As previously noted, information regarding a plan's benefit design as it pertains to all enrollees is not a coverage determination. We will allow plans the flexibility to determine how to structure their formularies, subject to our approval. As a result, plans are permitted to determine which medications are placed on their prior authorization lists. The decision to place a medication on a prior authorization list is not a coverage determination and is not subject to appeal. However, when a plan processes a prior authorization request, the plan's determination on whether to grant approval of a drug for an individual enrollee constitutes a coverage determination that is subject to appeal. In addition, if a plan denies a drug, because the enrollee failed to seek prior authorization, that would also constitute a coverage determination subject to appeal.

Comment: One commenter requested that we define ''State law'' where we stipulate in § 423.560 that a representative authorized under State law may act as an authorized representative on behalf of an enrollee. The commenter suggests that State law be defined as a constitution, statute, regulations, rule, common law, or other State action having the force and effect of law.

Response: We agree that ''State law'' may include a constitution, statute, regulation, rule, common law, or other State action having the force and effect of law. However, we do not believe that it is necessary to define State law under § 423.560.

Comment: We received one comment suggesting that we define the phrase ''furnished by the PDP'' in § 423.566(b)(1), which limits actions that are coverage determinations to the failure to provide or pay for a covered Part D drug that an enrollee believes may be furnished by the plan. The commenter is concerned that if an enrollee receives prescription drugs while satisfying the deductible or during the period between the initial coverage limit and the out-of-pocket threshold, a plan could determine that it did not furnish the drugs to the enrollee. As a result, enrollees who receive prescription drugs during such periods would not receive a coverage determination and would therefore be

excluded from the appeals process. The commenter maintains that enrollees should be entitled to appeal a determination that denies coverage even when a plan does not pay for the prescription drug because of the enrollee's cost-sharing obligations.

Response: Our intent in § 423.566(b)(1) was to indicate that the failure to provide or pay for a Part D drug that the enrollee believes may be covered by the plan results in a coverage determination. Rather than define what ''furnished by the PDP'' means, we replaced ''furnished'' with ''covered'' to make clear that coverage determination and appeals procedures do apply in these situations.

5. Formulary Exceptions Procedures (§ 423.578)

a. Exceptions to a Plan's Tiered Cost-Sharing Structure

The MMA specifies that an enrollee may request an exception to a plan's tiered cost-sharing structure and that plans must have a process in place to handle such requests. Under such an exception, a ''non-preferred drug *could* (emphasis added) be covered under the terms applicable for a preferred drug'' under certain conditions. At a minimum, the prescribing physician will have to determine that the preferred drug either will not be as effective for the individual, or will have adverse effects for the individual, or both. Unfavorable determinations constitute coverage denials and are subject to all the appeal rights discussed in subpart M of part 423.

We proposed under § 423.578 that a plan must establish a tiering exceptions process that addresses each of the following sets of circumstances: (1) the enrollee is using a drug and the applicable tiered cost-sharing structure changes during the year; (2) the enrollee is using a drug and the applicable tiered cost-sharing structure changes at the beginning of a new plan year; and (3) there is no pre-existing use of the drug by the enrollee.

While we thought it necessary to require plans to include certain criteria in the tiering exceptions process, we also recognized the need to avoid a situation where a plan's cost-sharing rules are effectively driven by the tiering exceptions criteria, rather than the other way around.

At proposed § 423.578(a)(2) we outlined a limited number of elements that must be included in any plan's tiering exceptions criteria: (1) a description of the process used by the plan to evaluate the physician's supporting statement; (2) consideration of the cost of the requested drug compared to that of the preferred drug; (3) consideration of whether the formulary includes a drug that is the therapeutic equivalent of the requested drug; and (4) consideration of the number of drugs on the plan's formulary that are in the same class and category as the requested drug.

Consistent with existing MA rules, we proposed that an enrollee, the enrollee's authorized representative, or the prescribing physician may request a tiering exception. The statutory requirement that the prescribing physician determine that the preferred drug either would not be as effective for the individual generally, or would have adverse effects for the individual, constitutes a minimum threshold for approving an exception request. We proposed at § 423.578(a)(4) that a plan may require a written supporting statement to that effect from the prescribing physician, as well as certain limitations on the content requirements that plans could impose for these supporting statements. We would permit plans flexibility in how this standard would be applied. For example, a plan could require that a physician certify that the preferred drug would be less effective than the non-preferred drug, or the plan could choose to apply a more stringent standard (such as requiring that the prescribing physician's supporting statement also include the enrollee's patient history or require the enrollee to first try the plan's preferred formulary drug, absent medical contraindications).

A plan's exceptions procedures will also be required to describe how a determination on an exception request will affect the enrollee's cost sharing obligations under the plan's tiering structure.

Comment: Several commenters expressed concern regarding our proposal to allow plans the flexibility to establish exceptions criteria. Some commenters opposed giving plans the flexibility to determine their own exceptions criteria because the MMA requires the Secretary to establish guidelines for the exceptions process. Other commenters stated that drug plans should establish their own criteria to determine whether a preferred drug would not be as effective or would have adverse effects for the enrollee's health condition.

Response: We agree with commenters that plans should impose some criteria for making tiering exception determinations, and in this final rule, we are requiring that plans grant exceptions when the plan determines that the lower-tier drug would not be as effective for the enrollee as the requested drug, would have adverse effects for the enrollee, or both. Other than the above requirement, however, we will not be overly prescriptive in how tiering exception criteria are designed and what criteria a plan uses to determine whether a preferred drug would not be as effective or would have adverse effects for the enrollee. Although the MMA requires plans to develop an exceptions process for requests involving a tiered cost-sharing issue that is consistent with the guidelines established by the Secretary, it does not require the Secretary to establish a comprehensive and uniform set of criteria that plans must meet when developing their exceptions processes. We have established specific requirements that plans must satisfy when processing exceptions requests that are the same as other coverage determinations. They include, for example, timeframes for decision-making; the consequences for failing to make timely decisions; expedited procedures when an enrollee's life, health, or ability to regain maximum function could be seriously jeopardized; detailed notices when exceptions are denied; the right to appeal through a 4–tiered administrative process, and if necessary, to request judicial review; and when the plan must continue benefits. However, while plans must design their exception criteria so that drugs determined by the plan to be medically appropriate for the enrollee are covered, we do not believe that we should require detailed standards that go beyond such a medical necessity requirement. This is particularly the case for the reasons previously mentioned, that is, allowing plans flexibility, and our uncertainty of how plans will develop formularies. Also, we still have ultimate authority over what the criteria will entail. Rather than exercise this authority through the establishment of specific exceptions criteria, we believe that the most appropriate policy is to review the plans' exceptions criteria as part of the approval process, to ensure that the criteria are reasonable and complete. For example, we would likely expect that a plan would establish different types of criteria for different classes of drugs. Thus, in some instances, tiering exceptions may be connected to demonstrated adverse effects based on previous use of the lower tiered drug, while in others, exceptions may be linked to predictive adverse effects based on knowledge of the enrollee's medical condition. While we are by no means dictating the establishment of separate criteria for each drug class or

category, a plan's criteria should encompass all drug classes. Thus, to the extent that the plan chooses to differentiate among drug classes, its exceptions procedures need to clearly explain which criteria apply for various types of drugs or situations. Additionally, we would not approve a plan's tiering procedures if they are unreasonable. Similarly, we would not approve a plan's procedure that would require demonstrated adverse effects in every situation. Clearly, there are situations in which enrollees would suffer significant harm if they are required to demonstrate adverse effects.

Comment: One commenter suggested that plans only be required to maintain an exceptions process for instances where an enrollee is receiving a drug that is affected by a plan's mid-year tiering change. The commenter believed that the four categories established under the proposed rule were unnecessary.

Response: We disagree with the commenter that a plan's exceptions procedures need only address instances where an enrollee is using a drug that is affected by a plan's mid-year change to its formulary tiers. We believe that a plan's exceptions procedures must encompass all types of tiering exception requests and have added language to § 423.578(a) to make clear that Part D sponsors must have complete exceptions procedures that grant exceptions when the plan determines that the factors under § 423.578(a)(4) exist (that is, the lower-tiered drug would not be as effective, would have adverse effects, or both). Nevertheless, we also recognize that the circumstances raised by the commenter involve perhaps the single most critical aspect of a plan's exceptions procedures.

To reflect and emphasize the importance of such circumstances (where a tiering structure changes mid-year and the enrollee has already been using the drug), we are modifying § 423.578(a)(1) and (b)(1) to mention only that circumstance as a situation that plans must specifically address in their exceptions procedures. By no means does this change obviate the need for complete exceptions procedures. A plan must have exceptions procedures that can be applied to all requests for exceptions. Thus, for example, plans' exceptions procedures would need to address situations where an enrollee has no pre-existing use of a drug in dispute and the tiering structure changes mid-year. However, the case of a beneficiary who has a preexisting use of a drug and where the tiering structure changes mid-year represents the only set of circumstances that needs to be addressed distinctly.

We recognize that each plan is required to notify enrollees of changes that will occur in an annual notice of coverage by October 31st each year. Since enrollees have the option of switching plans at the beginning of a new plan year, an exceptions request that has been approved may be reviewed at the end of the year. Consistent with plans notifying affected enrollees of changes to their formularies 60 days in advance under § 423.120(b)(5), a plan must also notify enrollees if the plan intends to change the cost-sharing for a drug on its formulary during the next enrollment period. Therefore, enrollees will have sufficient notice of any tiering changes made at the beginning of a plan year to either choose a new plan, or request an exception.

Comment: We received numerous comments concerning how the price for a drug will be determined when there are mid-year changes in the tiering structure and an exception is approved. Some commenters suggested that, when there is a mid-year change in the tiering structure, enrollees should be granted continued access to drugs at the price before the change. Other commenters argued that we should define who should receive continued access at the price before the change. One commenter argued that it would be impossible to manage a benefit if enrollees could obtain an exception that would permit non-preferred drugs to be priced at the generic drug level. A few commenters, however, believed that, when there is a mid-year change, we should not require plans to provide access to drugs at the price before the change.

Response: We agree that enrollees who are receiving a medication affected by a mid-year change in the tiering structure must have a method for ensuring that they are able to receive a medically necessary drug at a given cost-sharing amount when a tiering exception is granted. Consistent with section 1860D–4(g)(2) of the Act, § 423.578(c)(3) requires that where a plan grants an exception to its tiered cost-sharing structure, a non-preferred drug will be covered under the terms applicable for preferred drugs. Thus, if a plan has a generic level in its tiering structure, we would not expect the plan to provide a non-preferred drug at the generic level. In addition, if a plan has developed a tier in which it places very high cost and unique items, for example, genomic and biotech products, a plan may design its exception process so that such Part D drugs are not eligible for a tiering exception. We have added regulatory language to § 423.578 to make these two points clear.

As stated in § 423.578(c), if a tiering exception is granted, the enrollee will be approved for coverage as long as the prescribing physician continues to prescribe the drug; the drug continues to be safe for treating the enrollee's disease or medical condition; and the enrollment period has not expired.

Comment: Many commenters suggested that we develop a single well-designed exceptions process in which decisions are made based on the medical needs of the enrollee. The commenters maintained that a single process may help streamline administrative requirements and costs, and one based on the medical needs of the enrollee would address all three circumstances proposed in § 423.578, that is, where an enrollee is using a drug and the applicable tiered cost-sharing structure changes mid-year; the enrollee is using a drug and the cost sharing changes at the beginning of a new plan year; or there is no pre-existing use of the drug by the enrollee. Other commenters recommended that the certifying standard for physicians under proposed § 423.578(a)(4) be revised to comply with the statute.

Response: We partially agree with the commenters, and have added regulatory language that requires both off-formulary and tiering exceptions to be based on the medical needs of the enrollee. However, tiering exceptions are not typically offered in private industry currently. While tiering exception procedures must be reasonable, complete, and based on medical needs, as we discuss above, we do not believe that it would be appropriate at this stage to dictate a single type of tiering exception procedure that must be used by all plans.

We also agree with the commenters that the ''certifying'' standard for physicians must be revised to comply with section 1860D–4(g)(2) of the Act. Note that the statute does not use the term ''certification,'' and we believe that this term may be interpreted too formally. Therefore, we have modified § 423.578(a)(4) to require plans to obtain a ''supporting statement from the prescribing physician that the preferred drug for treatment of the same condition either would not be as effective for the enrollee, would have adverse effects for the enrollee, or both. We have made corresponding technical changes to the regulation wherever the term ''certification'' was previously used.

We also believe that a physician must be able to certify that the enrollee meets one or both of these conditions orally or

in writing. A plan may require a physician who provides an oral supporting statement to subsequently follow-up in writing, particularly where a plan decides not to grant an exception. The plan may require the prescribing physician to provide additional supporting medical documentation as part of the written follow-up. A plan may want to preserve the record in the event the enrollee or physician requests an appeal. However, we do not want to create a process whereby physicians must routinely provide written supporting statements. Otherwise, such an administrative burden could have the unintended consequence of discouraging exceptions requests when enrollees need non-preferred drugs. Finally, once a physician provides an oral or written supporting statement, the plan will review the request. The plan may obtain other evidence, including additional medical information from the prescribing physician. After performing its review, the plan must determine if the enrollee's condition can be treated with the preferred drug. We removed the content requirements for a physician's supporting statement, such as the enrollee's name, patient history, primary diagnosis related to the exceptions request, and why the non-preferred drug is needed. Again, we do not want to mandate that every exceptions request must be processed according to a listing of procedures. We believe that plans are in the best position to determine on a case-by-case basis the type of information they need to overcome the burden.

Comment: We received two comments suggesting that, instead of creating a separate definition of therapeutic equivalence in proposed § 423.578(a)(2)(iii), we should apply the same definition proposed in § 423.100.

Response: We agree with the commenter. Therefore, we have deleted the definition of therapeutic equivalence in the proposed rule and added a cross-reference to § 423.100.

Comment: A few commenters recommended that we adopt a uniform set of exceptions codes to be used by physicians and pharmacists. One commenter suggested that we work with the National Council for Prescription Drug Programs, Inc. to develop a standard claim processing field that payors and pharmacies would be required to use for purposes of communicating which tier is applied. Both commenters argued that adopting a uniform set of codes to be utilized by plans, pharmacists, enrollees, and physicians would streamline the exceptions process and make it easier to navigate.

Response: We appreciate the commenters' suggestions, but we believe the entities that provide Part D plans are in the best position to determine how to communicate with physicians and pharmacies. As we gain a better understanding of how plans intend to develop their formularies, we will work with interested parties to ensure that there are standard systems or procedures in place to make the process as simplistic as possible for pharmacists, physicians, and enrollees to navigate.

b. Exceptions and Appeals Rules for Non-Formulary Determinations

Section 1860D–4(h)(2) of the Act establishes a limitation on requests for exceptions when a particular drug is not on a plan's formulary at all. The statute specifies that an enrollee may appeal a determination not to provide coverage of a non-formulary drug ''only if the prescribing physician determines that all covered Part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual as the non-formulary drug, would have adverse effects for the individual, or both.''

Notably, this limitation is set forth under the ''appeals'' provisions of the statute, as opposed to under the preceding coverage determination and redetermination provisions that are discussed above for exceptions to tiered cost-sharing rules. Thus, we believe the intent of this provision is to limit appeals to cases where the prescribing physician has made the determination described by the law.

Unlike for the tiering exceptions, the statute does not specifically require that plans develop an exceptions process to review requests for exceptions for non-formulary drugs. However, the statute under section 1860D–4(h)(2) of the Act permits enrollees to appeal a determination not to provide for coverage of non-formulary drug only if the prescribing physician determines that all of the covered Part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the enrollee as the non-formulary drug, would have adverse effects, or both. As a result of the statutory requirement that enrollees obtain a physician's determination to request an appeal, we do not believe that the statute intends to preclude an enrollee from obtaining a coverage determination from a plan absent a determination by the prescribing physician, or to require that the physician's determination alone will result in a favorable coverage determination by the plan. Therefore, we proposed to require that plans also establish exceptions criteria for addressing these situations.

We stated our belief that requiring plans to use an exceptions process to review requests for coverage of non-formulary drugs would ensure that enrollees know what standards are to be applied and ensure that a plan's formulary is based on scientific evidence rather than tailored to fit exceptions and appeals rules for formulary drugs.

Under the exceptions process proposed at § 423.578(b), a plan would be required to allow enrollees to request (1) coverage of Part D drugs that are not on a plan's formulary; (2) continued coverage of a drug the plan has removed from its formulary; (3) an exception to a plan's policy regarding coverage for a step therapy; and (4) an exception to a plan's dosing limitation.

A plan's criteria would have to include a description of the criteria it would use to evaluate the prescribing physician's determination, clarify how the plan will evaluate the relative safety and efficacy of the requested drug, and describe the cost-sharing scheme that will be applied if coverage is provided. Again, an enrollee, the appointed or authorized representative, or prescribing physician could request an exception, and the plan could require a written supporting statement from the prescribing physician that the non-covered drug was medically necessary to treat the enrollee's disease or medical condition. We proposed that an enrollee would have the right to a redetermination by the plan of any unfavorable coverage determination.

Comment: One commenter suggested that we not require plans to develop and maintain an exceptions process for non-formulary drugs because it would make formulary adherence more difficult for plans to control.

Response: Although the statute does not specifically require that plans develop an exceptions process to review requests for exceptions for non-formulary drugs, we continue to believe that there is ample authority in the statute to require plans to have exception processes for off-formulary drugs. First, section 1860D–4(h) of the Act permits a beneficiary to request an appeal of an off-formulary drug if the prescribing physician determines that all covered part D drugs on any tier of the formulary under the plan for treatment of the same condition would not be as effective for the individual, would have adverse effects, or both. We do not believe that it is reasonable to require a beneficiary to wait until the appeal stage in order to receive an off-formulary drug, when the plan could

just as easily determine at the initial coverage determination stage that the on-formulary drugs are not appropriate for the beneficiary. In addition, the entire structure of the benefit, as explained in section 1860D–2 of the Act, is a structure that assumes that beneficiaries will have access to medically necessary drugs when appropriate, regardless of whether such drugs are on or off the formulary. Finally, under section 1860D–11(d)(2) of the Act we have the authority to set minimum standards for sponsors' benefit packages, and under section 1860D–12(b)(3)(D) of the Act, we have the authority to add contract terms to PDP sponsor contracts. Based on all of these authorities, we believe it is appropriate to require plans to maintain exception processes for off-formulary drugs. Requiring plans to use an exceptions process to review requests for coverage of non-formulary drugs will create a more efficient and transparent process and will ensure that enrollees know what standards are to be applied. In addition, this requirement is consistent with the industry standard where private plans allow enrollees to file exceptions to receive non-formulary medications.

Comment: Several commenters recommended that we require plans to establish additional exceptions criteria, including criteria that would preclude the use of a formulary drug where the enrollee experiences an adverse reaction from the drug previously tried and failed. Commenters believed that we should develop exceptions criteria for certain classes of drugs, namely those used by special populations such as beneficiaries with HIV/AIDS or mental health patients. Other commenters, however, believed that the exceptions criteria should be limited to whether the requested medication is appropriate for the patient, as documented by the prescribing physician.

Response: First, we agree with commenters that exceptions criteria should be designed to grant exceptions in cases where a plan determines that an off-formulary drug is medically appropriate for an enrollee and that the drug would have been covered but for the fact that the drug is off-formulary. We have added language to § 423.578(b) to this effect. As stated above, we believe the structure of the benefit under section 1860D–2 of the Act, the authority to create minimum standards and additional contract terms, and the requirement for off-formulary appeals, provide ample authority for this requirement. However, while plans must design their exception criteria so that drugs determined by the plan to be medically appropriate for the enrollee are covered, we do not believe that we should require detailed standards that go beyond such a medical necessity requirement. This is particularly the case because we do not know how plans will design their formularies. These comments illustrate the complexity of attempting to do so. Instead, the plan must establish criteria that encompass all exceptions requests and the procedural elements that must be followed to process a request. We will review these criteria as part of the plan approval process.

The primary issue that plans must address in a plan's non-formulary exceptions criteria is how it will determine medical necessity. Although plans must provide access to all Part D drugs that they determine are medically necessary (as that is described in § 423.578(b)(5)), we are not requiring prescriptive requirements for the methods that plans use to determine medical necessity. Therefore, plans will have some flexibility in creating the criteria or methods, such as prior authorization or step-therapy, to determine whether a non-formulary drug is medically necessary for an enrollee. We agree that where an enrollee's prior use of a drug has proven ineffective or caused adverse consequences to the enrollee's health, the plan must not require the use of the formulary drug as a condition in the exceptions process. This is a key component of the exceptions process, which entails a written statement from the prescribing physician that all covered Part D drugs on any tier of the formulary would not be as effective as the non-formulary drug, would have adverse effects for the enrollee, or both. Note that such a statement does not necessarily result in an automatic approval of the request. Clearly, nothing in this rule precludes a plan adopting a process whereby it grants automatic approval of a non-formulary drug upon a physician's supporting statement. However, some plans may want physicians to provide their rationale as to why, for example, the formulary drug would not be as effective for treating the enrollee's condition.

Finally, we do not believe that the statute permits us to develop unique exceptions criteria for certain classes of drugs used by special populations. Nevertheless, special populations will benefit from the rights and protections that the exceptions process affords all enrollees.

Comment: Several commenters requested us to provide an exception that would permit an enrollee to obtain a drug that is excluded from Part D.

Response: We strongly disagree with the commenters. The MMA mandates that we only provide access to Part D drugs and specifies certain categories of drugs as excluded. Therefore, we do not have the statutory authority to require plans to provide access to drugs that are excluded from Part D. As a result, we have strengthened § 423.578(e) to emphasize that nothing in the exceptions process shall be construed to allow an enrollee to use the exceptions process to request or be granted coverage for a prescription drug that is not a Part D drug. However, we note that while an enrollee cannot appeal the policy that a drug is not a Part D drug if excluded (that is, covered by Part B or otherwise excluded from the definition of Part D drug in § 423.100), the enrollee can request a coverage determination or an appeal regarding the policy as it applies to his or her set of facts. In other words, the enrollee can seek to demonstrate that the policy is not applicable in a particular instance based on the facts of his or her case. This is the same standard used in claims appeals where a beneficiary cannot appeal a national coverage determination (NCD) through the claims appeals process, but may appeal whether the NCD should apply in his or her case.

Comment: One commenter sought clarification on whether formulary use includes the type of the dosage, for example, liquid, capsule, tablet, and packaging, such as bubble wraps for long-term care facility residents. The commenter argued that ''formulary use'' includes more than just dose restriction, and § 423.578 must be revised to meet the statutory requirements that the Secretary establish guidelines for the exceptions process.

Response: We believe that an enrollee must be permitted to file an exception when he or she cannot take the dosage form of a medication that is included on a plan's formulary. If a medication is offered in tablet and liquid form but the plan only covers the tablet form on its formulary, an enrollee must be permitted to file an exception to obtain the liquid form of the medication if the prescribing physician indicates that the tablet form either would not be as effective for the enrollee, would have adverse effects, or both. For example, an elderly enrollee may not be able to swallow the tablet form. Therefore, we clarified in § 423.578(b) that ''formulary use'' includes the form of the dosage. However, we do not agree that ''formulary use'' includes packaging because the packaging of a drug, for example, bubble-wrapping, blister-cards, cassettes, does not impact the

effectiveness of a medication. In addition, activities related to the transfer of Part D drugs are included in the negotiation of the dispensing fee under section 1860D–2(d)(1)(D) of the Act.

Comment: A few commenters requested that we clarify who should make the determination as to whether a drug is no longer safe and effective for treating an enrollee's disease or medical condition. The commenters suggested that an authoritative agency or organization such as the FDA should make this type of determination.

Response: Plans may discontinue coverage of a medication for safety reasons, and in their exceptions procedures for non-formulary drugs, must include a process for comparing applicable medical and scientific evidence on the safety and effectiveness of the requested non-formulary drug with the formulary drug. Thus, in some instances, plans themselves may make an initial determination whether a drug is no longer safe and effective for the treatment of a disease or medical condition, subject to the appeals process. Plans also will rely on safety information generated by an authoritative government body such as the FDA (for example, relying on information released in an FDA Medwatch form) when discontinuing coverage of a medication for safety reasons.

c. Exceptions and Appeals Rules for a Plan's Tiered Cost-Sharing Structure and Non-Formulary Determinations

We received several comments that raise issues related to § 423.578(a) and (b). Instead of addressing the comments in each of the preamble discussions in sections 5.a. and 5.b. above, we have consolidated the comments and responses in this section since the issues are common to exceptions involving tiered cost-sharing structure and non-formulary issues.

Comment: We received numerous comments regarding the weight that plans will give a physician's supporting statement. Many commenters suggested that the physician's supporting statement carry great weight in determining whether an enrollee should receive a prescribed medication. Other commenters suggested that, if a physician prescribes a medication for an enrollee, he or she should automatically receive it. Still other commenters suggested that once a physician certifies that an enrollee should receive a prescribed medication, the burden should shift to the plan to show why the physician's supporting statement is not dispositive. The commenters argued that the burden on physicians to justify their drug selection decisions is too great under the proposed rule. In order to make the process faster and simpler for enrollees, physicians, and pharmacists, the physician's supporting statement should be the primary factor in determining whether an enrollee should receive a requested medication.

Response: As noted above, we agree with the commenters that a physician's opinion must carry great weight. However, we do not agree that a physician's supporting statement necessarily means that an enrollee must automatically receive a drug. If the Congress intended such an outcome, there would be no need for plans to develop exceptions procedures. Therefore, once a physician provides a supporting statement that an enrollee should receive a prescribed medication, the plan will review the request. The plan may obtain other evidence, including additional medical information from the prescribing physician. After performing its review, the plan must determine if the enrollee's condition can be treated with the preferred or formulary drug. We note that if an enrollee disagrees with the plan's exception determination, it can still appeal that determination through the regular appeals process.

Comment: We received several comments objecting to an option considered by us that would require an enrollee who is using a drug that is subsequently removed from the plan's formulary, or is no longer designated as the ''preferred drug,'' to try a preferred drug(s), and experience adverse effects, before being permitted to resume using the original drug.

Response: We agree with the commenters that we must not add an exceptions criterion that will require an enrollee to try a preferred drug(s) and experience adverse effects before being permitted to resume using the original drug. However, we wish to point out that nothing in this rule precludes a plan from establishing such a requirement in its exceptions process. As mentioned in our earlier response, we do not believe that an enrollee who has used a formulary or preferred drug and has already experienced adverse consequences should be required to take the same harmful drug, as certified by the prescribing physician. For instance, most clinicians find it inappropriate to change the medication of a patient stabilized on a selective serotonin reuptake inhibitor (SSRI) that was moved from a formulary, or from a lower tier to a higher tier, because the effectiveness level of SSRIs is not reached for two weeks. However, the scenario that the commenters have described is quite different. There, the situation involves a drug that has been removed from the plan's formulary or moved to a different tier, subsequent to an enrollee's use of a drug. Because the enrollee would be affected by the plan's formulary or tiering change, the plan is obligated to provide a notice to the enrollee 60 days in advance, or continue coverage of the drug as required under subpart C of this rule. Thus, this gives the enrollee sufficient time to request an exception. If the physician indicates that the formulary or preferred drug would have an adverse effect on the enrollee's health, the plan likely will not require the enrollee to take the drug. However, if the physician's supporting statement does not demonstrate that the drug would have adverse consequences or would be ineffective, we would not prohibit the plan from requiring the enrollee to try the formulary or preferred drug. For example, in many instances, a patient may be able to try a formulary alternative statin medication when their current statin medication is being removed from the formulary. However, if the enrollee experiences adverse effects after trying the drug, the plan must then grant the exception. In addition, as we state above, there may be some cases where requiring a beneficiary to try a drug and experience adverse effects would be unreasonable.

d. Treatment of Determinations Regarding Exceptions Requests

We proposed at § 423.578(c)(1) that determinations on exception requests would constitute plan coverage determinations under § 423.566 and should be completed in the same timeframes. Enrollees would then have an opportunity to request a plan redetermination. Unfavorable redetermination decisions could then be appealed to the IRE. If the IRE determines that the plan correctly applied its exceptions criteria, the plan's determination would be upheld.

Thus, we proposed that the IRE would not have any discretion regarding the validity of the plan's exceptions criteria or formulary. Instead, we would be responsible for evaluating and approving a plan's exceptions criteria and formulary as part of the annual plan approval process. In many instances, however, evaluating whether the plan had appropriately applied its own exceptions criteria for a formulary exception would necessarily involve an element of medical judgment (for example, if the plan had a rule that an enrollee would need to suffer significant adverse effects by using the Part D drug covered by the plan in order to obtain an exception, the IRE would need to

review whether such adverse effects had been experienced). In those situations, we stated the IRE's medical staff would be responsible for reviewing the plan's determination as to whether the formulary exceptions criteria had been applied properly. Because the final rule requires a Part D plan's formulary and tiering exceptions process to grant an exception when the plan determines it is medically appropriate, the IREs will likely be reviewing medical necessity in numerous cases.

Although not required by statute, we thought it important to put in place certain safeguards regarding the issuing and effect of a coverage determination made as part of the exceptions process. We believed that certain safeguards would help to ensure that the exceptions process was both fair and efficient for enrollees. First, to ensure that enrollees who file exceptions requests for drugs that are being removed from a plan's formulary are not disadvantaged by a plan's failure to issue a timely decision, we proposed in § 423.578(c)(1) and § 423.578(c)(2) that if a plan failed to issue a timely decision, the plan would be required to continue providing coverage until a decision was made on the request. Proposed § 423.578(c)(2)(i) allowed enrollees to receive up to a one-month supply of the requested drug, but a plan could adjust the supply to account for a shorter time frame. As noted above, we have revised proposed § 423.578(c)(2) to be consistent with our requirement in MA that an MA plan's failure to issue its reconsideration within the appropriate timeframe constitutes an adverse determination which must be automatically forwarded to the IRE within 24 hours of the expiration of the timeframe. We also provided, at proposed § 423.578(c)(3), that once a plan approved a drug pursuant to the exceptions process, an enrollee would be entitled to continue receiving refills of the drug at the prescribing physician's discretion.

The final safeguard implemented under proposed § 423.578 prohibited plans from assigning drugs approved under either exceptions process to a special formulary tier, co-payment, or other cost-sharing requirement. In other words, plans must employ reasonable criteria in determining the co-payments or other cost-sharing requirements of drugs approved for coverage under the exceptions process.

Comment: We received several comments regarding the level of cost-sharing that enrollees would be required to pay when an exception is approved. Some commenters suggested that all drugs be approved at the preferred level of cost-sharing. Another commenter agreed that non-preferred drugs should be approved at the cost-sharing level applicable for preferred drugs when an exception request is approved, but recommended that we clarify that non-preferred drugs can not be approved at the generic cost-sharing level.

Response: We agree with the commenters that, when an exceptions request involving a tiering issue is approved, the enrollee is entitled to the amount of cost-sharing that applies for a preferred drug, but not for a generic drug. We have clarified this under § 423.578(c)(3).

We do not agree that we must mandate the amount of cost-sharing that applies when an exception involving a non-formulary drug is approved. Section 1860D–4(h)(2) of the Act requires plans to treat non-formulary Part D drugs approved under the exceptions process as being included on the plan's formulary for purposes of determining whether an enrollee has reached the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B)(i) of the Act. However, the MMA does not mandate that plans apply the cost-sharing terms of a particular tier when plans establish tiers to manage covered Part D benefits. Therefore, we do not specify in § 423.578(c) the tier that must be applied when a plan approves an exceptions request that involves a non-formulary drug. Instead, § 423.578(b)(2)(iii) gives plans the flexibility to determine which level of cost-sharing will apply when it approves an exceptions request involving non-formulary drugs. Plans must explain in its exceptions criteria the cost-sharing scheme that will be applied. Allowing plans the flexibility to determine which level of cost-sharing will apply is consistent with section 1860D–2(b)(2) of the Act, which permits a plan to establish tiers to manage its covered Part D benefits so long as the co-payments associated with the plan's tiers meet the actuarial equivalence standard in section 1860D–2(b)(2)(A)(ii) of the Act. If we required plans to apply the cost-sharing amount that applies to covered part D drugs at a specific cost-sharing level, we would impede a plan's flexibility to develop its tiered cost-sharing structure.

We note that plans are prohibited under § 423.578(c)(4)(ii) from establishing a special formulary tier or other cost-sharing requirement that is applicable to non-formulary Part D drugs that are approved under the exceptions process. As mentioned previously, we will review all of the plans' exceptions criteria and determine if they are appropriate and meaningful. We have clarified under § 423.578(c)(3) through (4) the difference between how exceptions involving tiering and non-formulary issues must be treated after approval.

We would also like to clarify that, if a plan approves an exception for a non-formulary drug, an enrollee may not request a tiering exception for the non-formulary drug. Although, section 1860D–4(h)(2) of the Act requires plans to treat non-formulary Part D drugs approved under the exceptions process as being included on the plan's formulary, it does so only for purposes of determining whether an enrollee has reached the annual out-of-pocket threshold. Plans are not required to add a non-formulary drug to its formulary once an exception is granted. Therefore, although a non-formulary drug could be obtained at the amount of cost-sharing that applies to drugs on a plan's non-preferred tier under the exceptions process, the ''non-formulary drug'' is not a ''non-preferred drug,'' and only non-preferred drugs are subject to the exceptions process.

Comment: We received one comment recommending that we delete the requirement in proposed § 423.578(c)(3)(ii) which would prohibit plans from assigning drugs approved under an exceptions request to a special formulary tier, co-payment, or other cost-sharing requirement. The commenter acknowledges that the provision is derived from the statute, but maintains that the provision is unnecessary because the commenter believes that we have presented two options for cost-sharing (payment at the preferred and generic cost-sharing levels) that constitute a special formulary tier.

Response: We disagree with the commenter that we have created a special formulary tier. We believe that it is necessary to include in § 423.578(c)(4)(ii) a provision that will ensure that plans do not assign drugs approved under a non-formulary exceptions request to a special formulary tier, co-payment, or other cost-sharing requirement. This policy is consistent with the statute.

Comment: Several commenters contended that, when an exceptions request is approved, the approval should not be for an indefinite period of time. The commenters argued that we should include provisions for limiting indefinite exceptions based on safety or accepted clinical practice standards, including step-therapy and length of therapy edits. Some commenters suggested that plans be permitted to annually re-evaluate exceptions that

have been approved. However, other commenters believed that proposed § 423.578(c)(3) provided important beneficiary protections to the extent that the enrollee would not need to renew an exceptions request so long as the prescribing physician continues to prescribe the drug.

Response: We agree that plans must continue providing a drug that was approved under the exceptions process so long as the prescribing physician continues to prescribe the medication and the medication continues to be considered safe for treating the enrollee's condition. However, we do not believe that an approval should last indefinitely. Therefore, we have added § 423.578(c)(4) to provide that once an exceptions request is approved, the plan must provide coverage of the drug so long as the enrollee also continues to be a member of the plan, or the enrollment period has not expired, whichever is sooner. Thus, in no case will a plan be required to continue coverage beyond the plan year.

6. Appeals

a. Redeterminations (§ 423.580 through § 423.590)

Sections 423.580 through § 423.590 explain the right to a redetermination and the requirements that apply to plans for both standard and expedited redeterminations. If a decision regarding a coverage determination is unfavorable (in whole or in part) to the enrollee, the enrollee may file an oral or written request with the plan for a redetermination on the decision.

The proposed regulations did not identify Social Security Administration (SSA) field offices as possible locations for filing redetermination requests. Using any filing location other than the plan itself can significantly affect the speed with which the appeal is resolved. Moreover, given that section 931 of the MMA mandates the transfer of responsibility for Medicare appeals from SSA to DHHS by no later than October 1, 2005, we believed that an explicit regulatory reference to SSA field offices would not be appropriate.

For an expedited redetermination, an enrollee or the prescribing physician (acting on behalf of an enrollee) may submit an oral or written request for redetermination. However, requests for payment of drugs already received would not be expedited. The proposed requirements for making standard redeterminations for requests involving covered benefits in proposed § 423.590(a) specified that the plan would issue its redetermination as expeditiously as the enrollee's health condition required, but no later than 30 calendar days from the date of receipt of the request.

Under proposed § 423.590(b), for standard redeterminations involving requests for payment, the plan would be required to issue its redetermination no later than 60 calendar days from the date of receipt of the request. In the case of expedited redeterminations, § 423.590(d) specified that a plan would complete its redetermination and give the enrollee and the prescribing physician involved, as appropriate, notice of its determination as expeditiously as the enrollee's health condition required, but no later than 72 hours after receiving the request. For both the standard and expedited redetermination for covered benefits, the plan could extend the timeframe for making its determination by up to 14 calendar days if the enrollee requested the extension, or if the plan justified a need for additional information and how the delay would be in the interest of the enrollee. An extension would not be provided for redeterminations involving requests for payment. If the plan's redetermination resulted in an affirmation, in whole or in part, of its original adverse coverage determination, the plan would be required to give written notification to the enrollee and advise the enrollee of the right to file an appeal with the IRE that contracts with us.

Comment: Several commenters asked us to define ''good cause'' for extending the timeframe for filing a redetermination request in § 423.582(c).

Response: Although we have not defined ''good cause'' in the regulations applicable to either MA or prescription drug appeals, we believe that it is useful to provide examples of good cause to plans. Examples of circumstances when good cause may be found to exist include, but are not limited to, the following situations: (1) the enrollee was prevented by serious illness from contacting the plan in person, in writing, or through a friend, relative, or other person; (2) the enrollee had a death or serious illness in his or her immediate family; (3) important records were destroyed or damaged by fire or other accidental cause; (4) the plan, or its designated entity, gave the enrollee, appointed or authorized representative, or prescribing physician incorrect or incomplete information about when and how to request a redetermination; (5) the enrollee, appointed or authorized representative, or prescribing physician did not receive notice of the determination or decision; or, (6) the enrollee, appointed or authorized representative, or prescribing physician sent the request to another Government agency in good faith within the time limit and the request did not reach the correct plan until after the time period had expired. Again, these examples are not an exhaustive list, but are illustrative of the kinds of scenarios that a plan might find good cause for extending the filing deadline.

Comment: We received many comments that argued that the 30-day redetermination timeframes were unreasonably long and should be shortened.

Response: As mentioned earlier, we agree with the commenters that the proposed adjudication timeframes are too long. Therefore, redeterminations by the plan must be made as expeditiously as the enrollee's health condition requires, but no later than 72 hours for expedited cases and 7 days for standard cases. In response to the concern raised by the commenters regarding the length of time it takes for an enrollee to be reimbursed, we are no longer distinguishing between payment and service-related disputes. As previously mentioned, we reduced the timeframe for plans to make standard redeterminations to 7 days in § 423.590(a) and (b). Again, redeterminations that involve requests for payment cannot be expedited because a medical emergency does not exist for an enrollee who already obtained the medication in dispute.

Comment: Some commenters did not support the provision at § 423.586, which would require plans to have methods in place for receiving evidence in person because it is unduly burdensome for plans to receive evidence in person.

Response: We disagree that permitting enrollees or prescribing physicians to submit evidence in person is unduly burdensome. The right to present evidence in writing as well as in person is consistent with MA, and we anticipate that Part D enrollees may want to deliver evidence in person rather than mailing their materials to plans. Therefore, plans must have procedures in place for accepting evidence in person from enrollees, including, for example, the ability to accept evidence delivered by enrollees at the plan's physical location or by telephone. However, we note that this requirement is not intended to require plans to provide in-person hearings for enrollees.

b. Independent Review Entity (IRE) Reconsideration (§ 423.600 through § 423.604)

The MMA gives the Secretary the flexibility to establish an appeals process similar to that used for the MA appeals process. Thus, the proposed IRE

reconsideration process set forth at § 423.600 through § 423.604 was much like that applicable to MA organizations under Part C. Note that when the plan's redetermination affirms, in whole or in part, its adverse coverage determination, any issue remaining in dispute could be appealed by the enrollee to the IRE that contracts with us. However, unlike under the MA program, plan redeterminations involving tiering issues or coverage of a non-formulary drug would not be automatically forwarded to the IRE. Instead, an enrollee would need to request an IRE review. This proposed requirement modified the MA procedure that affords automatic referral to the IRE whenever the MA organization's original denial was upheld by the organization's redetermination.

At § 423.600, we proposed that an enrollee who was dissatisfied with the plan's redetermination could file a written request for reconsideration by the IRE. We also proposed that when an enrollee filed for an appeal, the IRE would be required to solicit the views of the prescribing physician. In order to request an off-formulary drug, the prescribing physician would be required to indicate that all covered part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual as the non-formulary drug, would have adverse effects for the individual, or both. To be consistent with our requirement in § 423.590(f), we added (e) to § 423.600, which requires reconsiderations to be made by a physician with expertise in the field of medicine that is appropriate for the services at issue when the issue is the denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity).

Section 423.602 proposed the requirements for the IRE reconsideration determination notice, including the requirement that if the determination were adverse, the enrollee must be informed of the right to request an ALJ hearing and the procedures that must be followed to obtain the hearing.

Section 423.604 of our proposed rule explained that a reconsideration by the IRE was final and binding on the enrollee and the plan, unless the enrollee requested an ALJ hearing.

Comment: We received a number of comments regarding automatic forwarding of redeterminations to the IRE. While a few commenters supported our decision to require enrollees to request an IRE reconsideration, many argued that cases should be automatically forwarded as provided in MA to ensure that enrollees receive an independent review of a plan's redetermination. The commenters maintained that the automatic forwarding of unfavorable redeterminations to the IRE is necessary to prevent enrollees from experiencing a lapse in coverage due to the length of time that it takes for an appeal to receive an independent review. Some commenters also disagreed that the dollar value of drug appeals would involve relatively small monetary amounts, which we reasoned that forwarding all adverse redeterminations to the IRE would be inefficient.

Response: As previously mentioned, we have streamlined the appeals process by shortening the adjudication timeframes and requiring plans to either provide notice to enrollees 60 days in advance of a change to its formulary or provide notice and a 60-day supply of a medication that is affected by a formulary change. Thus, enrollees will not be faced with any lapses in coverage of a medication they are already taking by being required to request a reconsideration with the IRE directly. In addition, even if the amount in controversy for reconsiderations is higher on average than originally anticipated by us, we do not believe that requiring enrollees to request appeals has any bearing on the process. Therefore, § 423.600 requires that an enrollee who is dissatisfied with the plan's redetermination may file a written request for reconsideration with the IRE. We note that we have eliminated the plan as an alternative filing location since the decision-making timeframe begins upon receipt of the IRE's request. This change ensures that there are no delays in enrollees receiving timely responses.

Comment: Some commenters stated that the scope of an IRE's review should not be limited to whether a plan applied its exceptions criteria correctly.

Response: We agree with the commenters that the IRE's review must not be limited to whether a plan applied its exceptions criteria correctly. As stated above, plans' exceptions procedures must include measures to grant an exception when the plan determines that an exception would be medically appropriate. Because these determinations will be subject to review by the IRE, the IRE will necessarily also review whether a drug is medically necessary. Therefore, the IRE's medical staff also must review the plan's medical necessity determination in addition to whether the plan properly applied its exceptions criteria for the individual in question. Examining the record de novo using the plan's exceptions criteria, as approved by us, and making an independent medical necessity determination will form the basis for the IRE's decision. However, the IRE is prohibited from ruling on the validity of a plan's exceptions criteria or formulary. Only we can evaluate and decide whether to approve a plan's exceptions criteria and formulary as part of the annual plan approval process.

Comment: We received several comments requesting that we specify the method under § 423.600(b) by which the IRE can solicit the views of the prescribing physician.

Response: The IRE may solicit the views of the prescribing physician either orally, or in writing. We also clarified that a written account of the prescribing physician's views (prepared by either the prescribing physician or IRE, as appropriate) must be contained in the IRE's record so that, if appealed, the ALJ, MAC, or Federal court will be able to review all of the evidence considered or disregarded by the reviewing entity.

Comment: A few commenters recommended that we require requests for IRE review to be filed directly with the IRE, as opposed to alternative locations, to avoid delays.

Response: We agree with the commenter, and as mentioned above, have modified § 423.600(a) to require enrollees to file requests for IRE review directly with the IRE instead of permitting enrollees to choose whether to file a request with the IRE or plan.

Comment: One commenter recommended that enrollees and prescribing physicians should be able to submit additional evidence to the IRE.

Response: We agree with the commenter, and like under MA, enrollees and prescribing physicians must have an opportunity to submit additional evidence to the IRE.

Comment: We received one comment suggesting that we require physician certifications to accompany all requests for reconsideration by an IRE and hearing by an ALJ. The commenter believed this requirement would ensure that the reconsiderations are focused on medical necessity rather than patient preference.

Response: We agree that supporting statements from prescribing physicians are often necessary for making proper determinations, especially when medical necessity is at issue. However, since the IRE is required to solicit the views of the prescribing physician, it is not necessary to require that supporting statements from physicians accompany all requests for IRE reconsiderations or ALJ hearings. In fact, IREs may not always be called upon to make medical

judgments. For example, the definition of a Part D drug excludes ''agents when used for anorexia, weight loss, or weight gain.'' See § 423.100 citing section 1927(d)(2) of the Act. An IRE may be called upon to review whether an agent was in fact used for anorexia, weight loss or weight gain (and therefore excluded from the definition of Part D drug), or whether it was used for some other purpose.

Comment: One commenter suggested that we require IREs to include information about an enrollee's right to an ALJ hearing, the procedure for requesting it, and the amount in controversy threshold amount required for an ALJ hearing in the notices of reconsideration.

Response: Section 423.602(b) specifies the requirements for the IRE reconsideration determination notice, including the requirement that if the determination is adverse, the enrollee must be informed of the right to request an ALJ hearing if the amount in controversy meets the requirements of § 423.610, and the procedures that must be followed to obtain the hearing.

c. Administrative Law Judge (ALJ) Hearings, Medicare Appeals Council (MAC) Appeals, and Judicial Review (§ 423.610 through § 423.630)

As stated above, section 1860D–4(h)(1) of the Act merely requires the Secretary to establish a reconsideration and appeals process that is ''similar'' to the process used for MA organizations under the authority of sections 1852(g)(4) and (5) of the Act. Although we believe the Congress gave us a good deal of discretion in designing these procedural rules under Part D, we determined as a policy matter to adopt most of the ALJ, MAC, and judicial review procedures currently used in the MA program.

Section 1852(g)(5) of the Act provides the right to a hearing and to judicial review for an enrollee dissatisfied by reason of the enrollee's failure to receive a Part D drug to which he or she believes he or she is entitled, and at no greater charge than he or she believes he or she is required to pay. Section 1852(g)(5) of the Act also specifies the amount in controversy needed to pursue a hearing and judicial review, and authorizes representatives to act on behalf of individuals that seek appeals.

As provided in proposed § 423.610, if the IRE's reconsideration determination is not fully favorable, the enrollee may request a hearing before an ALJ if the amount remaining in controversy meets the threshold requirement established annually by the Secretary. The threshold requirement will be published annually in the **Federal Register**. We note that in § 423.612 (a) of the proposed rule, we required enrollees to file their requests for ALJ review with the entity specified in § 423.582(a). However, we did not intend that requests for ALJ hearing be filed with the Part D plan sponsor. Therefore, we modified § 423.612(a) of this final rule to require enrollees to file written requests for an ALJ hearing with the entity specified in the IRE's reconsideration notice. The plan is not considered a party to the ALJ hearing, but may participate in the hearing at the discretion of the ALJ. If the ALJ hearing does not result in a fully favorable determination, the enrollee may request MAC review of the ALJ decision. Unlike under MA, the plans do not have the right to request an appeal of an ALJ decision with which the plan disagrees.

Following the administrative review process, the enrollee is entitled to judicial review of the final determination if the amount remaining in controversy meets the threshold requirement established annually by the Secretary and published in the **Federal Register**.

Comment: We received several comments expressing concern about how we will calculate the amount remaining in controversy. Many commenters noted that the proposed rule does not clearly state how ALJs and the MAC will determine whether an enrollee has met the applicable amount in controversy (AIC) threshold. One commenter recommended that calculation of the amount remaining in controversy include the projected cost of the drug at issue for at least the duration of the current calendar/plan year, including consideration of any cost sharing amount paid by the enrollee or a third-party. Additionally, commenters asked that we define the term ''projected value'' as used under § 423.610(b) of the final regulation.

Response: In order to clarify how the amount remaining in controversy will be calculated, we have adopted a modified version of the formula used in the Medicare fee-for-service program to determine the amount remaining in controversy. Therefore, the amount remaining in controversy will be calculated by subtracting any allowed amount under Part D, payments made by third parties, deductible, and coinsurance amounts applicable to the particular Part D drug at issue from either the projected value of the drug, or, where the enrollee is seeking reimbursement, the actual amount the enrollee paid for the Part D drug. Like the MA program, rather than putting this formula in regulation, we will include it in separate guidance, such as CMS manuals, in order to adjust the formula if necessary.

In response to comments we received about defining the term ''projected value,'' we have amended § 423.610(b) to state that the projected value of a Part D drug, for purposes of calculating the amount remaining in controversy, shall include any costs the enrollee could incur based on the number of refills prescribed for the drug in dispute during the plan year.

Comment: Two commenters were concerned that the aggregation of multiple enrollee appeals would limit the consideration given to individual cases. Both commenters felt strongly that the assessment of a particular prescription drug for an enrollee requires an evaluation of the enrollee's individual case, including his or her medical condition, medical history and other factors. To ensure that all enrollees' cases receive this type of consideration, the commenters recommended either reducing the AIC threshold at the ALJ level of appeal so that aggregation is almost never necessary or precluding aggregation of appeals by multiple enrollees.

Response: We first note that the ALJ AIC is a statutorily established threshold. Neither CMS nor the Secretary has discretion to alter this requirement. Nevertheless, we do not agree with the commenters' assessment of the consideration individual appeals will receive if multiple enrollees elect to aggregate their appeals for purposes of meeting the AIC threshold. Currently, in the Medicare fee-for-service program, two or more beneficiaries may combine claims to meet the AIC requirement for obtaining an ALJ hearing, so long as the claims involve common issues of law or fact. In adjudicating these appeals, ALJs often make individual medical necessity determinations for each beneficiary who received the item or service in dispute. Given the ALJ's experience in adjudicating aggregated cases, we believe that Part D appeals that are aggregated by multiple beneficiaries will receive appropriate individual consideration.

Comment: Several commenters requested that we clarify the applicable filing requirements for appeals that an enrollee wishes to aggregate for purposes of meeting the AIC threshold for requesting an ALJ hearing.

Response: We agree with the commenters' observation that the proposed rule was not clear regarding the applicable filing timeframes for appeals an enrollee wishes to aggregate. Therefore, we have to amended § 423.610(c)(1)(ii) and (2)(ii) in this final rule to specify that multiple appeals,

filed by either a single enrollee or multiple enrollees, may be aggregated to meet the AIC threshold for ALJ hearings so long as all of the appeals to be aggregated have been filed in accordance with the requirements in § 423.612(b).

Comment: One commenter suggested that we revise our proposal that plans are considered a ''party to the ALJ hearing'' for the limited purpose of participating in the hearing. The commenter believes that plans should be afforded full party status at the ALJ level so that they can defend their redetermination decisions, rather than just respond to questions asked by the ALJ. Additionally, the commenter suggested that when a plan is a party to an ALJ hearing, it should be permitted to file a request for review with the Medicare Appeals Council and the appropriate Federal court, just as MA organizations are permitted.

Response: In the proposed rule, we stated in the introduction of the preamble to § 423.610 that plans had party status for the limited purpose of participating in ALJ hearings. Part 422, subpart M gives MA organizations party status at the ALJ level. However, we do not agree with the commenter that plans should have full party status at the ALJ level as MA organizations. Section 1860D–4(h) of the Act, which requires plans to provide Part D enrollees with ALJ hearings and MAC review, allows only Part D enrollees to file appeal requests at these levels. Thus, the Congress did not grant plans with party status at the ALJ levels of the appeals process. To clarify this point, § 423.620 has been revised to state that the MAC provisions that apply to MA organizations apply to plans, to the extent applicable. Even though plans are not parties to ALJ hearings, we continue to believe that it is important to give plans the ability to participate in ALJ hearings. Therefore, plans may participate in hearings at the ALJ's discretion.

Comment: One commenter suggested that we modify the Part D regulations so that if the ALJ issues a decision that is favorable for an enrollee and the plan files an appeal with the MAC, the plan does not have to effectuate the ALJ's decision until the MAC upholds the decision favorably to the enrollee. The commenter also suggested that plans be required to effectuate ALJ decisions within 60 days after the decision has been issued if the plan does not request a review by the MAC within the 60-day timeframe. The commenter argued that adding these provisions would be consistent with the MA regulations.

Response: As indicated above, § 423.620 permits only Part D enrollees to appeal ALJ decisions. Therefore, in accordance with the requirements set out in § 423.636(c), plans are required to effectuate favorable ALJ decisions involving payment issues no later than 30 calendar days after a final decision is issued and all other cases as quickly as the enrollee's condition warrants, but no longer than 72 hours after a final decision is issued. These effectuation timeframes have been reduced from the proposed 60-day deadline in light of our decision to shorten the adjudication timeframes.

7. Effectuation of Reconsideration Determinations (§ 423.636 through § 423.638)

Section 423.636 and § 423.638 proposed the requirements for effectuation of coverage determinations reversed by the plan, redeterminations reversed by the IRE, or reversals by an ALJ or higher level of appeal. When the plan's redetermination is reversed by the IRE, § 423.636(b)(1) required that it must authorize the benefit under dispute within 72 hours from the date it received notice reversing the redetermination, or provide the benefit as expeditiously as the enrollee's health required, but no later than 14 calendar days from the date of the reversal notice. For redeterminations of requests for payment, proposed § 423.636(a)(2) required that if the plan reversed its coverage determination, it must pay for the benefit no later than 60 calendar days after the date it received the request for reconsideration. Under § 423.636(b)(2), if a plan's redetermination was reversed by the IRE, it must pay for the benefit no later than 30 calendar days from the date it received notice reversing the redetermination.

Section 423.638 proposed that for expedited redeterminations reversed by the plan or the IRE, the plan must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition required but no later than 72 hours after the date it received the request for redetermination, or in the case of reversal by the IRE, from the date it received the reversal notice.

Finally, for reversals by an ALJ or higher level of appeal, we proposed under § 423.636(c) and § 423.638(c) that the plan must pay for, authorize, or provide the benefit under dispute as expeditiously as the enrollee's health condition required, but no later than 60 calendar days from the date it received notice reversing its determination.

Comment: We received a number of comments requesting us to revise the effectuation timeframes. Several commenters recommended that plans effectuate IRE determinations within 24–48 hours, ALJ hearing decisions within 48 hours, and the MAC review decisions within 48 hours. The commenters also suggested that plans be required to authorize benefits within 72 hours after receiving notice from the IRE.

Response: As mentioned previously, we agree that the proposed adjudication timeframes were too long. As a result, we need to make corresponding changes to the effectuation timeframes in § 423.636 and § 423.638. Therefore, the effectuation timeframes for appeals involving non-payment issues are no later than 72 hours (expedited) or 7 calendar days (standard) from the date the plan receives the request for redetermination if the plan is reversing its previous determination, or no later than 24 hours (expedited) or 72 hours (standard) from the date the plan receives notice of a reversal by the IRE, ALJ, MAC, or Federal court. For payment issues, the plan must authorize payment within 7 calendar days from the date it receives the request for redetermination and make payment within 30 days from the date from the date it receives the request for redetermination if the plan is reversing its previous determination, or it must authorize payment for the benefit within 72 hours and make payment no later than 30 calendar days from the date it receives notice reversing the coverage determination by the IRE, ALJ, MAC, or Federal court.

Comment: We received a comment suggesting that we remove the term ''completely'' from § 423.638(a) when describing a plan's obligation to effectuate a coverage determination the plan reversed.

Response: We agree with the commenter. Under MA, the term ''completely'' was added to § 422.638(a) because any MA reconsideration that was not completely favorable was automatically forwarded to the IRE for reconsideration. However, under Part D, the regulations, except in limited circumstances where a Part D plan sponsor has missed its claims adjudication or redetermination deadline, do not allow automatic forwarding of unfavorable redeterminations to the IRE. Therefore, we have deleted the term ''completely'' from § 423.638(a).

8. Federal Preemption of Grievances and Appeals

Section 232(a) of the MMA amended section 1856(b)(3) of the Act so that it now reads: ''The standards under this part shall supersede any State law or regulation (other than State licensing laws or State law relating to plan solvency) with respect to MA plans which are offered by MA organizations under this part.'' Section 1860D–12(g) of the Act then incorporates this preemption rule for plans.

We believe that the grievance procedures for the Part D Drug Program under Title I must be the same as those that apply to the MA program under Title II. In the proposed rule, we proposed continuing to defer to State law on the issue of authorized representatives of enrollees in the appeals process.

We did not believe that the Congress intended for the Secretary to regulate matters for which the Secretary was not authorized to promulgate standards (for example, spousal rights, powers of attorney, or legal guardianship). Often, authorized representative matters are non-Federal issues. However, because we do have the authority to regulate in the field of grievances, we were concerned that State grievance requirements would now be preempted, thereby requiring us to reexamine our Federal grievance requirements. We requested comments on this preemption issue and the specific State grievance requirements that should be incorporated into Federal regulatory requirements at § 423.564.

We also noted that tort law, and often contract law, are generally developed based on case law precedents established by courts, rather than by legislators through statutes or by State officials through regulations. In addition, we did not believe we would have the authority under Part D to set specific tort remedies or to govern resolution of private contracting disputes between plans and their subcontractors. We believed that the Congress did not intend for our regulations to supersede each and every State requirement applying to plans—particularly those for which the Secretary lacks expertise and authority to regulate. Thus, we did not believe, for example, that wrongful death or similar lawsuits based upon tort law would be superseded by the appeals process established in these regulations. Similarly, State contract law would continue to govern private contract disputes between plans and their subcontractors.

Under principles of Federalism, and Executive Order 13132 on Federalism, which generally require us to construe preemption narrowly, we believe that an enrollee will still have State remedies available in cases in which the legal issue before the court is independent of an issue related to the organization's status as a stand alone PDP or an MA-PD plan.

Comment: We solicited comments on whether the proposed Federal grievance procedures should preempt State grievance requirements. We received several comments on this issue, which primarily supported adopting a single set of grievance procedures to reduce enrollee confusion and plan burden. Some commenters recommended that we adopt the provisions proposed by us for Medicare+Choice organizations in a January 24, 2001 proposed rule. See 66 FR 7,593. However, one commenter opposed Federal law preempting State law where Part D appeals are concerned.

Response: We agree with the commenters that establishing a uniform set of grievance standards will reduce confusion and burden for enrollees and plans. We also believe that one set of rules will ensure better beneficiary protections and achieve consistency among plan operations. Thus, § 423.564 implements the specific guidelines for Part D grievances that we proposed in January 2001 for Medicare+Choice organizations. We disagree with the commenter that Federal provisions should not preempt State requirements for appeals. We believe that such an approach is inconsistent with § 232(a) of the MMA, which preempts State appeal and grievance requirements and which is incorporated into the Part D laws through section 1860D–12(g) of the Act.

Under the grievance requirements, plans must notify enrollees of decisions as expeditiously as the enrollee's case requires, but no later than 30 calendar days after receiving a complaint. Plans may extend the timeframe by up to 14 calendar days if the enrollee requests the extension, or if the plan justifies a need for additional information and the delay is in the interest of the enrollee. We believe that the timeframes must be according to the enrollee's case as opposed to the enrollee's health since not all grievances involve medical care. For example, an enrollee may complain that a network pharmacy does not offer convenient hours for getting prescriptions filled. In addition, we believe that most plans will be able to respond to most grievances within 30 days. If an enrollee makes a grievance orally, the plan may respond to it orally or in writing, unless the enrollee requests a written response. If an enrollee files a written grievance, then the plan must respond in writing. In addition, a plan must provide information to enrollees on their right to request a review by a Quality Improvement Organization (QIO) if the grievance involves a quality of care issue. For any complaint involving a QIO, the plan must cooperate with the QIO in resolving the complaint. Plans must establish a 72-hour expedited grievance process for complaints involving certain procedural matters in the appeals process. Finally, plans must create a system to track and maintain records on all grievances.

We note that under MMA, enrollees will still have access to various State remedies available in cases in which an issue is unrelated to the plan's status as a PDP or MA-PD plan.

9. Employer Sponsored Prescription Drug Programs and Appeals

As explained above, MA-PDs and PDPs are subject to the requirements of Part 423 for Part D benefits. In addition, when an employer, whether by contracting with an MA-PD, PDP, or otherwise, provides prescription drug benefits in addition to those covered under Part C and Part D of Title XVIII of the Act to their retirees, such employer may have established a group health plan governed by both Title I of the Employee Retirement Income Security Act of 1974, as amended (ERISA), and State law (to the extent such State law is not preempted by ERISA).

In drafting our Part C, MA rules, we consulted the Department of Labor (DOL), employer groups, and the health plan industry in trying to eliminate unnecessary Federal regulation of claims and appeals issues that impact matters within the jurisdiction of both DOL and DHHS. Based on our experience under Part C, we have reason to believe that some Medicare eligible individuals may receive integrated prescription drug benefits, that is, Part D benefits through an MA-PD or PDP and supplemental benefits through an ERISA-covered plan. For example, an ERISA-covered plan could pay all or part of the retiree's cost sharing amount (for example, deductibles and coinsurance amounts specified in subpart C of Part 423) for a covered Part D drug provided through an MA-PD or PDP. Clearly, if the enrollee had a dispute about Part D coverage, he or she could file an appeal under the provisions in subpart M of Part 423. If the enrollee's dispute involved only the amount of cost sharing paid by the ERISA plan, he or she would file an appeal in accordance with the

procedures of the ERISA covered plan. In some cases, however, the dispute might involve independent coverage decisions under both Part D and the ERISA plan; possibly necessitating parallel appeal procedures on the same case. In this regard, we solicited comments on whether, and to what extent, the application of parallel procedures in this context might be a problem for plans, employers, and eligible individuals. We also solicited suggestions for addressing problems, if any, resulting from the application of parallel procedures.

Comment: Generally, commenters supported utilizing only the Medicare appeal procedures for claims involving integrated ERISA and Part D benefits. One commenter stated that enrollees probably do not distinguish between ERISA and CMS approved benefits when they are integrated, and therefore, a single appeals process would be less confusing. Another commenter agreed, recommending that to the extent any benefits received by an individual are part of an underlying Part D plan, including benefits separately negotiated between the Part D sponsor or organization and an employer (or labor organization), those benefits should be governed by the Part D regulations rather than by two separate processes. One commenter suggested that, where possible, we make our requirements consistent with the existing DOL final rule that establishes standards for processing benefit claims under an ERISA-covered plan.

Three commenters agreed that adopting and applying a single, uniform appeals process for all benefits would be easier for the enrollee to understand. Other commenters pointed out that parallel appeal processes for enrollees with Medicare and ERISA benefits were costly, redundant, and burdensome to administer, with the potential for conflicting determinations. Only one commenter promoted Part D plans to process appeals under an employer-sponsored plan.

Response: After reviewing the public comment and conferring with representatives of DOL, we have concluded that changes (not only to our regulations but also to the DOL regulations) are needed to properly address this issue. Accordingly, we have added § 423.562(d), which is intended to give ERISA plans the option, pursuant to regulations of the Secretary of Labor, of electing the Part D process rather than the procedures under 29 CFR 2560.503–1 for claims involving supplemental benefits provided by contract with a Part D plan. In this regard, DOL has agreed to work with us to develop such regulations. We note that the language in § 423.562(d) is intended to demonstrate our commitment to make the entire Part D process available in this context. The provision in § 423.562(d) will not take effect in the absence of regulations by the Secretary of Labor.

10. Miscellaneous

Comment: Two commenters believed that there would be an additional administrative workload for physicians and their staff in light of the appeals and exceptions processes. They asked whether we would provide reimbursement for these activities, as they are not currently reflected on the physician fee schedule.

Response: We were mindful of any administrative burden that physicians might encounter as they help enrollees pursue prescription drugs through the exception and appeals processes. As a result, we eliminated the requirement that a physician's supporting statement, which the statute requires for tiering and non-formulary exceptions, be in writing. We also provide that the IRE may solicit the view of the prescribing physician orally or in writing. Thus, a prescribing physician need not in all circumstances provide a written account of the medical necessity or appropriateness of the prescription drug. We anticipate that physicians and other healthcare providers will assist enrollees with their Part D appeals to the same extent that they currently help beneficiaries with Part A, Part B, and Part C appeals. We do not pay physicians for their assistance with appeals under Part A, B, or C. Likewise, we do not expect to pay physicians under Part D for certifying and sharing their views on an enrollee's need for a medication.

Comment: Some commenters expressed concern about the lack of enrollee participation in the formulary development process. These commenters felt that we should either include enrollees in the formulary development process or alternatively, allow enrollees to challenge the formulary development process.

Response: The formulary development process is outside the scope of the grievance and appeals process. Additionally, section 1860D–4(h) of the Act does not provide a mechanism for Part D eligible individuals to challenge the formulary development process. Finally, the MMA intends for plans to compete in regards to benefit package and premium, which ensures that enrollees receive the best package for the lowest premium. The competitive model contemplated by the MMA would be undermined if enrollees are permitted to challenge the formulary development process.

We also believe that that permitting enrollees to challenge the formulary development process is not necessary. Enrollees are aware of a plan's formulary before they choose a plan. If an enrollee does not agree with a plan's formulary, he or she is free to enroll in a different plan. Once enrollees choose a plan, we have required plans to provide significant protections that will ensure that enrollees either receive the drug in dispute or are switched to an appropriate alternative medication if a plan changes its formulary during the plan year. In addition, enrollees have available to them an exceptions and appeals processes under which they may request coverage of non-formulary drugs. If enrollees continue to be unsatisfied with a plan, they are able to change plans at the end of the plan year.

Comment: Another commenter suggested that we establish a drug manufacturer appeals process to evaluate the discriminatory effect of a plan's negative formulary inclusion decision and to review negative formulary inclusion decisions.

Response: We are required by MMA to model the Part D grievance and appeals procedures after the Part C grievance and appeals procedures. Neither the MMA, nor the applicable provisions of the Act provide for the type of appeals process suggested by the commenter. As a result, we do not have the statutory authority to create an appeals process for drug manufacturers. In addition, allowing manufacturers to challenge how plans choose to place drugs on their formularies would also undermine the competitive model since it would negate any benefit that could be obtained by negotiating with plans.

Comment: We received many comments about the new notification requirements established under Part D, particularly those regarding how plans must communicate information about coverage determinations and appeals. Several commenters recommended that enrollees, physicians, and authorized representatives receive appeals notices giving the reason for denial, right to appeal, and information about accessing the appeals process. Another commenter suggested that denial notices be written at a 6th grade reading level, while another commenter suggested that plans provide notices in alternative formats (for example for the visually impaired and in different languages). Other commenters requested that detailed appeals notices, like those provided for coverage determinations,

be provided at the redetermination level.

In addition to the appeals notices, many commenters also made recommendations about other important information they felt plans ought to be required to provide to enrollees. First, many commenters requested that we require plans to provide enrollees with written information about the exceptions and grievance processes. Finally, we received one comment suggesting that we require plans to notify enrollees of their potential cost-sharing obligations if an appeal is successful.

Response: We agree with many of the suggestions offered by the commenters. Therefore, in § 423.568(g) of the final rule, we require plans to include specific types of information in denial notices, including the reason for denial, the right to appeal, and information about the appeals process. We also require denial notices to be written in a readable and understandable form. These notices will be developed or approved by us based on consumer-testing and marketing guidelines. We agree that notices must be made available in alternative formats, and expect that they will be made available in all the same formats MA notices are currently offered. We also agree that plans must include information about the potential cost-sharing obligation if an exception regarding tiering is successful. As previously mentioned, we specify that when an exception for a lower cost-sharing is approved, the enrollee is entitled to the amount of cost-sharing that applies for a preferred drug, but not for a generic drug. Finally, as mentioned earlier, plans must provide written notices to enrollees 60 days in advance when plans change their formularies. These advance notices must contain information about the exceptions process. We also require plans to provide written information about the grievance, exceptions, and appeals processes in enrollment materials.

We agree with the commenters who suggested that we require detailed notices at the redetermination level. Therefore, we added § 423.590(g) to require plans to provide detailed written notices to enrollees whenever plans make adverse redeterminations. The redetermination notices must: be written in approved language that is in a readable and understandable; state the specific reasons for the denial; inform the enrollee of his or her right to a reconsideration (including a description of the standard and expedited reconsideration processes, and the enrollee's right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeals process); and comply with any other notice requirements specified by us.

Finally, as previously mentioned, the final rule requires that notice of any determination be sent to enrollees or their appointed or authorized representative.

Comment: We received a few comments indicating that plans should be required to track and report denial rates for the purpose of identifying plans with high rates of inappropriate denials. One commenter suggested using the IRE to evaluate the data submitted by the plans.

Response: We appreciate the commenters' suggestions and share their desire to have plans provide information on the disposition of their decisions. We are in the process of developing an appeals system that will capture case-specific appeals data. Because appeals are generated as a result of coverage denials, we believe that the appeals information will enable us to identify potential inappropriate denials.

Comment: We received one comment suggesting that we create a special election period of 30 days during which enrollees who receive unfavorable coverage determinations or responses to exceptions requests may elect to enroll in a different plan.

Response: We strongly disagree with the commenters that enrollees should be granted a special election period (SEP) to enroll in a different plan when they receive unfavorable coverage determinations or responses to exceptions requests. Although section 1860D–1(b)(3)(C) and section 1851(e)(4) of the Act provides us with the authority to grant SEPs for exceptional circumstances, we decline to establish an SEP for enrollees who have received unfavorable determinations because we do not view this as an exceptional circumstance under the Part D program. The Congress anticipated that unfavorable determinations would be made, and therefore required us to establish an extensive appeals process. However, we do retain the authority to establish additional SEPs through operational guidance if necessary.

Comment: A few commenters suggested that we require plans to assign consumer advocates to enrollees who need assistance with the appeals process. One commenter suggested that we make available the Medicare Beneficiary Ombudsman to assist Part D enrollees, or provide the telephone number of an appropriate ombudsman in coverage determinations and appeal notices.

Response: The commenters raise a very valid point and we agree that Part D enrollees must be permitted to obtain assistance with the grievance and appeals processes, but we do not believe that we have the authority to use Trust Fund dollars to pay for consumer advocates on behalf beneficiaries accessing the appeals process.

The Medicare Ombudsman is designed to utilize most inquiry and appeals processes in place, while providing enhancements and efficiencies through monitored performance metrics, continuous quality improvement feedback, and standardized data management. Fiscal Intermediaries, Carriers, Regional Offices and SHIPs are all part of the whole Ombudsman system. These entities, in addition to others, are being trained in Part D enrollment, will handle most routine concerns, and have the ability to forward any serious concerns to the Office of the Ombudsman for resolution.

In addition to obtaining assistance from the Medicare Ombudsman, we permit Part D enrollees who are in need of assistance to select an individual or an entity to serve as their appointed representative. Additionally, we recognize individuals who are authorized under State or other applicable law to represent the enrollee. Both appointed and authorized representatives may act on behalf of Part D enrollees in obtaining coverage determinations or in dealing with any of the levels of the appeals process, subject to the rules described in part 422, subpart M.

Comment: One commenter suggested that we clarify the difference between a ''non-preferred'' drug and a ''non-formulary'' drug since there are different processes for requesting each and the differences may not be apparent to enrollees.

Response: We have required plans to establish different exceptions processes for handling exceptions requests involving tiered formulary drugs and exceptions requests involving non-formulary drugs. Under a tiered cost-sharing structure, drugs are assigned to different co-payment tiers based on cost-sharing, clinical considerations, or both. An enrollee's level of cost-sharing is based on the tier into which the prescribed drug falls. Typically, drugs fall into one of three tiers—generic drugs, preferred brand-name drugs, or non-preferred brand-name drugs. All of a plan's cost-sharing tiers make up its formulary, and an exceptions request that involves a drug covered under one of a plan's tiers must be processed in accordance with § 423.578(a). A non-

formulary drug is simply a drug that is not on a plan's formulary. An exceptions request that involves a non-formulary drug must be processed in accordance with § 423.578(b). Alternatively, if a plan organizes its drug benefits by providing coverage only for formulary drugs and requires enrollees to pay for prescriptions out-of-pocket if they are not on the formulary, the plan has established a closed formulary. A drug that is not on a plan's formulary under this type of cost-sharing arrangement is also considered a non-formulary drug and must be processed in accordance with § 423.578(b).

N. Medicare Contract Determinations and Appeals

1. Overview

Subpart N implements section 1860D–12(b)(3)(F) of the Act which directs the ''procedures for termination'' in section 1857(h) of the Act be incorporated into the requirements for PDP sponsors. As we stated in the proposed rule, to enhance the flow of the rule, we have separated the provisions of section 1857(h) of the Act into two portions and addressed the two portions in separate subparts—subpart K (Application Procedures and Contracts with PDP Sponsors) and this subpart of the preamble and regulations.

2. Provisions of the Final Rule

Subpart N establishes administrative appeals procedures available to an applicant or PDP sponsor in the event that we—

- Determine that an entity is not qualified to contract with us as a PDP sponsor under Part D of title XVIII of the Act.;
- Determine that an entity is not authorized to renew its contract as a PDP sponsor in accordance with § 423.507(b); or
- Make a determination to terminate the contract with a PDP sponsor in accordance with § 423.509.

We note that in subpart K, in response to comments, we have explained that the contract application (or renewal) process and the bid process under subpart F will run concurrently. In other words, we could review and pre-approve a contract even though the bid process was not yet complete. In this situation, the actual approval of the contract would be dependent upon us and the sponsor reaching agreement on the bid. We have revised our regulations at § 423.506(d) to reflect this change. As discussed in the subpart K preamble, we will make determinations that an entity is qualified to contract as a PDP sponsor or authorized to renew its PDP sponsor contract, and these determinations will be subject to the procedures of subpart N. However, although an entity may be determined qualified to enter into or renew its contract, the contract might not be signed if we are unable to reach agreement on the bid with the entity under subpart F. This failure to reach an agreement on the bid will not be subject to the procedures of subpart N. We revised our proposed regulation by adding § 423.502(c)(2) to subpart K in order to clarify this distinction. We refer readers to subpart K for a full discussion of the concurrent processes and an explanation of those policies.

In order to clarify the timeline for valid contracts, in the event of a redetermination, we have added new § 423.647(c) to subpart N. This provision specifies that in the case of a favorable redetermination, to include favorable decisions as the result of a hearing or Administrative review, such determination must be made by July 15 for the contract in question to be effective on January of the following year. We have made a corresponding change to the MA regulations by adding § 422.654(c).

We had proposed that a single set of procedures relating to contract determinations and appeals would apply to both MA and PDP sponsor contractors and that the requirements in § 423.641 through § 423.669 would mirror the requirements at § 422.641 through § 422.698 for the MA program. We refer readers to the preamble of the Medicare Prescription Drug Benefit proposed rule (69 FR 46723–4) for a fuller discussion of our proposals.

Comment: We received one comment on this subpart. The commenter—while acknowledging the provisions in this subpart duplicate those relating to MA contractors in part 422, subpart N—asked that we state in the final rule specifically that part 423, subpart N, applies only to PDP sponsors, not to MA plans.

Response: We do not believe it is necessary to amend the regulation text to make clear that the subpart N rules apply only to PDP sponsors, since the MA organization contracts will, by definition, be subject to the appeals procedures in part 422 and not part 423. We have, however, clarified that because fallback prescription drug plan contracts are entered into using a competitive process, except to the extent a fallback contract is terminated, fallback entities will not be subject to the procedures of subpart N. We thank the commenter for the suggestion and do acknowledge that the subpart N procedures of part 423 would apply only to PDP sponsors or PDP sponsor applicants.

With the clarifying language noted above, in this final rule we have adopted these proposed changes almost entirely without change.

O. Intermediate Sanctions (§ 423.750)

As required by 1860D–12(b)(3)(E) of the Act, Subpart O provides that the provisions governing ''intermediate sanctions'' for MA organizations, with two exceptions, will apply to contracts for Part D Plan sponsors. Specifically, we would not impose sanctions on a Part D Plan sponsor in the event it fails to enforce the limit on balance billing under a private fee for service plan, as required at § 422.216(a)(4), or fails to prohibit interference with practitioners' advice to enrollees, as required at § 422.206, since we do not believe these provisions are applicable in the context of the Part D drug benefit. We did not receive any comments regarding this proposal. We also proposed that the requirements in § 423.750 through § 423.760 would mirror the requirements at § 422.750 through § 422.760. However, we recently discovered that these requirements do not mirror each other and, further, that recent changes to the requirements at § 422.750 through § 422.760 require us to make conforming changes in this final rule. We learned that the regulation text, as proposed, did not reflect revisions made to the requirements at § 422.750 through § 422.760 in the August 22, 2003 final rule for MA plans entitled, ''Modifications to Medicare Rules'' (68 FR 50840). However, several errors were made in modifying the regulation text in the August 2003 final rule. Consequently, an interim final rule with a comment period was published on December 30, 2004 to correct this technical error. We are making changes to the provisions in Part 423 to reflect the substance of changes to the regulations at § 422.750 through § 422.760 as corrected by the interim final rule published on December 30, 2004. Additionally, we proposed, and asked, for comments on our goal to have a consistent policy on how sanctions are imposed. The MMA requires at least two qualified plans, at least one of which is a Part D Plan per region. If we were to freeze the enrollment or marketing of a Part D Plan sponsor, that is one of only two plans in a region, beneficiaries would no longer have the breadth of choice the MMA intended. If we are contemplating sanctioning a plan that is one of only two Part D Plan sponsors in a region, we may have to consider using other remedies including

civil monetary penalties (CMPs) to maintain an adequate level of choice for beneficiaries. However, we would like to have consistent policies and procedures for Part D Plan sponsors and across all regions with regard to sanctions. We received two comments asking us how we would expect to preserve beneficiary choice if the above instance should occur. In this final rule, we decided to adopt the proposed requirements as final and rely on the number and kinds of sanctions available to us under subpart O and deal with offending entities on a case-by-case basis.

While we are adopting the substance of the proposed rule as final, in reviewing and responding to comments we discovered a need for some technical revisions in the interest of clarity. Consequently, we are making the following changes in this final rule:

- At § 423.752 (Basis for imposing sanctions.), paragraph (a), we clarified our authority to impose more than one sanction at a time.
- At § 423.752, paragraph (a)(6), we added the word ''excluded'' for clarification.
- Under § 423.752, paragraph (b), we are deleting references to § 423.756(c)(1) and (c)(3) because they are listed under procedures for imposing sanctions, and replacing them with § 423.750(a)(2) and (a)(4) which fall under ''Kinds of Sanctions''. This clarifies in this final rule that we are cross-referencing the basis for sanctions with the kind of sanctions that could result and not the procedure for imposing sanctions.
- At § 423.756(f)(2) a reference to ''part 1005 of this chapter'' was incorrect. The reference should be to ''part 1003 of this chapter'' since part 1003 includes the OIG procedures for imposing sanctions, whereas part 1005 is appeal procedures.
- At § 423.756(f)(3), we have deleted a reference to ''part 1005 of this chapter,'' because this subparagraph discusses CMS' authority to impose CMPs, as opposed to the OIG's authority.
- At § 423.758, we revised the language to better clarify the basis for CMPs imposed by us.

1. Kinds of Sanctions (§ 423.750)

Comment: Several commenters requested that the final regulation clarify how the imposition of the sanction of suspension of enrollment of Medicare beneficiaries (§ 423.750(a)(1)) would impact the statutory requirement that a consumer have a choice of at least two Part D Plans. One commenter suggested that, in the event CMS imposes an enrollment freeze on a Part D Plan sponsor which results in there being only Part D Plan in a given region, that we add a fallback plan to the region.

Response: While freezing marketing or enrollments has generally been our first and most frequently used sanction authority, other kinds of sanctions are available to us under Subpart O. These include suspension of our payments to the Part D Plan sponsor and CMPs (or a combination of both). The MMA intends for beneficiary choice to be preserved and directs us to make every reasonable effort to preserve that choice. We have the option of imposing these other sanctions if the suspension of enrollment of one of only two Part D Plans in the same region would eliminate beneficiary choice.

Comment: Several commenters suggested that CMS establish a range of civil money penalties that vary according to the nature and extent of the Part D Plan sponsor's noncompliance with legal requirements.

Response: Section 423.750 allows us to impose CMPs from $10,000 to $100,000 depending on the offense.

2. Basis for Imposing Sanctions (§ 423.752)

Section 423.752(a) and (b) of this final rule lists the seven violations for which sanctions may be imposed on a Part D Plan sponsor organization. These violations are the same as those that warrant the imposition of sanctions for MA organizations, with the exception of two deletions we are proposing below. Specifically, sanctions are imposed if the Part D Plan sponsor engages in any of the following:

- Fails substantially to provide, to a Part D Plan enrollee, medically necessary services that the organization is required to provide (under law or under the contract) to a Part D Plan enrollee, and that failure adversely affects (or is substantially likely to adversely affect) the enrollee.
- Imposes, on Part D Plan enrollees, premiums in excess of the monthly basic and supplemental beneficiary premiums permitted under section 1860D of the Act and subpart F of this final rule.
- Acts to expel or refuses to reenroll a beneficiary in violation of the provisions of subpart O of this final rule.
- Engages in any practice that may reasonably be expected to have the effect of denying or discouraging enrollment of individuals whose medical condition or history indicates a need for substantial future medical services (that is, health screening or ''cherry picking'').
- Misrepresents or falsifies information furnished to us, any other entity, or individual under the Part D drug benefit program.
- Employs or contracts with an individual or entity excluded from participation in the Medicare program as specified under sections 1128 or 1128A of the Act (or with an entity that employs or contracts with an excluded individual or entity) for the provision of certain services.

Additionally, as an alternative to the sanctions listed above, we would be able to decline to authorize renewal of the organization's contract (or may elect to terminate the contract entirely in accordance with § 423.509). In addition, § 423.509(a) will provide that a Part D Plan sponsor organization may be sanctioned if it fails to carry out the terms of its contract as specified under this section.

We will not impose sanctions on a Part D Plan sponsor in the event it fails to enforce the limit on balance billing under a private-fee-for-service plan as required at § 422.216(a)(4), or fails to prohibit interference with practitioners' advice to enrollees, as required at § 422.206, since we do not believe these provisions are applicable in the context of the Part D drug benefit.

We received three comments asking us to detail our methodology for imposing sanctions. As we have noted below, we believe that since the law grants us the discretion to choose from multiple options on a case-by-case basis we should retain this approach. We received other comments asking that we explain how we determine if a Part D Plan sponsor deserves to be sanctioned. Additionally, one comment suggested that we amend § 423.752(a) to clarify that CMS may impose more than one sanction at a time. In this final rule, we clarify that one or more sanctions may be imposed by us when a sanctionable offense as described under § 423.752 has been discovered.

Comment: Several commenters asked that CMS provide a methodology as to what sanction, or sanctions, will be imposed on a Part D Plan sponsor in response to a specific set of circumstance(s). Additionally, the commenters note that it is their understanding that all of the sanctions are permissive and they believe this increases the likelihood that sanctions will not be imposed.

Response: We have intentionally retained discretion as to what sanctions will be imposed on a Part D Plan. The rule lists a variety of sanctions that may be imposed so as to permit us to tailor the sanction to the particular offense. As a condition of contracting with Medicare, we require that a Part D Plan sponsor agree to be subject to these

sanctions. This approach has been successful in the Medicare managed care program, and we believe it will also be successful in sanction actions against Part D Plan sponsors. We should not be confined to only one sanction option for a certain violation, since the law grants us the discretion to choose from multiple options on a case-by-case basis. We believe that this approach will improve the oversight of Part D Plan sponsors and the protection of Medicare beneficiaries.

Comment: Three commenters state that it is not clear from the proposed rule how CMS would determine that a Part D Plan sponsor is not in compliance with legal requirements. The commenters also suggest that CMS publicize, through press releases in the **Federal Register**, an annual report, or other statements, citations against Part D Plan sponsors and any sanctions imposed against Part D Plan sponsors.

Response: We will determine compliance by a variety of means. We will be monitoring field reports, performing random periodic audits and conducting enrollee surveys. In addition, we perform random audits annually in order to ensure that those entities contracting with us are in compliance. The corrective action plans of contractors are subject to public disclosure under the Freedom of Information Act. Therefore, we do not believe it is necessary to publicly disclose the compliance status of each contracted organization. Some organizations that have received sanctions have later become solid examples of compliant contract administration. We believe that a public listing of sanctioned Part D Plans may not portray the current level of compliance by contracted organizations and could unfairly impede business opportunities for fully compliant contractors that were sanctioned in prior years. The purpose of a sanction is to protect beneficiaries and public funds by improving the compliance of contracted organizations. When an organization resumes compliant behavior, the sanction is ended. Sanction authority is not designed to be punitive.

Comment: Two commenters recommend that we revise one of the bases for sanctions under § 423.752(a). Section 423.752(a)(1) currently states that sanctions may be imposed if a Part D Plan sponsor ''[f]ails to provide required medically necessary services with an adverse effect on the enrollee.'' (emphasis added) The commenters recommend that we remove the phrase ''adverse effect'' from this provision.

Response: The specific wording of this provision is based on the language in the statute. We have not included the phrase ''adverse effect'' in an attempt to impose an obstacle that prevents the imposition of a sanction on a Part D Plan sponsor that fails to provide a medically necessary service to an enrollee.

Comment: One commenter suggested we amend § 423.752(a) to clarify that CMS may impose more than one sanction at a time, as we stated in the preamble to the proposed rule.

Response: We do have the authority to impose more than one sanction at a time, but we have taken the commenter's suggestion and made this authority explicit under § 423.752(a).

3. Procedures for Imposing Sanctions (§ 423.756)

Section 423.756 details our procedures for imposing sanctions on Part D Plan sponsor organizations. This process would mirror that used for the MA program. A brief summary of the process is as follows:

- We must send a timely written notification of the sanction to the Part D Plan sponsor, outlining the nature and basis of the proposed sanction, and copy OIG.
- We must provide the Part D Plan sponsor with 15 days, or if an extension is granted, 30 days to respond. If requested, an uninvolved CMS official will conduct an informal reconsideration of the determination with a written decision.
- Non-monetary sanctions would be effective 15 days from the organization's receipt of a final notice of sanction and remain in effect until we determine that the violation is corrected. CMS or the OIG, depending on the basis for the sanction, may impose civil money penalties.

Comment: One commenter suggested that § 423.756(e) be expanded to allow CMS to impose civil money penalties when CMS declines to renew or terminate a Part D Plan contract.

Response: We have authority to impose CMPs under the circumstances described in § 423.758. If we make a determination under § 423.509(a) (except a determination under § 423.509(a)(4)), we may impose CMPs.

P. Premiums and Cost-Sharing Subsidies for Low-Income Individuals

Section 1860D–14 of the Act requires us to subsidize the monthly beneficiary premium and cost-sharing amounts incurred under this Part by Part D eligible individuals with lower income and resources. The regulations in this subpart and regulations published by the Social Security Administration (SSA) adding a subpart D to a new part 418 of title 20 of the Code of Federal Regulations, implement section 1860D–14 of the Act.

The statute divides subsidy eligible individuals into two different groups based on income and resources: (1) full subsidy eligible individuals; and (2) other low-income subsidy eligible individuals. The different groups are entitled to different amounts of premium assistance and reductions in cost-sharing. Full-benefit subsidy eligible individuals are entitled to further reductions if they are eligible for full benefits under both Medicare/Medicaid and have income below a certain income threshold or if they are institutionalized in medical institutions or nursing facilities for which Medicaid will make payment.

In the proposed regulation, we defined the eligibility criteria and the amounts of subsidy assistance provided. We received several hundred comments on subpart P. Below we summarize our proposed rule and respond to comments. (For a detailed discussion of our proposals, please refer to the August 2004 proposed rule.)

General

We received general comments related to delayed implementation of the Part D program for full-benefit dual eligible individuals (as defined under 423.772) as well as the transition of shifting coverage for Part D drugs from the Medicaid program to the Medicare program for full-benefit dual eligible individuals, as discussed below.

Comment: Many commenters suggested that we delay implementation of the Part D program for full-benefit dual eligible individuals by at least five or six months, and some recommended a year's delay, although the commenters recognized that such a delay would require a legislative change. The commenters also expressed concern about the feasibility of identifying, educating and enrolling the population of full-benefit dual eligible individuals in time for a smooth transition. Some commenters pointed out the need to ensure adequate time for physicians and patients to navigate administrative barriers and change medications to comply with formularies. Others expressed concern that full-benefit dual eligible individuals tend to have complex medical or mental health problems, thus reinforcing the need for an appropriate transition from coverage for Part D drugs under Medicaid to Medicare.

Response: As mentioned by the commenters themselves, such a delay requires a legislative change. Absent

such a change we cannot delay implementation of the Part D program for dual eligibles.

Comment: Many commenters also expressed concern about the transition of coverage for Part D drugs from Medicaid to Medicare for the population of full-benefit dual eligible individuals. Commenters were particularly concerned about identifying, educating, and enrolling these individuals in Part D plans in a timely and efficient manner and desire to avoid noncoverage on plan formularies of drugs currently used for this vulnerable population, particularly those with AIDS or mental illness.

Response: We recognize the special needs of the dual eligible population and those with serious medical or mental health conditions. We have addressed in Subpart B of this rule the efforts to be made to avoid any interruption in coverage for this population by auto-enrolling full-benefit dual eligible individuals in Part D plans no later than January 1, 2006. Full-benefit dual eligible individuals and those eligible for Medicare Savings Programs as QMBs, SLMBs, and QIs are automatically deemed eligible for the low-income subsidy. We are working with State Medicaid Directors to develop strategies to educate dual eligible beneficiaries about the new Medicare prescription drug benefit, how this new program impacts their coverage under Medicaid, and the process to enroll in prescription drug plans.

We note that Subpart C addresses the steps that will be taken as part of the formulary review process to provide safeguards that ensure a drug coverage transition process for new enrollees taking a drug not covered under a plan. We expect that our review of Part D plan formularies and transition plans as outlined broadly under the requirements in subpart C, and our review of the plan appeals process as described in subpart G, will ensure that all Medicare beneficiaries, including dual eligibles, have prompt access to the prescriptions they need.

1. Definitions (§ 423.772)

In the proposed rule we discussed definitions relevant to the low-income subsidy provisions of this subpart. These definitions were explained in detail in the Preamble discussion related to § 423.773 of the proposed rule. Comments related to these definitions are addressed below.

2. Eligibility for the Low-Income Subsidy (§ 423.773)

The proposed rule provided that full subsidy eligible individuals are eligible for the premium assistance and cost-sharing subsidies set forth in § 423.780 and § 423.782 of the proposed rule. We have added a definition of full subsidy at 423.772 of the final rule to mean the premium assistance and cost-sharing subsidies for which full subsidy eligible individuals are eligible for under § 423.780(a) and § 423.782(a) of the final rule.

In order to qualify as a full subsidy eligible individual, an individual must live in one of the fifty States or the District of Columbia and have countable income below 135 percent of the Federal poverty line for the individual's family size. For purposes of this section, we said in the proposed rule that ''Federal poverty line'' (FPL) has the meaning given that term in section 673(2) of the Community Services Block Grant Act (42 USC 9902(2)), including any revision required by that section.

In addition, the proposed rule provided that to be considered a full subsidy eligible individual, an individual must have resources that do not exceed three times the resource limit under section 1613 of the Act for applicants for Supplemental Security Income (SSI) under title XVI, which in 2006 is $6,000 if single, or $9,000 if married. Thereafter, this resource limit would be increased annually by the percentage increase in the Consumer Price Index (all items, U.S. city average) as of September for the year before, rounded to the nearest multiple of $10.

Individuals not eligible as full subsidy eligible individuals may be eligible as other low-income subsidy eligible individuals if they live in one of the fifty States or the District of Columbia and have income below 150 percent of the FPL for their family size, and have resources in 2006 that do not exceed $10,000 if single, or $20,000 if married. Beginning in 2007 and for each subsequent year, the resource limit would be increased annually by the percentage increase in the Consumer Price Index (all items, U.S. city average) as of September for the year before, rounded to the nearest multiple of $10. The proposed rule provided that other low-income subsidy eligible individuals are entitled to the premium assistance and cost-sharing subsidies set forth in § 423.780 and § 423.782 of the proposed rule.

Low-income Part D eligible individuals who reside in the territories are not eligible to receive premium and cost-sharing subsidies under this subpart. Subpart S of the proposed rule addressed the provision of covered Part D drugs to low-income individuals residing in the territories.

For making income and resource determinations for the low-income subsidy for Part D, the statute refers to certain sections of the SSI statute. For example, the MMA refers to income being determined in the same manner as for Qualified Medicare Beneficiaries (QMBs) under the Medicaid program, without use of the more liberal methodologies that States are permitted to use. The QMB provisions reference the SSI statutory provisions(specifically, section 1612 of the Act, which applies to determining income under the SSI program). Our proposed definition of income was consistent with the MMA in that it references SSI statutory provisions.

The MMA provides that we will compare the individual's income to the appropriate FPL applicable to ''the family of the size involved.'' As there is no reference in the MMA statute to using existing definitions of family size, we proposed to define family size to include the applicant, his or her spouse who lives in the same residence, and the number of individuals related to the applicant who live in the same residence and who depend on the applicant or the applicant's spouse for at least one-half of their financial support.

We said in the proposed rule that we considered limiting family size to 1 or 2 individuals to more closely resemble the SSI statutory provisions, where family size is not actually defined but where benefits are paid on the basis of an eligible individual or eligible couple. This is the definition we use in determining eligibility for Transitional Assistance under the Medicare-approved prescription drug card program (See 42 CFR 402.802). The decision to limit family size under the Medicare-approved prescription drug card program was based on the short duration of that program (18 months), the limited benefit ($600 a year), and the fact that we would have to rely entirely on a computer and systems-based process for determining Transitional Assistance eligibility and verifying income and other information from applicants. However, we did not believe it was the intent of the Congress to similarly limit the definition for purposes of determining eligibility for subsidies under the Part D program. Unlike the provisions authorizing the Medicare-approved drug discount card program, there are no provisions for the low-income subsidy program that give the Secretary specific authority to define family size. Instead, we believed that the term ''family of the size involved'' implies a definition that is greater than an individual or couple and that includes other dependent relatives residing in the applicant's household. In

addition, in order for the term ''family size'' to have meaning in the context of subsidy determinations, the notion of dependency needs to take into account the impact of a dependent on the relative need of the applicant or the applicant's spouse in attaining the subsidy. Accordingly, we specified that dependents included in the calculation of family size are only those relatives residing in the residence who are financially dependent on the applicant or the applicant's spouse for one-half of their support.

In determining the income to be compared to the FPL for the size of the family involved, we included income of the Medicare beneficiary and spouse, if any. Thus, if a married individual applies, both the income of the applicant and his or her spouse who lives in the same residence, regardless of whether the spouse is also an applicant, is counted and measured against the appropriate standard for the low-income subsidy.

In our view, this best comported with the statutory reference to determining income in the manner described in section 1905(p)(1)(B) of the Act (for QMBs). In making a standard QMB income determination, States would consider the income of one spouse as available to the other spouse. Moreover, since both spouses would be considered in the family size determination, it would be illogical to count a spouse's presence while not including that spouse's income. Other members who meet the one-half support test would be counted in the family size calculation, but income of these dependents will be ignored in the eligibility determination. The one-half support test ensures that a family member with sizable income is not erroneously counted as a dependent while that person's income is ignored.

Section 1860D–14(a)(3)(D) of the Act provides that resources will be determined according to section 1613 of the Act. The resource standard depends upon whether the applicant is a single individual or a member of a married couple and whether the resources will be measured against the basic or alternative resources standards. See sections 1860D–14(a)(3)(D) and (E) of the Act and H.R. Conference Report No. 108–391 at 470.) However, section 1613 of the Act does not define resources, but rather only defines what are not resources.

Sections 1860D–14(a)(3)(E)(ii) and (iii) of the Act also provides for the development of a simplified application in which applicants attest to their level of resources and submit only minimal documentation. The implication of this provision is that the Congress envisioned a simple process. In order to keep the process simple and minimize administrative cost, we intended to only consider liquid resources (that is, those that could be converted to cash within twenty days) and real estate that is not an applicant's primary residence as resources that are available to the applicant to pay for the Part D premiums, deductibles and copayments. Thus, we would not consider other non-liquid resources (for example, a second car) to be available to the applicant for this purpose.

We did not believe this policy would have a significant impact on program costs. We believed any program costs that would result from counting only liquid resources and countable real estate would be offset by the administrative savings resulting from a more simplified program. As we indicated further in this section, we are working with SSA on a quality assurance strategy that would strike an appropriate balance between administrative costs and program goals and objectives.

Under Medicaid, the term ''dual eligibles'' generally refers to low-income Medicare beneficiaries who qualify for some level of medical assistance. Those entitled to full benefits under Medicaid generally have most of their health care expenses, including prescription drugs, paid for by a combination of Medicare and Medicaid. However, Federal law also specifies several groups of dual eligibles who, while not entitled to full Medicaid benefits, are entitled to more limited medical assistance, specifically payment of Medicare Part A or Part B premiums or cost sharing, such as payment of Medicare deductibles and coinsurance. These groups are certain qualified Medicare beneficiaries (QMBs), specified low-income Medicare beneficiaries (SLMBs), qualified disabled and working individuals (QDWIs), and certain qualifying individuals (QIs).

For purposes of the low-income subsidy under Part D, in the proposed rule we proposed to define the term ''full-benefit dual eligible individual'' as an individual who for any month has coverage under a PDP or MA-PD plan and is determined eligible by the State for medical assistance for full benefits under title XIX for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under Section 1115 of the Act. We proposed that comprehensive benefits referred to in this section do not include those benefits received under Pharmacy Plus demonstrations authorized under section 1115 of the Act. For individuals who become medically needy by ''spending down'' excess income; that is, incurring medical expenses which are subtracted from the individual's income, the individual is not eligible as medically needy until he or she satisfies their spenddown obligation. This requirement was reflected in the proposed regulations at § 423.772.

Section 1860D–14(a)(3)(B)(v)(II) of the Act authorizes the Secretary to treat QMBs, SLMBs, and QIs who are not full- benefit dual eligible individuals as full subsidy eligible individuals. This authority does not apply to QDWIs. As proposed at § 423.773(c), the Secretary elects to exercise this authority and treat these QMBs, SLMBs, and QIs as being eligible for the full subsidy.

This decision was based on the fact that nearly all QMBs, SLMBs, and QIs, by definition, would likely meet the requirements to be considered a full subsidy eligible individual. Generally, QMB, SLMB, and QI individuals have income below 135 percent of the FPL applicable to their family size and resources that do not exceed twice the SSI limit. The exception would be in the few States that have more liberalized income and asset rules for these groups under section 1902(r)(2) of the Act. We did not believe that treating these groups as full subsidy eligible individuals will have a large cost impact. Further, we believed that it would ease the administrative burden of having to educate these individuals on the need to apply for the subsidy.

Finally, the statute gives the Secretary the option to permit a State to make subsidy eligibility determinations by using the methodology it uses under section 1905(p) of the Act if the Secretary determines that this would not result in any significant difference in the number of individuals who are made eligible for the subsidy. This would permit a State to use the same resource methodologies that it uses to determine Medicaid eligibility for QMBs, SLMBs, and QIs if the Secretary determines that the use of those methodologies would not result in any significant differences in the number of individuals who are made eligible for a subsidy. This includes the less restrictive methodologies the State uses under section 1902(r)(2) of the Act to determine eligibility for QMBs, SLMBs, and QIs. In the proposed rule, we chose not to exercise this option.

This means that when making eligibility determinations for other low-income subsidy eligibles, all States would use the same resource methodologies across the country. The rationale for not electing this authority was twofold. First, uniformity in the

application process is a desired goal and having alternative resource methodologies that would vary among States would detract from that goal. Second, based on the administrative burden and complexity that would be involved in administering this alternative process, we saw very little benefit in terms of the number of individuals who would be determined subsidy eligible.

Comment: A number of commenters supported our definition of family size. Some of those supporting our definition further urged that the regulations specify that applicants will be able to self-attest as to the number of family members they claim without the need for further documentation.

Response: As explained elsewhere in the preamble in our discussion of the use of a simplified low-income subsidy application, we anticipate that such things as income and resources will be verified to the extent possible using automated data matches. This reduces both the administrative cost of making eligibility determinations, and the burden on applicants to provide documentation as to their income and resources. Similarly, we anticipate that in most cases an applicant's declaration of the size of his or her family will be accepted without the need for further documentation from the applicant.

Comment: While a number of commenters supported our definition of family size, a number of other commenters requested clarification or objected to the definition. All of these commenters argued that our definition did not follow SSI statutory rules, and therefore would make it more difficult and complex to determine eligibility for a low-income subsidy. Many of these commenters argued that since low-income subsidy eligibility was supposed to be based on SSI statutory income and resource rules, the rules under which SSI pays benefits to individuals or couples should also be followed.

Response: We understand the concerns expressed by these commenters. As explained previously, and in the preamble to the proposed regulations, we did consider using the SSI statutory framework of individual or couple. However, as we also explained, we do not believe that the Congress intended the definition of family size to be so restrictive for low-income subsidy eligibility purposes. Moreover, the SSI statute does not include a definition of family size. Therefore, we proposed to define family size to include the applicant, his or her spouse who lives in the same residence, and any individuals related to the applicant who live in the same residence and depend on the applicant or the applicant's spouse for at least one-half of their financial support.

While we recognize that our definition may result in some additional complexity in making eligibility determinations, we believe the definition we have adopted is necessary to take into account the impact that supporting dependent family members may have on the need of an applicant for a low-income subsidy.

Comment: A few commenters suggested that our definition of family size should be revised to automatically include any children under the age of 21 as members of the family, regardless of other considerations such as whether the applicant was providing one-half of the child's support. This commenter also suggested that a pregnant woman should be counted as two family members.

Another commenter stated that the one-half child support test is different than what is used for Medicaid and that there will be additional burden placed on States to do this test.

Response: We do not agree with either of this commenter's suggestions. We included relatives who are dependent on the applicant for one-half of their support in the definition in recognition of the impact supporting such relatives can have on the applicant's financial situation. For this reason, we do not believe it is appropriate to include all children in the applicant's household under age 21 even if they are not dependent on the applicant, or to count a pregnant woman as two family members.

Comment: One commenter said that the definition of family size is vague as to whether relatives of the spouse of an applicant can count toward family size, and suggested that the definition be revised to make that explicit.

Response: We do not believe the definition is as vague as the commenter suggests. Under our proposed definition, family size includes the number of individuals living in the household who are related to the applicant or applicants, and who are dependent on the applicant or the applicant's spouse for at least one-half of their support. The definition places no restrictions on what is meant by ''related'' to the applicant other than that a recognized family relationship exists, and further provides that dependence on the applicant's spouse will allow a person to be counted as a family member. Therefore, we do not believe the definition needs revision as suggested by the commenter.

Comment: We received two comments on our definition of ''full-benefit dual eligible individuals'' in § 423.772. One commenter noted that the proposed regulation defines the term (in part) as someone who has coverage for the month under a prescription drug plan under Part D of title XVIII, or under an MA-PD plan under Part C of title XVIII. The commenter believes this language creates a technical problem with the auto-enrollment provisions set forth in § 423.34(d) of the proposed regulations. That section provides that full-benefit dual eligible individuals who fail to enroll in a PDP or MA-PD during their initial enrollment period will be automatically enrolled into a plan.

The commenter believes these two sections are inherently contradictory because one requires a person to be enrolled in a PDP or MA-PD to be considered a full-benefit dual eligible individual, while the other provides for automatically enrolling someone who is considered to be a full-benefit dual eligible individual in a PDP or MA-PD, even though under the first section the person could not be a full-benefit dual eligible individual because he or she was not already enrolled in a PDP or MA-PD. The commenter suggests revising the language in § 423.772 to define (in part) a full-benefit dual eligible individual as someone who has coverage, or who will have coverage as a result of automatic enrollment for the month under a prescription drug plan.

Response: We understand the commenter's concern. The definition of a full-benefit dual eligible individual in § 423.772 reflects the statutory definition of that term found at section 1935(c)(6) of the Act, which defines a full-benefit dual eligible individual to include individuals who have coverage under a Part D plan. We do not believe we have the authority to change our regulatory definition of ''full-benefit dual eligible individual'' for purposes of this subpart. However, we agree with the commenter that this definition of the term ''full-benefit dual eligible individual'' is problematic for application of the auto-enrollment rules under § 423.34. As discussed more fully in subpart B, section 1860D–1(b)(1)(C) of the Act requires CMS to auto-enroll into PDPs an individual ''who is a full-benefit dual eligible individual'' who ''has failed to enroll in a prescription drug plan or an MA-PD plan.'' Although this statutory provision specifically references the statutory definition of ''full-benefit dual eligible individual'' under section 1935(c)(6) of the Act, if interpreted literally, section 1860D–1(b)(1)(C) of the Act would require CMS to auto-enroll into Part D plans only individuals receiving full-benefits under Medicaid who are already enrolled in

Part D but who have ''failed to enroll in'' a Part D plan, a patently absurd result. We have an obligation to interpret the statute so as to avoid an absurd result and give full effect to the Congress' intended policy. We think it is clear that the Congress required CMS to establish an auto-enrollment process to ensure that individuals who currently receive coverage for Part D drugs under Medicaid continue to receive coverage for such drugs through enrollment in Part D beginning in 2006. Therefore, for purposes of implementing the auto-enrollment process of full-benefit dual eligible individuals, at § 423.34 of subpart B the final rule we define ''full-benefit dual eligible individuals'' as Part D eligible individuals who meet the conditions under section 1935(c)(6)(A)(ii) of the Act but are not enrolled in a Part D plan.

Comment: One commenter expressed concern about what the commenter saw as a possible inequity in the definition of a full-benefit dual eligible individual. Under that definition in our proposed rule, anyone with coverage under a PDP or MA-PD plan who is determined by a State as eligible for full Medicaid benefits under any eligibility group is a full-benefit dual eligible individual. However, the commenter noted that some eligibility groups in some States are not subject to an asset test. The commenter believes this can lead to situations where some persons receiving the full subsidy under Part D would be subject to an asset test but others would not, depending on whether they were in an eligibility group to which an asset test did not apply in a particular State.

Response: While we understand the point the commenter is making, we must note that the definition of a full-benefit dual eligible individual as someone who has been determined eligible for Medicaid under any eligibility group covered under a State's plan is a statutory definition. Accordingly, we have no authority to change that definition in the Part D low-income subsidy regulations.

Comment: One commenter argued that the definition of full-benefit dual eligible individual should be interpreted to include persons participating in that State's optional work incentives buy-in eligibility group, as well as persons eligible because of the State's use of more liberal income disregards under section 1902(r)(2) of the Act. The commenter suggested that if this was not our intention, the regulatory definition should be clarified. Another commenter suggested we clarify the definition to include other protected classes of Medicaid-covered individuals, specifically, individuals covered under Medicaid pursuant to 1915(c) and 1619(b) of the Social Security Act.

Response: As we believe the definition makes clear, a full-benefit dual eligible individual is a person who is eligible for full Medicaid benefits under any group covered under a State's plan. Therefore, we do not believe the definition needs further clarification.

Comment: One commenter noted that full-benefit dual eligible individuals include all persons eligible for full Medicaid benefits under a group covered under a State's plan even if they have income in excess of 135 percent of the Federal poverty line applicable to the individual's family size. The commenter asked if any analysis has been done to determine whether tying eligibility for a low-income subsidy to eligibility for Medicaid will lead to an increased use of qualifying income (also known as Miller) trusts in States where the trusts are recognized under Medicaid.

Response: We are not aware of any analysis that has been done on that subject. Further, even if analysis were to indicate the possibility of increased use of the trusts under these circumstances, the statutory definition of a full-benefit dual eligible individual is clear, and therefore is not subject to change under our regulations to address the possibility.

Comment: We received one comment on the definition of ''full subsidy eligible individuals'' in § 423.772. That section provides that a full subsidy eligible individual is an individual who meets the eligibility requirements under § 423.773(b). The commenter suggested that the latter reference should be changed to § 423.773(b) and (c) to avoid ambiguity.

Response: We do not agree with the commenter's suggestion. Section 423.773(b), as cited in section 423.772, defines a ''full subsidy eligible'' individual, while § 423.773(c), which is the reference the commenter suggests adding, provides that certain individuals must be treated as if they did meet the definition of full subsidy eligible individuals as defined in § 423.773(b). Section 423.773(c) does not change the definition of a full subsidy eligible individual. We believe that adding the reference the commenter suggests would create ambiguity where none exists now.

Comment: One commenter indicated that for any subset of individuals for whom States provide pharmacy-only benefits under a section 1115 demonstration, that subset be excluded from the definition of full-benefit dual eligible, since these programs generally provide the same benefits as offered under Pharmacy Plus Programs.

Response: We agree with this commenter and have further clarified the definition of full-benefit dual eligible individual at § 423.772 to exclude those individuals enrolled in 1115 demonstration programs that provide pharmacy-only benefits to a portion of its demonstration population.

Comment: We received some comments on our proposed definition of income. One comment, which was submitted by several different commenters, was that the definition of income should make it clear that income not legally owned by the applicant, even if his or her name is on the check, should not be counted. Another comment, submitted by two commenters, was that the definition should exclude the same income currently excluded under the Medicaid program when determining Medicaid eligibility for American Indians and Alaska Natives. And finally, one commenter asked if income of another family member from SSI and TANF will be included.

Response: For these comments it is important to note that under the Part D statute, income eligibility for a low-income subsidy is determined using the statutory provisions of the Supplemental Security Income (SSI) program. The statute does not give us the authority to change the way those provisions apply to subsidy eligibility determinations for the low-income subsidy under this subpart. Under the SSI statutory provisions, some income may be counted even if the person does not actually receive it, just as some income a person does receive may not be counted. Similarly, SSI excludes certain types of income received by American Indians and Alaska Natives. The Social Security Administration (SSA), which operates the SSI program, is publishing its own regulations which will explain how the SSI statutory provisions will apply to eligibility determinations for the low-income subsidy. We expect that SSA's regulations will explain in detail how income will be counted when determining eligibility for a low-income subsidy.

Comment: Another commenter noted that under § 423.772, income is defined differently from Medicaid in two ways; the regulatory definition does not include the use of more liberal income methodologies under the authority of section 1902(r)(2) of the Act, and eligibility is based on a family size that can be greater than the one or two that Medicaid normally uses when determining eligibility for the aged and

disabled. The commenter further noted that this means that if States are making eligibility determinations for low-income subsidies, they will have to use different rules than they use under their Medicaid programs.

Response: While the commenter is correct on both points, we note that section 1860D–14 (a)(3)(C) of the Act specifically precludes the use of income disregards authorized under section 1902(r)(2) of the Act in determining low-income subsidy eligibility. With regard to the commenter's point about family size, as we explain elsewhere, we believe the definition of family size we have adopted most closely reflects the intent of the Congress with regard to low-income subsidy eligibility. Therefore, we do not believe we can or should revise the proposed regulations to accommodate the commenter's arguments.

Comment: We received a number of comments about the definition of an institutionalized individual as it applies to cost-sharing subsidies under § 423.782 of the proposed regulation. That section provides that institutionalized individuals have no cost-sharing for covered Part D drugs under their Part D plans. The term ''institutionalized individual'' is defined in § 423.772 of the proposed rule as a full-benefit dual eligible individual who is an inpatient in a medical institution or nursing facility for which payment is made under Medicaid throughout a month, as defined in section 1902(q)(1)(B) of the Act.

Almost all of the commenters urged that persons receiving home and community-based waiver services under the waiver authority under section 1915(c) of the Act be treated as institutionalized individuals for purposes of § 423.782 so that they would not be subject to cost-sharing. Several commenters also suggested that institutions for the mentally retarded (ICFs/MR) be specifically included in the regulations as meeting the definition of a medical institution for purposes of this section. At least one commenter believed that persons in other living arrangements such as assisted living facilities, residential care homes, and boarding homes should be treated as institutionalized individuals under § 423.782. One commenter urged that persons receiving PACE services also be treated as institutionalized individuals for purposes of this Subpart.

The commenters' rationale was that in most of the situations cited in the various comments, the individuals were receiving services in the community as an alternative to institutionalization. Individuals eligible for Medicaid under a waiver under section 1915(c) of the Act are often eligible for waiver services using rules that normally apply in institutions. Therefore, the commenters believe these persons should also be treated as institutionalized individuals for Part D cost-sharing purposes. Some commenters also cited the Olmstead U.S. Supreme Court decision, which requires States to place persons with disability in community rather than institutional settings when possible, as a basis for the commenters' position.

Response: For comments suggesting that ICFs/MR be specifically included in the regulations meeting the definition of a medical institution, we do not believe such inclusion is either necessary or desirable. If we state that ICFs/MR in general meet the definition of a medical institution it could be misleading because one ICF/MR could meet the various certification and service provision requirements set forth in current regulations while others would not. Therefore, we would not want to give the erroneous impression that all ICFs/MR would meet the definition of a medical institution for purposes of the provision under discussion.

For comments urging that persons receiving waiver services, PACE services, or those in various living arrangements such as assisted living facilities and residential care homes be treated as institutionalized individuals for purposes of cost-sharing under § 423.782, we understand why the commenters believe such treatment would be to the advantage of those persons. However, the regulatory provisions under discussion are based on specific statutory language, and we do not believe that language contains the latitude necessary to treat persons in the various situations described by the commenters as institutionalized individuals.

Section 1860D–14(a)(1)(D)(i) of the Act provides that for purposes of cost-sharing, an institutionalized individual is one who meets the definition of that term in section 1902(q)(1)(B) of the Act. That section in turn defines an institutionalized individual as someone who is an inpatient in a medical institution or nursing facility for which payments are made under the Medicaid program throughout a month, and who is determined to be eligible for medical assistance under the State plan. An inpatient is someone who is physically in a medical institution. However, assisted living facilities, boarding homes, residential care homes, etc., do not meet the general definition of medical institutions under the Medicaid or Medicare programs. Individuals receiving services under the waiver authority provided by section 1915(c) of the Act, or under the PACE program, are not inpatients of a medical institution since they are living in the community. When the Congress intends to include such individuals, or give States the option of including such individuals, within the definition of ''institutionalized individuals'', it does so explicitly in the statute. In the absence of such explicit inclusion in the Part D statute, we cannot consider the persons to whom the commenters refer to be institutionalized individuals for Part D cost-sharing purposes. We believe the Congress intended this provision to address the fact that dual-eligible persons residing as inpatients in medical institutions are permitted to retain only a small personal needs allowance, which preclude payment of even nominal copayments. For PACE enrollees, we refer commenters to Subpart T.

Comment: Three commenters objected to the language in the definition of institutionalized individual concerning payment being made under the Medicaid program throughout a month, arguing that an individual could be a full-benefit dual eligible individual recently returned from a hospital stay whose nursing facility stay would be paid for by Medicare Part A for the entire month.

Response: While we understand the commenters' concern, the language in question is a specific statutory requirement under section 1902(q)(1)(B) of the Act. Therefore, we do not believe we can eliminate or even revise that requirement in the regulations. It is worth noting that that if Medicare Part A is paying for the nursing home stay, an individual's drug costs will in all likelihood be covered through Medicare Part A payment, and so the issue of Part D cost-sharing liability does not apply.

Comment: We received several comments on our proposed definition of a personal representative in § 423.772. In the proposed rule we defined a personal representative as someone who is (1) authorized to act on behalf of the applicant; (2) someone acting responsibly on behalf of the applicant if the applicant is incapacitated or incompetent, or (3) an individual of the applicant's choice who is requested by the applicant to act as his or her representative in the application process.

One commenter urged that ''authorized'' to act on behalf of the applicant be defined to mean authorized under State law, and that ''State law'' in turn be defined as including a constitution, statute, regulation, rule,

common law, or other State action having the force and effect of law.

Response: While we understand the commenter's concern, we do not believe that the term ''authorized'' should be restricted in the manner suggested. The intent of this portion of our proposed definition was to enable applicants to designate someone whom they trust to act on their behalf in filing an application for a low-income subsidy. Defining the term ''authorized'' to mean only persons who meet State law-based requirements could effectively restrict an applicant's choice of personal representative to someone with what could amount to a guardianship relationship with the applicant, even if the applicant is not in need of a formal guardian. This could make it very difficult if not impossible for an applicant to even find a qualified personal representative.

Comment: Several commenters suggested that the term ''acting responsibly'' needed further clarification as to who would determine that a personal representative is acting responsibly, and under what circumstances a conflict of interest could be presumed to exist. Two commenters suggested that certain entities for whom the commenters apparently believe a conflict of interest can be presumed to exist, such as insurance agents, Medicare and PDP marketing representatives, and anyone charging a fee for assistance, should be prohibited from acting as a personal representative.

Response: We understand the commenters' concerns about the possibility of personal representatives not acting in the best interests of the applicant. However, we do not believe it is appropriate to establish rules that effectively prohibit entire classes of individuals from acting as personal representatives for applicants based solely on a possibility. If, based on actual program experience, we find that personal representatives are abusing the trust placed in them by applicants and the low-income subsidy program, we will refer for investigation these potential program abuses and publish guidelines to address any specific patterns of abuse that emerge. In the absence of evidence to the contrary, however, we believe that at this time we should assume that personal representatives will for the most part act in the best interests of the applicants who appoint them.

Comment: One commenter expressed concern about a requirement in § 423.904(d)(2)(ii) of the proposed regulations that when taking a low-income subsidy application, States must require a personal representative to certify under penalty of perjury as to the accuracy of the information provided. The commenter believes this requirement will greatly inhibit outreach and enrollment activities by social workers and community service organizations. The commenter believes this requirement would expose any agency, volunteer, SHIP program staff, friend or neighbor to legal liability.

Response: We do not believe this requirement will have the dire consequences the commenter fears. The requirement the commenter cites is a standard part of most if not all applications for Federal benefits, and in all likelihood the majority of State benefits as well. This requirement is intended to deter applicants or their representatives from knowingly falsifying applications for low-income subsidies, and thus only requires the applicants or their representatives to the best of their knowledge. It is not intended to lead to, nor would it be used for the purpose of, prosecuting applicants or representatives for simple errors or inadvertent omissions.

Comment: One commenter indicated that the definition of personal representative should also include an SPAP when the SPAP is functioning as an authorized representative.

Response: Our definition would encompass an SPAP when the SPAP is functioning as an authorized representative. In such a case, the SPAP as an authorized representative, can exercise all the rights of the applicant including completing the low-income subsidy application.

Comment: We received a number of comments on our proposed definition of ''resources'' in § 423.772, and referenced elsewhere in the proposed regulations. In that section we proposed defining the term ''resources'' to mean liquid resources of the individual (and if living in the same household, his or her spouse if the individual is married), such as checking and savings accounts, stocks, bonds, and other resources that can be readily converted to cash within 20 days, that are not excluded from resources in section 1613 of the Act, and real estate that is not the applicant's primary residence or the land on which the residence is located. We included this definition of resources because individuals are subsidy eligible individuals only if they have resources (or assets) below certain limits established under section 1860D–14(a)(3)(D) and (E).

Several commenters urged that the asset test eligibility for the low-income subsidy be eliminated entirely. Eligibility would then be based solely on an applicant's income.

Response: An asset test for low-income subsidy eligibility is specifically required under section 1860D–14(a)(3)(D) and (E). In view of this clear statutory requirement, we have no authority to eliminate the asset test in its regulations.

It should be noted that the Social Security Administration (SSA), which operates the SSI program, is publishing its own regulations which will explain how the SSI statutory provisions, including those pertaining to resources, will apply to low-income subsidy eligibility. We expect that SSA's regulations will explain in detail how resources will be counted when determining eligibility for a low-income subsidy.

Comment: Several commenters suggested that if the asset test could not be eliminated entirely, at least certain specific assets should be excluded from being counted when determining eligibility for a low-income subsidy. Specifically mentioned by commenters were any life insurance, including the cash surrender value of life insurance, burial funds and burial plots, all officially designated retirement funds such as IRAs and 401(k) plans, and vehicles.

Response: We note that of the specific assets mentioned by commenters, burial plots are already excluded from being counted as assets under the SSI program, and vehicles are also excluded from being counted for low-income subsidy purposes because they are not considered liquid assets. For the other assets mentioned, we do not agree that they should be eliminated from the resource test. Section 1860D–14(a)(3)(D) provides that resources will be determined according to section 1613 of the Act, which designates the exclusions from resources for the SSI program. As we explain in the preamble to the proposed rule, we believe that we have some flexibility to narrow our definition of resources to exclude non-liquid resources that would be counted under the SSI program, since the section 1860D–14(a)(3)(E)(ii) of the Act also provides for the development of a simplified application in which applicants attest to their level of resources and submit only minimal documentation. We believe that the implication of this provision is that the Congress envisioned a simple process. Therefore, in order to keep the process simple and minimize administrative cost, we will only consider liquid resources (that is, those that could be converted to cash within twenty days) and real estate that is not an applicant's

primary residence as resources that are available to the applicant to pay for the Part D premiums, deductibles and copayments. While, in the interest of simplicity, we were willing to exclude certain non-liquid resources, we do not believe that the Congress intended to authorize a wholesale departure from SSI resource rules in making subsidy eligibility determinations. Therefore, for purposes of counting liquid resources, we believe it is important to adhere to the resource rules of the SSI program. These include counting items such as the cash surrender value of life insurance and the value of IRAs and 401(k) plans.

Comment: Some commenters suggested that if the assets discussed above could not be excluded entirely from being counted, any disregards applying to them should be substantially increased.

Response: For the reasons explained in the previous discussion, we will not increase disregards for these or any other assets beyond whatever disregards are applicable under the SSI program.

Comment: Many commenters said that the examples of countable resources we included in the proposed definition of resources under § 423.772 was not detailed enough. They urged that the final rule provide a specific list of the resources that would be counted (or, alternatively, that would not be counted) in determining low-income subsidy eligibility. Many commenters also expressed concerns about the provision that resources that can be readily converted to cash within 20 days would be counted. These commenters said the 20-day conversion rule was vague, and needed to be clarified. Another commenter suggested that we exclude resources if liquidating that resource would result in a financial loss or penalty.

Response: For these comments, and as we explain in our discussion of the definition of income elsewhere in this section of the preamble, it is important to note that under sections 1860D–14(a)(3)(D) and (E) of the Act , the resource component of the eligibility determinations for a low-income subsidy is generally determined using the statutory rules of the Supplemental Security Income (SSI) program which govern resource exclusions under that program. As noted earlier, the Social Security Administration (SSA), which operates the SSI program, is publishing its own regulations which will explain how the SSI statutory provisions, including those pertaining to resources, will apply to eligibility determinations for the low-income subsidy. We expect that SSA's regulations will explain in detail how resources will be counted when determining eligibility for a low-income subsidy.

Comment: A few commenters suggested that the rules for counting resources for making eligibility determinations of the low-income subsidy be exactly the same rules as are used by the SSI program when counting resources. These commenters argued that any deviation from the standard SSI rules would make it more difficult for States to determine low-income subsidy eligibility.

Response: As we explained in the preamble to the proposed regulations, the rules for counting resources for low-income subsidy determination purposes are for the most part the same as the standard SSI resource rules. The primary difference is that most non-liquid resources will not be counted when determining eligibility for the low-income subsidy, whereas many such non-liquid resources would be counted under SSI. We believe that rather than making eligibility for a subsidy more difficult to determine, not counting most non-liquid resources will actually make the eligibility determination process easier.

Comment: Several commenters noted that under the Part D statute, the Secretary has the option of allowing States to use the more liberal resource rules that the States may use to determine resource eligibility for QMBs, SLMBs, and QIs when determining low-income subsidy eligibility. These commenters urged that we exercise that option and allow States to use their more liberal resource rules rather than require States to use only the SSI statutory resource provisions, as we have proposed.

Response: As we explained in the preamble to the proposed regulations, a primary goal under the low-income subsidy program is to have nationally uniform standards and rules for determining eligibility for a subsidy. We believe national uniformity is desirable because the low-income subsidy is a national program, and thus to the greatest extent possible should be operated under the same rules regardless of where in the country an applicant lives. Allowing States to use resource rules that would vary from State to State would compromise that uniformity. Also, as we explained in the preamble, we do not believe allowing States to use different resource rules to determine low-income subsidy eligibility would significantly change the number of persons who might be found to be eligible for the low-income subsidy. This is because the option to allow States to use more liberal resource rules could be exercised only in cases where the Secretary found, in a particular State, that use of those rules would not materially increase the number of individuals who would be subsidy-eligible individuals.

Comment: One commenter suggested that in addition to allowing States to use more liberal resource rules, we should require SSA to use a State's more liberal rules as well when making low-income subsidy eligibility determinations.

Response: As explained above, we are not exercising the option to allow States to use more liberal resource rules. However, even if we were to exercise that option, the option applies only to eligibility determinations for the low-income subsidy by a State. The Part D statute contains no authority under which a requirement such as the commenter suggests could be imposed on SSA.

Comment: One commenter suggested that we apply the low-income subsidy resource rules across the board to the Medicare Savings Program groups (that is, the QMBs, SLMBs, and QIs). The commenter believes this would make more people eligible for the Medicare Savings Program because the basic subsidy resource rules count fewer resources than the basic Medicare Savings Program rules.

Response: We would note that to a large degree individual States already have the option to do as the commenter suggests. Under the authority of section 1902(r)(2) of the Act, States can elect to count fewer resources, or disregard greater amounts of resources, for Medicare Savings Program groups than they would otherwise under the basic resource rules. However, while this is an option for States, we do not have the statutory authority to impose the low-income subsidy rules on States' Medicare Savings Programs.

Comment: A few commenters urged that we consider not applying transfers of resources for less than fair market value penalties to low-income subsidy applicants, as we have proposed in our regulations.

Response: For purposes of determining eligibility for the low-income subsidy, we will not be considering the value of assets transferred for less than fair market value. We do not believe that penalties associated with transfers translate into an appropriate method of counting resources for the low-income subsidy.

Comment: We received at least one comment that our definition of resources should exclude the same resources currently excluded under the Medicaid program when determining

Medicaid eligibility for American Indians and Alaska Natives.

Response: As we have explained previously in this section of the preamble, under section 1860D–14(a)(3)(D) and (E) of the Act, resource eligibility for a low-income subsidy is determined using the statutory provisions of section 1613 of the Social Security Act, which governs resource exclusions under the SSI program. Under the SSI program, a number of types and amounts of resources belonging to American Indians and Alaska Natives are already excluded. If they are excluded under SSI statutory provisions, they will also be excluded when determining low-income subsidy eligibility.

Comment: One commenter objected to the provision under which the low-income subsidy resource standards will be increased each year by the percentage increase in the Consumer Price Index, rounded to the nearest multiple of $10. The commenter believes this adds complexity to administering the low-income subsidy program, and suggested that resource standards be consistent across all poverty-level-based Federal programs.

Response: While we understand the commenter's concern, we must note that the process for increasing the resource standards is mandated by section 1860D–14(a)(3)(D) and (E) of the Act. Therefore, we do not have authority to change or eliminate that process under its regulations.

Comment: Several commenters suggested that we clarify the regulations to reflect that an individual can apply and be determined a subsidy eligible individual before enrolling in a Part D plan. Other commenters remarked that the proposed rule implies that an individual must be enrolled in a Part D plan in order to apply for low-income subsidies. They assert that the final regulations should make clear that determinations could be made both before and after enrollment in a Part D plan, and specify the effective date of that coverage. Other commenters suggest that we clarify how information verifying enrollment in a plan is provided to States and how States will be notified if an individual disenrolls from a plan.

Response: Determinations for the low-income subsidy program can be made in advance of a person enrolling in a Part D plan. We believe that fact is clearly articulated in the proposed regulation which requires States to take subsidy applications starting July 1, 2005, well in advance of the open enrollment period for the new Part D benefit, a requirement we retain in the final rule. Therefore, we do not believe we need to make further clarifications in the final rule.

We believe it is important to emphasize here that while determinations may be made in advance of the initial enrollment period beginning on July 1, 2005, a subsidy eligible individual is not entitled to the subsidy until such time as the person's enrollment in a plan is effective. Up until that time, there are no premiums or cost sharing obligations under Part D for which we must subsidize payment under the low-income subsidy. Accordingly, States need only to send us information on whether a person is eligible for the low-income income subsidy. We will provide information on subsidy eligible individuals to Part D plans and will reimburse plans for enrollees who are subsidy eligible individuals as provided under § 423.329(d). We acknowledge that States may require plan enrollment information for purposes of coordination of benefits, but we do not believe that such information is necessary for purposes of determining whether a beneficiary is eligible for the low-income subsidy. Therefore, we will not share enrollment data with the States on a routine basis for the purpose of determining eligibility for the low-income subsidy. In Subpart J, we address the need for this information sharing for coordination of benefit purposes.

Comment: One commenter indicated that the proposed rule disadvantages Social Security Title II beneficiaries who receive Medicare and will receive low-income subsidies. The proposed regulation provides that low-income Medicare beneficiaries will pay little or nothing for prescriptions, while those earning over 150 percent of the Federal poverty line applicable to the individual's family size may have to pay as much as 50 percent of the cost of their prescription for covered Part D drugs, giving them a financial disincentive to return to work if they incur significant prescription expenses. The commenter urges us to consult with SSA about these changes.

Response: The income threshold of 150 percent of the Federal poverty line for low-income subsidy eligibility is established by section 1860D–14(a)3)(E) of the Act, and cannot be changed without a change in the law itself. However, while eligibility for the low-income subsidy is based on income, it is important to be aware that income can be earned income or unearned income. Under the statutory rules of the supplemental Security Income (SSI) program, which are used to determine low-income subsidy eligibility, there are significant disregards for earned income. Under those rules, the first $85 of earned income, plus one-half of any remaining earned income, will not be counted when determining low-income subsidy eligibility. Other earned income disregards may also apply, depending on each applicant's personal situation. Thus, those Social Security Title II beneficiaries who choose to return to work will have the potential for total income that is actually higher than 150 percent of the Federal poverty line as a result of the earned income disregards that will be applied in determining low-income subsidy eligibility.

Comment: Several commenters suggested that our regulations should indicate that the indexing of resources would be rounded up in multiples of $10.

Response: We do not have authority to make this change in the final rule. The reference in sections 1860D–14(a)(3)(D) and (E) of the Act to the ''nearest multiple of $10'' does not provide the discretion to always round up or to always round down. For purposes of indexing, the nearest multiple will be rounded up if it is equal to or greater than $5 and down if it is less than $5.

Comment: Several commenters suggested that we needed to clarify that individuals deemed to be subsidy eligible do not have to take any further action for the low-income subsidy; rather, they only need to enroll in a Part D plan.

Response: We have further clarified in the final rule that individuals deemed subsidy eligible individuals do not need to apply for the low-income subsidy.

Comment: Several commenters expressed support for the proposed deeming of Medicare Savings Program individuals as full subsidy eligible individuals, but expressed concern that SSA will not apply more generous income and asset eligibility rules under Medicaid for individuals potentially eligible for Medicare Savings programs. These commenters indicated that the requirements should be the same for all subsidy-eligible individuals in a State, regardless of where and how they apply.

Response: While States may use more liberalized methodologies under Medicaid for purposes of determining eligibility for Medicare Savings Programs, they may not employ more liberal methodologies under the Medicare Part D low-income subsidy eligibility should an individual apply and request a State eligibility determination. (However, if the State determines the individual is Medicare Savings Program-eligible under its rules

(that is, as a QMB, SLMB, or QI), the individual is deemed eligible for the subsidy) The requirements for counting income and assets are the same under the low-income subsidy program regardless of whether an individual applies at a State office or an SSA field office. These requirements are based on the statutory provisions of the SSI program. For counting income, States and the SSA are specifically precluded from using the more liberalized methodologies permitted under Medicaid under section 1902(r)(2) of the Act. For counting resources, we acknowledge in the proposed rule that we could have permitted States to use the same resources standards that States employ under Medicaid for purposes of determining eligibility for Medicare Savings Programs. However, we elected not to exercise this discretion since this authority does not extend to SSA and we believe national uniformity for purposes of eligibility determinations is a desirable goal.

Comment: Some commenters expressed concern that the proposed rule does not address eligibility issues for Medicaid beneficiaries who become eligible after a spenddown period, either under a medically needy program or in a 209(b) State (that is, a State which does not provide Medicaid automatically to all of its SSI recipients but which uses more restrictive rules than those of the SSI program). They suggested that these beneficiaries should be informed of their eligibility for the low-income subsidy and given an opportunity to apply for the subsidy. When they have met their spenddown, they should be informed of their entitlement to the low-income subsidy as a full-benefit dual eligible individuals.

Response: We agree that the eligibility rules may be confusing for Medicare beneficiaries who become eligible for Medicaid after a spenddown period. In the final rule, we have clarified that individuals treated as full-subsidy eligible individuals will be deemed eligible for a period up to one year. Thus, individuals who have met their spenddown obligation and are eligible for full Medicaid coverage will be notified that they are eligible for a full subsidy under Part D for up to one year without interruption. If the individuals periodically go off Medicaid because they have to meet a new spenddown budget, they will still be ''deemed'' full subsidy eligible individuals for the remaining period of subsidy eligibility. We have specified ''a period up to one year'' to allow us the operational flexibility to deem full subsidy eligible individuals for a period less than 12 months during a calendar year if they are newly identified to us in a month later than January. Thus, an individual may be deemed subsidy eligible for 9 months if they are reported by the State as a full-benefit dual eligible individual in March, for example. If the same person continues to be a full-benefit dual eligible individual in the fall of the same year, he or she will be deemed a full subsidy eligible the next year for the full calendar year.

Comment: We received several comments that proposed § 423.773(c), which requires the State to notify full-benefit dual eligible individuals that they are full subsidy eligible, should conform to proposed § 423.904(c)(3) in subpart S which requires States to notify all individuals deemed full subsidy eligible individuals of their eligibility for the full subsidy. These commenters suggested that the notice be given by July 1, 2005, for those eligible at that time, or at the time they attain eligibility for the Medicaid program that enables them to be treated as full subsidy eligible, if after July 1, 2005. Further, the commenters suggested that the notice should make clear the actions required of individuals treated as full subsidy eligible individuals, should direct individuals to information sources where they may gather additional information, counseling and assistance; and apprise individuals of appeal rights for loss of Medicaid coverage and appeal rights associated with the determination on the level of subsidy. They also suggest that we should develop model notices based on input from beneficiaries and encourage States to include a reminder in their notice letter of the need to recertify their eligibility under the applicable benefits program.

Other commenters suggest that we should modify its final rule to clarify that States will notify full-benefit dual eligible individuals and low-income Medicaid beneficiaries participating in the Medicare Savings Program that they qualify for a full subsidy under the new drug benefit. In addition, we should develop a similar notification with the SSA, or require States to coordinate with SSA, for to SSI recipients in 209(b) States and non–1634 States (that is, a non–209(b) State which requires SSI recipients to file a separate Medicaid application) since there could be SSI recipients in these States who are not receiving Medicaid and who would not appear under the States' eligibility systems.

Response: We have clarified in the final rule that we will send notices of eligibility to all deemed full subsidy eligible individuals. We believe that if we send the notices to all the individuals rather than States, it will ensure more uniformity in the content of and timeliness of the notices. Additionally, our sending the notices to individuals deemed eligible for the full subsidy will ensure we reach people States may not be able to identify, namely Medicare beneficiaries receiving SSI benefits in States where SSI does not automatically entitle a person to Medicaid. Our goal is to begin sending notices to individuals deemed to be subsidy eligible in the Spring of 2005, before the start of taking applications for individuals who are not deemed eligible for the low-income subsidy. We will ensure that the notices clarify that individuals deemed eligible for a full subsidy need not apply to receive the subsidy.

Comment: One commenter suggested that we explain how Part D plans are notified of an enrollees' eligibility for a low-income subsidy.

Response: Once a subsidy individual enrolls in a Part D plan, CMS, through a data match, will inform Part D plans that the individual qualifies for a low-income subsidy.

Comment: One State commenter remarked that the draft regulation does not specify which agency is financially responsible for sending notices to individuals deemed eligible for the full subsidy. The commenter pointed to section 1860D–14(a)(3)(B)(i) of the Act, which references funds to be appropriated to the SSA necessary for the determination of the low-income eligibility determinations. Some commenters asked if the SSA would provide an appropriation to each State to enable States to provide notices to dual eligibles as specified in the proposed rules. The commenters also wondered which entity had responsibility for explaining to full-benefit dual eligible individuals how coverage of Part D drugs in Part D plans work and how such coverage will differ from the coverage they received under the State's Medicaid program.

Response: For reasons discussed above, we have clarified in the final rule that we will send notices of eligibility to all individuals deemed full subsidy eligible individuals. This should relieve States of the financial burden of sending notices to these individuals. We will also educate Medicare beneficiaries, including full-benefit dual eligible individuals, through a variety of methods about prescription drug coverage under the new Part D benefit. (See discussion in Subpart B). However, we expect that States will have an important role in educating Medicare beneficiaries, particularly full-benefit

dual eligible individuals, about the low-income subsidy program and the new Medicare drug benefit. We also note that during Federal Fiscal Years 2005 and 2006, a total of $125 million in grants are made available under 1860D–23(d) of the Act to States with SPAPs to assist in the outreach and education of SPAP enrollees transitioning to Medicare Part D.

Comment: A few commenters suggested that proposed § 423.773(c) should be edited to replace the term ''full-benefit dual eligible'' with ''full subsidy eligible,'' where appropriate. They specifically reference the requirement on States to notify full-benefit dual eligible individuals that they are eligible for full subsidy premiums and deductible, noting that in subpart S a similar requirement is imposed on States to notify full subsidy eligible individuals. The commenters suggest that this inconsistency represents an error in the proposed rule.

Response: We agree that this inconsistency is an error. For reasons previously addressed, we have clarified the final rule to correct this inconsistency and to indicate that we (not States) will send notices to all individuals deemed to be full subsidy eligible individuals.

Comment: Some commenters suggest that SSA should screen applications to identify individuals who appear to have excess assets or income for the subsidy but who may qualify for Medicare Savings Programs in States that use more liberal eligibility rules for such programs. Alternatively, the commenters suggest SSA forward such applications to State offices or use State-specific income and asset rules to determine eligibility.

The commenters noted that by qualifying for Medicare Savings Programs, an individual will automatically be eligible for the low-income subsidy, despite the fact that if the same individual applied, he or she may not have qualified for the subsidy as a result of excess income or resources. The commenters suggest that individuals who qualify should be automatically enrolled by States in Medicare Savings Programs with an opt-out provision. Further, we should make benefit counseling available to these beneficiaries since enrollment in a Medicare Savings Program can affect the amount of assistance a beneficiary may receive through other public assistance programs. Finally, the commenters suggest that individuals who do not enroll in a Medicare Savings Program but who qualify for such a program should still be considered automatically eligible for the subsidy.

Response: We acknowledge that some individuals who apply and qualify for a Medicare Savings Program (as a QMB, SLMB, or QI) with a State's Medicaid office will be considered automatically eligible for the full subsidy, despite the fact that if the same individual applied for a low-income subsidy at the State or SSA, they may not have qualified for the full subsidy as a result of excess income or resources. This scenario is more a function of Medicaid rules permitting States to use more liberalized income and asset methodologies than a lack of uniformity for the rules of the low-income subsidy program. In those States that use more liberalized income and asset methodologies under section 1902(r)(2) of the Act for purposes of determining eligibility for Medicare Savings Programs, individuals may find it more advantageous to apply for Medicare Savings Programs rather than applying for the low-income subsidy directly with States or SSA.

We are working with SSA to design a process that will provide high-level information which does not include income or resource information but will provide the outcome of the subsidy determinations to States for purposes of identifying individuals who apply at SSA and who may also qualify for full Medicaid benefits or Medicare Savings Programs. With this process, we hope to avoid situations in which an individual applies for a low-income subsidy at an SSA office, finds out that he or she has excess income or resources to qualify for the full subsidy or even the subsidy available to other low-income subsidy eligible individuals, and remains unaware that he or she may automatically qualify for a full subsidy if the individual chooses to enroll in a State's Medicare Savings Program (as a QMB, SLMB, or QI).

Comment: We received one comment that SSA needs to use information provided from beneficiaries applying for low-income subsidies to better target the mailings that SSA is required to do under section 1144 of the Act. Commenters note that this provision requires SSA to annually identify beneficiaries potentially eligible for Medicare Savings programs, notify them about the programs, and send copies of the list of individuals identified as potentially eligible for the Medicare Savings Programs to the appropriate State agencies. In addition to using the data on income and assets for the section 1144 of the Act mailings, the commenters suggest that SSA could provide States the income and resource data for determining eligibility for Medicare Savings Program eligibles. Providing this information could reduce the burden on beneficiaries from having to submit this information twice (that is, to SSA for the low-income subsidy and to States for enrollment in Medicare Savings Programs). The commenters suggest that while privacy issues may be of concern, one option to address those concerns would be to allow applicants to consent to sharing information with their State agency to assist the State in determining whether they are eligible for Medicare Savings Programs.

Response: Again, we are working with SSA to design a process to provide subsidy determinations to States for purposes of identifying individuals who apply at SSA and who may also qualify for a Medicare Savings Program in the State. We expect that States will use the determination to contact individuals who may qualify and to assist them in the application process. As the commenter suggests, SSA is unable to provide income and resource information directly to States for privacy reasons. Therefore, the information provided to States will be limited to high-level information on the outcome of the subsidy determination.

Comment: Some State commenters noted that States lack a practical way to determine whether applicants have also applied for the low-income subsidy through SSA. They note that if SSA and States make separate determinations that do not agree some form of reconciliation will be needed. They further note that this need for reconciliation will further complicate processing and add to administrative burden and costs.

Other commenters requested clarification on the data exchange process. The commenters assert that they cannot envision a data exchange process that would be fast enough to prevent an applicant from receiving a denial from SSA and subsequently applying at the State office. They noted that this could result in duplicative work for the State and SSA. The commenters ask that the rule be clarified for this coordination.

Response: We agree that it will be important to design a process in which States can determine if an individual has already filed an application with SSA, and vice versa. We expect to provide further information on this process through operational guidance. We also note that, based on comments, we have clarified in the final rule that multiple applications will not be permitted in cases where an individual has received a positive determination from either SSA or the State. In other words, an individual may not file a second application for the remainder of the eligibility period with the alternate

agency if he or she has received a positive determination from the State or SSA. This requirement is not intended to preclude an individual from reporting subsidy changing events in accordance with the determining agency's rules, but rather to prevent confusion that could arise if a State and SSA process determinations for the same individual.

3. Eligibility Determinations, Redeterminations and Applications (§ 423.774)

In accordance with section 1860D–14(a)(3)(B)(i) of the Act, an application for subsidy assistance may be filed with either a State's Medicaid program office or SSA. Inquiries made by individuals to Part D plans concerning application or eligibility for the low-income subsidy should be referred to State agencies or SSA. Eligibility determinations would then be made by the State for applications filed with the State Medicaid agency or by the Commissioner of Social Security for those filed with SSA.

While our goal is to provide a single application and determination process for the low-income subsidy, we recognize that the statute provides that redeterminations and appeals of eligibility determinations are to be made in the same manner as for medical assistance for those individuals who are determined eligible by the State Medicaid agency. Similarly, the Commissioner will decide how to conduct redeterminations and appeals for those subsidy determinations made by Social Security.

In the proposed rule we noted that eligibility determinations for low-income subsidies would be effective beginning with the first day of the month in which the individual applies for a subsidy, but no earlier than January 1, 2006, provided the applicant meets the requirements for eligibility when he or she applies and has enrolled with a Part D plan . Initial eligibility determinations would remain in effect for a period not to exceed 1 year, beginning no earlier than January 1, 2006.

Because States and Social Security offices will be performing subsidy determinations, States and SSA would need to share data with us. We would then use the data to notify the Part D plan in which the individual is enrolled of the individual's eligibility for the low-income subsidy. We would also use the data to provide information on the individual's income bracket so that Part D plans may identify the cost-sharing amounts and, in the case of other subsidy eligible individuals, the monthly beneficiary premiums that may be charged to a subsidy eligible individual as discussed later in this subpart of the preamble.

Section 1860D–14(a)(3)(E)(ii) of the Act directs the Secretary and the Commissioner of SSA to develop a model simplified application form for the determination and verification of Part D eligible individual's assets or resources. We believe it is important to develop a simplified application for income as well as resources and to develop an application that will address both the full and the other low-income subsidy provisions. Therefore, we have been working with SSA to develop a model application form to be used to determine eligibility for all subsidies. The application will reflect the definitions of income and resources discussed earlier in this subpart.

For the method and degree to which income and resources will be verified, our general policy is to not spend more on verification than the expected return in terms of benefit savings to the Medicare program from such verification. Therefore, as stated in the proprosed rule, we intend to use the most efficient and cost-effective process that will balance the need for program integrity with the goal of reducing the paperwork burden and cost.

We envisioned a process based on an operations research strategy whereby States and SSA would build on existing verification processes used for other programs. We planned on maximizing the use of automated data matches for verification of income and certain liquid resources (which minimize both paperwork burden and cost), and relying on specific targeting or profiling criteria derived from a database that would identify a subset of applications for purposes of in-depth verification. This in-depth verification process would enable SSA and States to focus on elements attested to by the applicant that do not lend themselves to verification by electronic means (that is, countable real estate). By developing a targeted approach, we believed we could strike an appropriate balance between administrative costs and program goals and objectives. We requested comments on this approach.

In developing a simplified application, we also considered a number of other issues in order to streamline the application process. For example, the proposed rule permits a personal representative to assist in the application process. We proposed to define personal representative as an individual who is authorized to act on behalf of the applicant, an individual acting responsibly on behalf of an applicant who is incapacitated or incompetent, or an individual of the applicant's choice who is requested by the applicant to act as his or her representative in the application process.

In addition, we would permit the use of a proxy signature process to allow applications to be taken over the phone or by an Internet process. Under a proxy signature process, an individual attests to the accuracy of the information provided under penalty of perjury prior to submitting the information for processing. Our proposed requirements specify that the individual applying for the low-income subsidy, or a personal representative on his or her behalf complete the application for the low-income subsidy, and certify as to the accuracy of the information provided. Section 1860D–14(a)(3)(E)(iii)(II) of the Act provides that statements from financial institutions shall accompany applications in support of the information provided therein. We believe States and SSA will be able to verify information through data matches with other sources that will substantially eliminate the need for the beneficiaries to bring statements from financial institutions with them when they apply.

As a result, we would reduce an applicant's burden in producing financial statements by not requiring paper copies except when specifically requested. For example, SSA and States may verify some resources for the low-income subsidy through data matches with 1099 files from the IRS, which show the annual amount of interest earned on interest bearing accounts. If the data from the 1099 files indicate the applicant's interest is below a threshold amount relating to the resource limit and the applicant has no countable real estate, the State or SSA could decide that no further information is needed from the applicant relating to certain types of resources. When the threshold is exceeded, additional information may be requested of the individual to support the application. Use of this process would ease the burden on individuals preparing to file an application and will reduce the administrative burden on States and SSA in handling paper verification. Accordingly, § 423.774(d) required the submission of statements from financial institutions only if requested by the State or SSA.

Comment: Some commenters suggested that the regulations should specify that a determination notice be sent to the applicant no later than 30 days after the application is filed. Additionally, they suggested that SSA and States should be required to notify

CMS within 24 hours of an individual being determined eligible for the subsidy. Other commenters questioned whether the State Medicaid agency is required to complete determinations within 45 days as is required for most Medicaid eligibility determinations under § 435.911. These commenters argue that the regulations should specify a time standard that would apply to determinations made by either the State or SSA.

Response: We do not have authority to direct SSA to determine subsidy eligibility within a given time period, and have decided not to impose a specified period on States through regulation. Instead, we will provide operational guidance to States, monitor the time period for determining subsidy eligibility, and take action as appropriate. As general guidance, we expect that States will determine subsidy eligibility within time periods that are at least consistent with the processing of State Medicaid applications.

Comment: Some commenters suggested that in order to avoid delays in beneficiaries being able to use their subsidy benefits while their application is pending, the final rule should offer beneficiaries the option of applying through a presumptive eligibility system. Commenters suggested that the system could be designed in a manner whereby an applicant can complete a form at a provider's office or other location where they declare their family size, income and assets. If the individual's income and resources are below the eligibility levels, they could be found presumptively eligible. The individual could then have the obligation placed on him or her to fill out the complete application within a prescribed period of time. The commenters argue that such a system would encourage beneficiaries to apply since they would see the benefits of the system.

Response: We appreciate that it is important for subsidy determinations to be made as quickly as possible so that individuals will be able to receive extra help with the payment of cost sharing and premiums when enrolled in a Part D plan. We are working with States and SSA on an outreach strategy to try to encourage individuals potentially eligible for the low-income subsidy to apply for the subsidy as early as possible, starting July 1, 2005. Under this outreach strategy, we will encourage individuals to apply and ''pre-qualify'' for the low-income subsidy before enrolling in a Part D plan so that they will know ahead of time whether or not they are eligible for extra assistance with the payment of premiums and cost sharing. However, the subsidy will not be effective until the start of the program when the individual is actually enrolled in a Part D plan.

At this time, we decline to implement a presumptive eligibility process for individuals not deemed to be subsidy eligible individuals. We believe our streamlined process that relies on self-attestation of the information on the application with such verification as SSA or the States determine is appropriate will ensure that individuals quickly receive subsidy determinations from SSA or States, so that they can get the extra help they need. It is worth noting that the simplified application being developed in consultation with SSA will be available on the Internet and will be available to providers if they choose to offer them at their locations. In addition, it is important to note that individuals do not need to apply at State offices or SSA field offices in person. They may apply over the phone via SSA's 1–800 number, they may send applications via the mail or over the internet, and they may have individuals assist them in completing the applications on their behalf.

Comment: Some commenters suggest that we clarify whether individuals who currently receive benefits as a full-benefit dual eligible individual, SSI recipient or under the Medicare Savings Program (as a QMB, SLMB, or QI) are required to undergo a separate and new eligibility determination in order to qualify as a full subsidy eligible individual. The commenters suggested that these individuals should be required to recertify their eligibility under these programs in accordance with existing requirements pertaining to recertification or redetermination.

Response: Individuals who currently receive benefits as a full-benefit dual eligible, SSI recipient or under the Medicare Savings Program are not required to undergo a separate eligibility determination in order to qualify as a full subsidy eligible. They are ''deemed'' or treated as full subsidy eligible individuals without having to complete a separate application. We have clarified this in the final rule at § 423.773(c).

As part of our yearly notice to deemed subsidy eligibiles, we will explain that the loss of Medicaid near the end of the calendar year could impact an individual's status as a full subsidy eligible individual in the next year. Thus if someone loses Medicaid and does not regain eligibility during a year, he or she will retain subsidy eligibility during the remainder of the calendar year, but will no longer be automatically deemed for the full subsidy in the next calendar year.

Comment: Some commenters would like us to better define eligibility determination periods for the low-income subsidy. The commenters suggest that the eligibility determination should be defined as one year. Further, it should not be associated with either a State Medicaid program redetermination or an SSA redetermination.

Another commenter suggested that we should interpret the ''month of application'' for a low-income subsidy individual to mean the first day of the month a Part D plan is notified by us of the individual's eligibility for the low-income subsidy. Alternatively, the commenter suggests that the application processing timeframes be developed and implemented in such a way as to avoid administrative burden and beneficiary confusion. For example, we should specify that the application processing timeframes would start beginning with the month in which the State agency received a ''complete'' application. The commenter asserts that incomplete applications must be rendered ''complete'' or rejected within 30 days. Further, complete applications should be processed no later than 30 days from the date the application was rendered complete, meaning Part D plans should be notified within 30 days of the date the application was rendered complete that an individual is eligible for a low-income subsidy. Once notified, these individuals would be moved into the appropriate internal plan and cost-sharing would be appropriately reflected for that individual sooner rather than later.

Response: We do not have the authority to accept the first commenters' suggestion. Under section 1860D–14(a)(3)(B)(ii) of the Act, the statute, initial determinations for individuals who apply for the subsidy are effective beginning with the month the individual applies, but no earlier than January 1, 2006. These initial determinations shall remain in effect for a period specified by the Secretary, but not to exceed one year, regardless of whether the determination is made by a State or SSA. Redeterminations of eligibility for those applications processed by States are to be made in accordance with the frequency and manner in which the State makes Medicaid redeterminations, which must be conducted at least annually. Redeterminations made by SSA may be of a frequency determined by the Commissioner.

We will address the issue associated with the completeness and timeframe

for processing an application through operational guidance. It is important to note that we do not have authority to direct SSA to determine subsidy eligibility within a given time period, and we have decided not to impose a specified period on States through codification.

Comment: Some commenters question whether retroactive eligibility will be allowed for full-benefit dual eligible individuals. They suggest that the regulations be clarified for that possibility.

Response: Retroactive eligibility for the low-income subsidy is only an issue if a full-benefit dual eligible individual is already enrolled in a Part D plan. For instance, if a person is enrolled in a Part D plan and decides not to apply for the subsidy, he or she may have retroactive subsidy eligibility if the individual later qualifies for Medicaid. By extension of being entitled to full benefits under Medicaid, the individual will automatically be eligible for the low-income subsidy. In this case, subsidy eligibility will extend back to the start date of Medicaid eligibility, which could be up to three months earlier if the individual would have qualified for Medicaid during the three month retroactive period. As such, the individual will be reimbursed by the plan for any extra cost sharing he or she otherwise would not have paid as a full subsidy eligible individual. This would also apply to individuals eligible under a Medicare Savings Program as a SLMB or a QI(but not as QMB, because QMBs cannot receive retroactive benefits under Medicaid statute). For QMBs and other, non-dual eligible individuals who are enrolled in a Part D plan, and later apply and are determined eligible for low income subsidy assistance, their eligibility, consistent with the statute, would be effective on the first day of the month in which they applied for the low income subsidy.

Comment: One commenter indicated that the proposed regulations do not address whether eligibility determinations in one State are transferable to another State. The commenter also noted that there is no discussion of the transfer of information between the State agency and SSA, or the transfer of information between States.

Response: If the eligibility determination for an individual not deemed to be a full subsidy eligible individual was processed by SSA, then SSA ''owns'' the beneficiary for redeterminations and appeals. Since SSA is a national agency applying uniform national standards, redeterminations and appeals will be processed even if a beneficiary moves between States. However, if the beneficiary no longer resides in a State and the State processed the subsidy determination under its own system, the State can no longer reasonably be expected to be held liable for the subsidy redeterminations and appeals, consistent with the manner and frequency a State would redetermine eligibility under Medicaid. The beneficiary in this instance would need to apply in the new State of residence, or could apply with SSA unless otherwise deemed eligible for the full subsidy.

Comment: Several commenters question whether changes in circumstances, such as increases or decreases in income, need to be reported by the beneficiary.

Response: For individuals who apply for the low-income subsidy, changes in financial circumstances that could impact the individual's eligibility for the low-income subsidy should be reported to the agency that processed the subsidy application in accordance with that agency's rules.

SSA will be publishing rules regarding subsidy changing events that could impact low-income subsidy eligibility. For individuals who are deemed eligible for the full subsidy, changes in circumstances that would impact eligibility for Medicaid or SSA should be reported as required under those programs. However, it is important to note that, for administrative ease, we will deem individuals as subsidy eligible for a period not to exceed one year, even if changes in circumstances may cause someone to lose Medicaid or SSI for a period of time. If the person is no longer eligible for Medicaid or SSI after the period of deemed subsidy eligibility, he or she will no longer be automatically eligible for the low-income subsidy and must apply in order to continue receiving the benefit.

Comment: One commenter believes that we should provide prompt identification of an individual's institutional status for the purpose of overriding the cost sharing at the point of sale.

Response: States will be providing information on a full-benefit dual eligible individual's institutional status on a monthly basis to us. We will provide this information to Part D plans. We will address through operational guidance how plans should address situations in which an enrollee's institutional status is different than the information provided to them from us.

Comment: One commenter makes an argument that the statute permits SSA to contract with SPAPs to make determinations of eligibility for financial assistance in accordance with SSA's procedures. In addition, the commenter argues that there is no legal impediment to a State's designation of its SPAP as the State enrollment agency, so long as eligibility determinations and redeterminations are made in the same manner as for Medicaid recipients. The commenters assert there is precedent for this practice. One commenter said that we should ensure that any arrangements with SPAPs to make eligibility determinations are considered for Federal matching funds. Finally, the commenters suggest that SPAPs have direct on-line access to on-line reporting systems to facilitate the SPAP's ability to determine a person's eligibility for the low-income subsidy. They suggest that we clarify in the final regulations and in guidance that State Medicaid programs have the option to permit SPAPS to make initial eligibility determination and redeterminations for subsidies for low-income persons who apply for benefits through an SPAP.

Response: By statute, eligibility for the low-income subsidy program must be determined by the State Medicaid agency or the Social Security Administration. While it cannot be the entity ultimately responsible for determining eligibility, SPAPs can serve as an intake point for low-income subsidy applications. SPAP offices will be able to access the SSA application from the Internet in order to assist individuals in applying for a subsidy. We also note that entities other than SPAPs, including community organizations and other non-Medicaid State offices, can provide assistance to individuals in completing the SSA application.

Comment: Some commenters note that the enrollment process for Part D plans is separate from the application process for the low-income subsidy. They note that there is no mechanism in the proposed rule to permit a beneficiary to apply for the low-income subsidy at the time of enrollment in a Part D plan. They also note that Part D plans are not required to inform beneficiaries that a subsidy may be available to them. They suggest that SPAPs should be allowed to make determinations and redeterminations of subsidy eligibility in order to facilitate applications for SPAP enrollees.

Response: Again, while SPAPs may serve as an intake point for low-income subsidy applications the State Medicaid agency or the Social Security Administration retains ultimately responsible for eligibility determinations. For the comment that

Part D plans are not required to inform beneficiaries that a subsidy may be available, we agree. However, we believe many Part D plans will encourage their enrollees to apply if they indicate they are low-income and need extra assistance with premiums and cost sharing. We also encourage SPAPs to inform their members of the availability of the low-income subsidy to provide extra assistance with premiums and cost sharing under Medicare Part D, and to assist their members in completing the SSA application.

Comment: Many State commenters suggest that States should be allowed to meet their statutory obligation for the low-income subsidy by receiving applications and passing them to SSA for the determination process. They assert that use by States of a streamlined low-income subsidy application process through SSA would reduce the burden on States of doing separate determinations. They also suggest that the process include use of web-based applications accessed with Federally funded computers at Medicaid eligibility sites, paper applications that are batched and sent to SSA by the eligibility sites, and phone applications conducted directly with SSA. Another commenter suggested that States that only collect applications and forward them to SSA should not be responsible for redeterminations and appeals for these applications. This commenter also believes these States should not be responsible for screening applications for Medicare buy-in programs.

A few State commenters also assert that we have made contradictory statements with regard to the role of SSA and States in taking applications for the low-income subsidy. They indicate that we have issued guidance that States could batch up applications and ship them to SSA for processing, and that SSA would make the determinations, send the notifications, and conduct the appeals for the low-income subsidy program. However, the commenters point out that the regulations in § 423.774 and § 423.904(a), and the statute at section 1935 of the Act, direct States to make eligibility determinations and redeterminations for low-income premium and subsidies.

Finally, several State commenters seek clarification on whether States could be required to perform administrative functions such as providing personnel resources for answering questions and assisting applicants, making determinations and redeterminations, making systems changes to record determinations and redeterminations made by the State, printing applications, conducting appeals, sending notices to clients, coordinating with financial institutions for verification and developing and sending reports to us.

Response: The statute clearly sets forth the requirement that eligibility for the low-income subsidy program will be determined by either State Medicaid agencies or by the Social Security Administration. As such, States must have the ability to determine eligibility if someone requests a ''State'' subsidy determination. As part of this obligation, States are required to send notices of subsidy determinations, process redeterminations, and handle appeals.

We encourage States to consider using the SSA application form and process as their default process for processing low-income subsidy applications. Under this process, States would assist individuals who agree to complete an SSA application. Once completed, States would submit the applications to SSA for processing. While States would still have to develop a process to determine eligibility for an individual who specifically requests a ''State'' determination as opposed to an ''SSA'' determination, States could offer the SSA low-income subsidy application process to individuals in order to reduce the administrative burden associated with sending notices, processing appeals and redeterminations, and verifying information reported on subsidy eligibility applications. Again, States should be mindful that the statute does not permit States to refuse to accept and act on subsidy eligibility applications if the applicants insist on having them treated as applications with the State agency.

We will be working with SSA to provide operational guidance to States on how they may utilize the SSA process for those applicants who agree to use the SSA application. The SSA process includes an internet-based application that may also be accessed in paper form. Under this process, individuals need not apply in person with the SSA or States; however, if they do apply in person at a State office, the State would be obligated to assist individuals in completing the application and to screen individuals for Medicare Savings Program eligibility.

Comment: Some State commenters expressed concern that, should the States process determinations, redeterminations, and appeals, as well as SSA, it is not possible to create equal systems for clients, resulting in two competing processes in an already complex system. They note that in some States, beneficiaries have limited access to field offices compared to State offices. They also argue that, even if the State follows the Federal guidelines, it does not seem likely that a beneficiary following the State process will experience the same procedure as a client using the SSA process. The commenters ask for reconsideration of this issue, or alternatively, clarification about how continuity would be assured.

Response: For individuals who apply for the subsidy, one notable area of inconsistency could be the timing and manner of redeterminations of subsidy eligibility. This process, by statute, is dependent on which entity processed the application. If SSA processed the application, SSA will determine the manner and frequency of the redeterminations. If a State processed the application through its own subsidy eligibility determination system, the manner and frequency of the redetermination will be consistent with how the State redetermines eligibility for Medicaid. For individuals deemed eligible for the full subsidy, the redetermination process will be based on the underlying program that automatically qualified the individual for the subsidy, for example, Medicaid or SSI.

Comment: Some State commenters indicated that they did not believe States would be able to achieve the degree of automation at the start of the program as envisioned by CMS in the preamble of the proposed rule for purposes of verifying an applicants' income and resources. They also noted that existing State eligibility systems are not easily modified or adapted without considerable State expense. Finally, a few commenters suggested that the regulation implies that States may be able to access other agencies' databases to verify income and resources. The commenters suggest that such databases be listed or otherwise specified.

Response: We recognize that existing State eligibility systems are not easily modified or adapted without considerable State expense; however, the law is clear that States must be able to determine low-income subsidy eligibility. States therefore need to develop a process to support the determinations when specifically requested of them.

We strongly recommend that States consider using the SSA application as their default application for processing low-income subsidy applications and encourage States to assist applicants in filing their applications with SSA. While States would still have to develop a process to determine eligibility for an

individual who requests a ''State'' determination as opposed to an ''SSA'' determination, States may use the SSA low-income subsidy application and process in order to reduce the administrative burden associated with sending notices, processing appeals and redeterminations, and verifying information reported on subsidy applications. States could focus most of their attention on assisting individual with completing the SSA application, and screening and enrolling individuals in the Medicare Savings Program.

Comment: One commenter asks that we keep the period of comment on the proposed rule open until comments are due on the SSA's regulation.

Response: We cannot keep the comment period open on this proposed rule until the comments are due on the SSA regulation regarding low-income subsidy determinations. We are working closely with SSA during the regulations process to ensure consistent rules regarding low-income subsidy are put in place by both agencies.

Comment: Since generally only 50 percent Federal financial participation (FFP) is provided for the State's role in the administration of the low-income subsidy program, several State commenters asserted that the cost associated with administration of the Medicare program could prohibit the provision of other State services. States noted that they would have to use a significant amount of resources from their general fund and asked us to consider reducing the State's responsibilities due of the lack of funding for the costs associated with implementation of the low-income subsidy program. The State commenters suggest that FFP associated with the State role in this program should be derived from a cost allocation methodology that attributes 100 percent to the Medicare program.

Response: While we sympathize with the commenters' concerns, we do not have the authority to change the Federal financial participation rate available to States. The statute specifies that States are to be reimbursed according to the normal Federal match for administrative costs, which is generally 50 percent.

Comment: A few commenters expressed concern that the eligibility process for the low-income subsidy is different than the process the State uses to determine eligibility for Medicaid. The commenter indicated that by having different methodologies, States will be more error prone in making determinations. The commenters also noted that they would incur programming costs and additional staff training to incorporate this new method, and suggested that Federal financial participation be increased to 100 percent to account for these costs.

Response: The process for determining eligibility for the low-income subsidy is based on statutory provisions that specifically preclude States and SSA from using the more liberalized methodologies permitted under Medicaid for purposes of counting income. For counting resources, we acknowledge in the proposed rule that we could have permitted States to use the same resources standards that States employ under Medicaid for purposes of determining eligibility for Medicare Savings Programs, if such standards would not significantly increase the numbers of individuals who are eligible for the low-income subsidy. However, as we noted in the preamble to the proposed rule, we elected not to exercise this discretion since, as we noted in responses to previous comments, we believe national uniformity for purposes of eligibility determinations is a desirable goal.

For the suggestion that the Federal financial participation rate should be 100 percent, we note that we do not have the authority to change the Federal financial participation rate available to States. The statute specifies that States are to be reimbursed according to the normal Federal match for administrative costs, which is generally 50 percent.

Comment: Some commenters believe that it is unclear whether the Federal government will require subsidy applicants to show proof of Medicare enrollment in order to apply for the subsidy. If not, the commenters expect that States will have coordination problems, as they are reliant on periodic, and not real-time, data matches to assess Medicare enrollment.

Response: We are exploring options for States to verify Medicare eligibility if the applicant cannot provide proof.

Comment: Some commenters suggested that low-income subsidy applicants, no matter where they apply, should have the opportunity to be considered for full Medicaid eligibility. They suggest that the simplified application form should include an option for persons to have their application reviewed for Medicaid eligibility.

Response: The statute specifies that, in addition to determining eligibility for the low-income subsidy, States are directed to screen for eligibility for medical assistance programs for the payment of Medicare cost sharing, and to offer enrollment to eligible individuals for such programs. As a practical matter, we believe States will identify individuals with limited income and resources who may qualify for full Medicaid benefits as part of this process. In addition, it is important to emphasize that we are working with SSA to design a process to provide subsidy eligibility determinations to States for purposes of identifying individuals who apply at SSA and who may also qualify for a Medicare Savings Program in the State. We expect that States will use this information to contact individuals who may qualify for assistance with Medicare cost sharing and to assist them in the application process for the Medicare Savings Programs.

Comment: Some commenters suggest that the verification process for information provided on low-income subsidy applications should not impose an undue burden on applicants. They argue that the need to provide documentation of income and assets is one of the most significant barriers to enrollment in Medicare Savings Programs. They suggest that States should have access to SSA's automated systems to verify financial eligibility information for the low-income subsidy program. Further, States should only be permitted to ask for one bank statement and only in such cases where an applicant refuses to sign an authorization form to permit the eligibility worker to obtain the information directly from the financial institution. Some commenters also suggest that documentation should be produced as a last possible resort.

Response: Individuals will not have to bring volumes of information with them when they apply using the SSA application process. The simplified application developed by SSA, in consultation with CMS, is based on the principle of self-attestation. While some information may be requested from applicants on an exception basis, based on responses to certain questions or based on inconsistencies from electronic data matches, the majority of applicants will not need to provide additional information beyond what is submitted and attested to in the application form.

As we have indicated in other responses, we recommend that States encourage and assist applicants in applying for the low-income subsidy using the SSA application (that is, assist applicants in completing the SSA application and forward it to the SSA to make the determination). In such cases, SSA would verify income and resources for the low-income subsidy utilizing its automated systems. For individuals who prefer a ''State'' rather than ''SSA'' determination, we encourage States to use an application form similar to the

one utilized by SSA and also to find ways to streamline the verification process by utilizing electronic data matches to the greatest degree possible. However, we recognize that States may not be able to achieve the same verification process utilized by SSA. This may encourage some applicants to apply using the SSA process rather than the State process.

Comment: Some commenters encourage CMS and SSA to retain the strategy to devise a uniform application that reflects uniform eligibility requirements. The commenters suggest that the application be designed to serve as the Medicare Savings Program application and full Medicaid application as well. The commenters also suggest that the combined form should reflect our proposed definition of countable assets in § 443.772 and be at least as streamlined as the model Medicare Savings Program application adopted by CMS and States. The commenters assert that the draft SSA application includes questions on life insurance, burial accounts, in-kind support and maintenance, and transfers of assets that do not appear on the model Medicare Savings Program application.

Response: While nothing prevents a State from developing a special addendum to the low-income subsidy application to address questions specific to Medicaid or Medicare Savings Programs eligibility, the application for the low-income subsidy program must reflect the definition of countable income and resources outlined in this final rule. For reasons we have previously explained, the definition of income and resources used for purposes of the low-income subsidy program could vary from the definitions used by State Medicaid programs for purposes of determining eligibility for full Medicaid or for programs that provide assistance with Medicare cost sharing. Some States may use more liberalized methodologies than the basic SSI statutory rules for counting income and resources, on which the low-income subsidy application is based. For these reasons, questions on life insurance, burial accounts, and in-kind support and maintenance need to be clearly articulated in the application in order to determine income and resources for the low-income subsidy. Questions regarding transfers of assets for less than fair market value will not be included on the application as we do not believe that penalties associated with such transfers are appropriate when counting resources for the low-income subsidy.

Comment: A few commenters suggest that § 423.774 be strengthened and revised to ensure that eligible older adults and persons with disabilities remain enrolled in the low-income subsidy from year to year. They suggest that we rewrite the final rule to define the eligibility period as one year, regardless of which entity made the determination. They argue that the statute and Congressional intent support an interpretation giving the Secretary of HHS the authority to determine the term of the eligibility determination period and the Commissioner and the States the authority to determine the manner in which redetermination or appeals are made. They argue that redeterminations in this context are meant to convey reconsiderations, not renewals of eligibility. Commenters further suggest the Secretary use his discretion to establish an annual, passive reenrollment process that would apply regardless of whether the initial determination was made under a State Medicaid plan or by the Commissioner of SSA. They suggest that the process should entail the use of a pre-printed renewal post-card with instructions to return the card only if there are corrections about eligibility status.

Response: We do not agree that we have the discretion outlined by the commenter. Consistent with the statute, the proposed and final regulations state that the initial determination is effective for up to a year. Thereafter, the timing of redeterminations of eligibility depends on which entity processed the application. If SSA processed the application, SSA will determine the manner and frequency of the redetermination. If a State processed the application under its own subsidy eligibility determination system, the manner and frequency of a redetermination will be consistent with how the State redetermines eligibility for Medicaid.

Comment: One commenter questioned whether the proxy signature process discussed in the preamble meant that we are relaxing its requirement for signatures on applications.

Another commenter suggested that the regulation clearly set limits as to how telephonic proxy designations are made and acted upon. Also, proxy certification should only apply to the accuracy of the proxy's transcription, and not to the accuracy of the underlying information.

Response: Under a proxy signature process, an applicant verbally attests under penalty of perjury that the information provided in an application is correct and valid. As specified in the preamble to the proposed rule, we permit the use of proxy signatures for the low-income subsidy application. SSA plans to use a proxy signature for the application it is developing to allow individuals to attest to their income and resources when applying over the telephone and Internet. If States develop their own application, we encourage them to consider a similar signature proxy process. We do not agree that we need to provide further specificity in the regulation on this issue. This process does not alter our position on requirements for signatures in any other contexts.

Comment: Some commenters suggest that the Commissioner of SSA should handle all appeals in order to ensure uniformity in the appeals process. One commenter suggested that requiring the States to handle Medicare appeals would require an investment in additional staff and resources and represent an unfair burden on States because only one-half the costs would be covered by the Federal government. Another commenter recommends that the redetermination and appeals process be consistent among SSA and Medicaid agencies to eliminate confusion among applicants.

A few other commenters request clarification in the final rule as to whether fair hearing rights under State Medicaid programs apply to adverse eligibility or renewal decisions made by the State. Similarly, they request clarification as to whether decisions made by the State or SSA to reduce or terminate a subsidy upon renewal triggers continued coverage at the pre-reduction levels pending the appeal. One commenter argued that this right derives from Supreme Court precedent which established the absolute right to a pre-determination hearing pending the loss of welfare of Medicaid benefits.

Response: Appeals of subsidy eligibility determinations will be handled by the entity that made the underlying decision. If SSA processed the initial application or redetermination, SSA will handle the appeal based on procedures established by the Commissioner. If a State processed the application or redetermination, the appeal will be consistent with the process the State uses for appeals under Medicaid. Consistent with the statute, States will receive normal administrative match for activities associated with appeals of eligibility for the low-income subsidy.

For the question of continued coverage, we agree with the commenter that decisions made by the State or SSA to reduce or terminate a subsidy would trigger a right to continued coverage at the pre-reduction levels pending the appeal. This is based on the fact that the subsidy program, unlike the Medicare

drug benefit itself, is a needs-based program. This is also consistent with how States process appeals under Medicaid.

Comment: Some commenters assert that there should be a provision for prompt reconsideration of a subsidy eligibility determination for beneficiaries who believe that they have been erroneously denied eligibility or approved for the wrong subsidy category.

Other commenters suggest that we need to clarify that all aspects of subsidy determinations, including eligibility, calculation of subsidy or copayment categories, the premium subsidy amount, or the amount of any late enrollment penalty, are subject to appeal.

Response: As indicated earlier, subsidy eligibility determinations or appeals are acted upon by the entity that made the underlying decision. We will be implementing operational guidance regarding when someone does not agree with the premium subsidy amount or late enrollment penalty.

4. Premium Subsidy (§ 423.780) and Cost-Sharing Subsidy (§ 423.782)

In accordance with section 1860D–14 of the Act, the proposed regulations specified the Part D premium subsidy and the Part D cost-sharing subsidy amounts available to subsidy eligible individuals, with the specific subsidy amounts varying depending upon the individual's income and resources/assets level.

a. Full Subsidy Eligible Individuals

In accordance with section 1860D–14(a)(1)(A) of the Act, full subsidy eligible individuals are entitled to a full premium subsidy equal to 100 percent of the ''premium subsidy amount,'' not to exceed the monthly beneficiary premium for a Part D plan (other than an MA-PD plan) offering basic prescription drug coverage, that portion of the monthly beneficiary premium attributable to basic prescription drug coverage for a Part D plan (other than an MA-PD plan) offering enhanced alternative coverage, or the MA monthly prescription drug beneficiary premium (as defined in section 1854(b)(2)(B) of the Act) for a MA-PD plan selected by the beneficiary.

Under section 1860D–14(b)(2) of the Act, the premium subsidy amount for a PDP region is equal to the greater of the low-income benchmark premium or the lowest monthly beneficiary premium for a prescription drug plan that offers basic prescription drug coverage in the region. Further, under section 1860D–14(b)(2) of the Act, the low-income benchmark premium amount for a PDP region equals either the weighted average of the monthly beneficiary premiums for all basic prescription drug plans (if all prescription drug plans in the PDP region are offered by the same PDP sponsor), or if the PDPs in the region are offered by more than one PDP sponsor, the weighted average of (i) the monthly beneficiary premiums for all PDPs in the region (including any fallback plans) consisting of basic prescription drug coverage, (ii) the monthly beneficiary premiums attributable to basic prescription drug coverage for all PDPs in the region offering alternative prescription drug coverage, and (iii) the MA monthly prescription drug beneficiary premium for MA-PD plans. Because section 1860D–14(b)(2)(A)(ii) of the Act references section 1851(a)(2)(a)(i) of the Act, the premiums of cost plans under section 1876 of the Act, PACE plans, and private fee-for-service plans are excluded for purposes of determining the weighted average in the region. This is because section 1851(a)(2)(a)(i) of the Act refers only to MA coordinated care plans.

Table P–I below is an illustration of the premium subsidy determination.

TABLE P–1
DETERMINATION OF THE PREMIUM SUBSIDY AMOUNT

Plan Options in Region		Low-Income Premium Subsidy (Full)		
Plans	Monthly Beneficiary Premium 1	Percentage of Part D enrollees in each plan 2	Premium times Percentage (weighted average)	Maximum Premium Subsidy for Eligible Individual Enrolling in Plan
PDP 1 Offered by Sponsor A	40.00	15%	6.00	36.00
MA-PD Plan 1	38.00	5%	1.90	36.00
PDP 2 Offered by Sponsor B	36.00	40%	14.40	36.00
MA-PD Plan 2	20.00	15%	3.00	20.00
MA-PD Plan 3	0.00	25%	0.00	0.00
Weighted Average Basic Premium in Region =			25.30	
The greater of the Low Income Premium Benchmark Amount (25.30) or the lowest PDP premium in the region (36.00) equals 36.00, so the maximum premium subsidy is the lower of 36.00 or the actual plan premium for basic coverage.				
1 Assumes no supplemental premium or late enrollment penalties, and for MA-PD plans, any reduction in premium due to application of a credit against the premium of a rebate under 42 CFR 422.266(b).				
2 Assumes enrollment weights from the prior year's reference month (not first year of program)				

Table P–1 illustrates the determination of the premium subsidy amount in a hypothetical region in which there are 2 PDPs, each offered by different sponsors, and 3 MA-PD plans. Because there are PDPs offered by more than one sponsor, the maximum premium subsidy amount is the greater of 2 amounts: the low-income premium benchmark amount or the lowest PDP premium in the region. The former is calculated by summing the products of the plan monthly beneficiary premium for basic prescription drug coverage and the plan percentage of Part D enrollment in the region, and equals $25.30. The lowest monthly beneficiary premium for a PDP in the region, however, is $36.00. Therefore, in this exhibit, the full monthly premium subsidy amount for the region is determined to be $36.00. Consequently, a full subsidy eligible individual would have a choice of 3 zero-premium plans in which to enroll

(PDP 2, MA-PD plan 2, and MA-PD plan 3), because the maximum premium subsidy amount equals or exceeds the monthly beneficiary premiums for these plans. However, if a full subsidy eligible individual chose to enroll in PDP 1 or MA-PD plan 1 , he or she would be obligated to pay the difference between the plan premium and the premium subsidy amount ($4 or $2, respectively) each month.

We also stated in the proposed rule that fallback plan premiums would be treated the same as those for risk-bid plans in the calculation of the low-income benchmark premium amount.

In accordance with section 1860D–14(b)(2) of the Act, the low-income benchmark premium amounts are determined without the addition of any amounts attributable to late enrollment penalties.

Individuals eligible for the full premium subsidy who are subject to late enrollment penalties under proposed § 423.46 would also be entitled to an additional subsidy equal to 80 percent of any late enrollment penalty for the first 60 months in which the penalties are imposed, and 100 percent of any penalties in any subsequent month, in accordance with section 1860D–14(a)(1)(A)(ii) of the Act and proposed § 423.780(c).

Section 423.782 of the proposed rule incorporates the provisions of sections 1860D–14(a)(1)(B), 1860D–14(a)(1)(C), 1860D–14(a)(1)(D), and 1860D–14(a)(1)(E) of the Act relating to the elimination of the deductible, continuation of coverage above the initial coverage limit (that is, no coverage gap), and reductions in cost-sharing. Specifically, full subsidy eligible individuals have no deductible. In addition, these individuals have continuation of coverage from the initial coverage limit (under paragraph (3) of section 1860D–2(b) of the Act and § 423.104(d)(5)) through the out-of-pocket threshold (under paragraph (5) of the same section and § 423.104(d)(5)(iii)). In other words, there is no coverage gap, for these individuals and Medicare pays for the full benefit once the catastrophic level is reached. In addition, the cost-sharing subsidies paid by CMS under this subpart will count toward the application of the out-of-pocket threshold.

In accordance with section 1860D–14(a)(1)(D)(i) of the Act, institutionalized full-benefit dual eligible individuals have no cost-sharing below, or above, the out-of-pocket threshold. We proposed to define ''institutionalized individual'' for this subpart as a full-benefit dual eligible individual who is an institutionalized individual as defined in section 1902(q)(1)(B) of the Act.

Under section 1860D–14(a)(1)(D)(ii) of the Act, non-institutional full-benefit dual eligible individuals in 2006 with incomes that do not exceed 100 percent of the Federal poverty line for their family size will pay no more than $1 for generic drugs or preferred drugs that are multiple source drugs (as defined in section 1927(k)(7)(A)(i) of the Act),$3 for any other drug, or, if less, the amount charged to other full subsidy eligible individuals (other than institutionalized full-benefit dual eligible individuals) for costs below the out-of-pocket threshold. These $1 and $3 copayment amounts are increased beginning in 2007 by the percentage increase in the CPI (all items, U.S. city average), rounded to the nearest multiple of 5 cents.

In accordance with section 1860D–14(a)(1)(D)(iii) of the Act, all other full subsidy eligible individuals and full-benefit dual eligible individuals with income above 100 percent of the FPL for their family size in 2006 will pay copayment amounts of $2 for a generic drug or preferred drugs that are multiple source drugs (as defined in section 1927(k)(7)(A)(i) of the Act) and $5 for any other drug, for costs up to the out-of-pocket threshold. In accordance with section 1860D–2(b)(4) and 1860D–2(b)(6) of the Act, these copayments are indexed based on an annual percentage increase in average per capita aggregate expenditures for covered Part D drugs, rounded to the nearest multiple of 5 cents (see § 423.104(e)(5) of this proposed rule).

In the proposed rule we noted that a question had been raised concerning whether an MA-PD plan could choose to reduce or eliminate copayments for full-benefit dual eligible individuals. We stated that specialized MA plans (under section 231 of the MMA, as defined in proposed Title II regulations at § 422.2) offering benefits only to dual eligible individuals could choose to reduce or eliminate copayments for their members as a supplemental benefit. Otherwise, the Part D copayments stipulated by the MMA for low-income individuals cannot be reduced or eliminated. This is because any reduction of the copayments must apply to all plan members under the uniformity of benefits provisions, set forth in § 423.265(c) of the proposed rule. Accordingly, MA-PD plans other than special MA-PD plans for dual eligibles may not offer their members who are dual eligible lower co-payments or co-insurance than those paid by its other plan members.

b. Other Low-Income Subsidy Eligible Individuals

In accordance with section 1860D–14(a)(2)(A) of the Act, for other low-income subsidy eligible individuals who do not qualify for the full subsidy, we proposed and in the final rule set a scale for the premium subsidy in a stepped fashion. The sliding scale premium subsidy will range from 100 percent of the benchmark premium amount for individuals at or below 135 percent of the FPL for their family size, to no subsidy for individuals at 150 percent of the FPL for their family size. In contrast to full subsidy eligible individuals, other low-income subsidy eligible individuals subject to the late enrollment penalties under § 423.46 will be responsible for 100 percent of the penalties. In the proposed rule we invited comments concerning the manner in which the sliding scale premium subsidy would be calculated for individuals with income from 135 percent up to 150 percent of the FPL for their family sizeOther low-income subsidy eligible individuals will have their annual deductible reduced from $250 to $50 in 2006. This $50 is indexed to grow in accordance with section 1860D–2(b)(6) of the Act beginning in 2007 based on the annual percentage increase in average per capita aggregate expenditures for Part D drugs, rounded to the nearest multiple of $1. Other subsidy eligible individuals will have continuation of coverage from the initial coverage limit (under paragraph (3) of section 1860D–2(b) of the Act and 423.104(d)(4) through the out-of-pocket threshold (under paragraph (4) of that section and 423.104(d)(5)), meaning no coverage gap or ''donut hole.'' For coverage through the out-of-pocket threshold, these individuals would pay cost sharing that would not exceed the 15 percent coinsurance, substituting for the higher beneficiary coinsurance described in section 1860D–2(b)(2) of the Act (see § 423.104(d)(2) of this proposed rule). The cost-sharing subsidies will count toward the application of the out-of-pocket threshold. After the out-of-pocket threshold is reached, these individuals' cost-sharing will be limited to the copayment or coinsurance amount specified under section 1860D 2(b)(4)(A)(i)(I) of the Act (see § 423.104(d)(5)), which, in 2006, means co-payment amounts of $2 for a generic drug or preferred multiple source (as defined in section 1927(k)(7)(A)(i) of the Act) and $5 for any other drug. In accordance with sections 1860D–2(b)(4) and 1860D–2(b)(6) of the Act, the $2 and $5 copayments will be indexed based on

an annual percentage increase in average per capita aggregate expenditures for covered Part D drugs, rounded to the nearest multiple of 5 cents.

- Premium Subsidy (§ 423.780)

Comment: Some commenters were interested in what types of data interfaces we envisioned so that States would know coverage details.

Response: We are working through the data system requirements and will address these issues in further operational guidance.

Comment: Several commenters requested clarification on how we plan to arrive at the weighted average required to calculate the premium subsidy amount for a given region. Some were concerned that the term ''weighted average'' is not defined in the context of calculating the low-income premium benchmark.

Response: In response to public comment on this methodology, we are including new language in regulatory text to clarify our policy on how the weighted average will be determined for the low-income benchmark premium. We intend to use the same methodology for determining the weighted average for the low-income premium benchmark as is used in § 423.279(b) for determining the weighted average for the national average monthly bid amount. The low-income benchmark premium amount for a region is a weighted average of the monthly beneficiary premiums for plans, with the weight for each plan equal to a percentage with the numerator equal to the number of Part D eligible individuals enrolled in the plan in the reference month (as defined in § 422.258(c)(1)) and the denominator equal to the total number of Part D eligible individuals enrolled in all Part D plans in a PDP region included in the calculation of the low-income benchmark premium amount in the reference month.

For purposes of calculating the low-income benchmark premium amount for 2006, we assign equal weighting to PDP sponsors (including fallback entities) and assigns MA-PD plans a weight based on prior enrollment. New MA-PD plans are assigned a zero weight. Again, PACE, private fee-for-service plans and 1876 cost plans are not included.

Comment: One commenter recommends that PDP premium amounts be regulated to ensure that subsidy eligible individuals may enroll in any PDP and be assured a fully subsidized premium. Another commenter suggested that full- benefit dual eligible individuals not pay additional amounts over the premium subsidy amount. The commenter argued that if a dual enrolls with a higher premium plan, that is the fault of the enrollment system. Another commenter also suggests that CMS or the Part D plans provide clear notice to consumers about set premium standards, ''benchmark premiums,'' so consumers can evaluate plans with full understanding of their premium options and liability.

Response: We disagree with the first two comments. Subsidy eligible individuals, including full subsidy eligible individuals, may choose to pay a higher premium in order to enroll in the Part D plan of his or her choice, and we do not have the authority under the statute to limit these individuals' choices. The Part D plan with the higher premium may provide a richer benefit package that better meets the individual's prescription needs than other plans. We will ensure that beneficiaries are provided complete information in which to evaluate their options, including understanding premium liability, if any.

Comment: Several commenters requested certain clarifications in the regulations regarding American Indian and Alaska Native (AI/AN) Medicare beneficiaries. The Indian Health Service (IHS), Indian Tribes and Tribal organizations, and urban Indian organizations (collectively, I/T/Us) provide various services and other benefits to AI/ANs, including operating pharmacies and sometimes paying premiums, cost sharing, and similar charges for those AI/ANs who are eligible for various public and private health insurance and health care programs. Commenters requested that the regulations clarify that I/T/U pharmacies may pay Part D premium amounts, either in full for non-subsidy eligibles, or amounts remaining after application of low-income subsidies, for AI/AN Medicare beneficiaries that they also serve.

Response: The clarification requested by the commenters is a matter for the Indian Health Service rather than for CMS and we therefore will not address this issue in this regulation.

Comment: Commenters asked for clarification in the regulations as to how the requirement to apply the ''greater'' premium calculation (for example, premium subsidy amount) options will be applied and enforced.

Response: We are working through the data system and collections requirements and will address these issues in further operational guidance.

Comment: Some commenters requested clarification about the linear sliding scale for the premium subsidy and whether this will be for ranges of percentages of the Federal poverty level or by individual percentages. The commenters prefer the simplest methodology to implement the scale and request guidance from us on how this should be calculated. We received comments suggesting that there should be as few as possible different premiums reductions for low-income beneficiaries between 135 percent and 150 percent of FPL (that is, as few ''steps'' as possible). Commenters said the administrative burden of tracking and implementing a multitude of different premiums for these other low-income beneficiaries would vastly outweigh any perceived equity achieved by setting the premium in many steps carefully calibrated to relate directly to the individual's income level.

Response: We requested comments on this issue and had proposed the breakdown be in 5 percent increments. Given the comments received, we will be implementing the sliding scale premium in four groups as follows: beneficiaries with incomes at 135 percent of the FPL will receive a 100 percent premium subsidy; beneficiaries with income greater than 135 percent but at or below 140 percent of the Federal poverty level will receive a 75 percent premium subsidy; beneficiaries with incomes greater than 140 percent but at or below 145 percent of Federal poverty level will receive a 50 percent premium subsidy; and beneficiaries with incomes greater than 145 percent but below 150 percent of Federal poverty level will receive a 25 percent premium subsidy.

Comment: One commenter indicated that there should be no late penalty, or at most a minimum late penalty, if an SPAP is paying for an individual's premiums for Part D.

Response: We do not have the legal authority to make the changes requested by this commenter. In addition, SPAPs are not obligated to pay a late penalty fee on behalf of the subsidy eligible individual.

Comment: Some commenters requested that the premium subsidy for any late enrollment penalty should be 100 percent for at least the first year in which a beneficiary is enrolled in the Part D program.

Other commenters argued that imposing any late enrollment premium penalties on individuals eligible for the low-income subsidies is overly punitive. They suggested that we delay the late enrollment penalties for those eligible for the low-income subsidies or waive any late enrollment penalties for this population.

Some commenters suggested that we should allow the 100 percent subsidy of

the late enrollment penalty as soon as a beneficiary becomes eligible for the full premium subsidy just as it now proposes to do after month 60.

Comments were also received requesting that the reduced late enrollment penalty under § 423.780(c) apply for beneficiaries for whom SPAPs pay premium costs, including the late enrollment penalties.

Response: We recognize the concern of the commenters for the needs of low-income beneficiaries. However, this change would require a legislative change as § 1860D–14(a)(1)(A) of the Social Security Act requires late enrollment penalties. Section 1860D–13(b) of the Act imposes the same late penalty on all beneficiaries; section 1860D–14(a)(1)(A)(ii) of the Act however, provides that full subsidy eligible individuals will only be responsible for paying 20 percent of any late enrollment penalty imposed for the first 60 months during which these beneficiaries are enrolled in a Part D plan and no late enrollment penalty thereafter. Late enrollment penalties for full subsidy eligible individuals enrolled in SPAPs are subsidized in the same manner as full subsidy eligible individuals who are not enrolled in an SPAP.

Comment: Some commenters asked for operational clarification as to how we will determine that the enrollee is subject to a late enrollment penalty. Clarification was requested as to who will ask for information and documentation; how the information would get to us; and, how the enrollee can question or appeal the imposition of the penalty.

Response: We will issue further operational guidance on these processes.

- Cost-sharing subsidy (§ 423.782)

Comment: Many commenters expressed concern that the cost-sharing requirement would impose a burden on full-benefit dual eligible individuals and were particularly concerned that a beneficiary could be forced to choose between paying for medications and meeting other needs. Under the Medicaid statute, an individual cannot be denied medication for failure to pay a copayment, and commenters urged inclusion of the same standard for full-benefit dual eligible individuals under the Medicare prescription drug program.

Response: Requiring providers to give prescriptions to individuals who cannot meet copayment requirements would necessitate a legislative change because the MMA does not include the same prohibition that is contained in the Medicaid statute. Therefore, we are unable to make this recommended change.

We note that institutionalized full-benefit dual eligible individuals have no cost-sharing responsibilities. For the remaining full-benefit dual eligible individuals with income below 100 percent of the Federal poverty level, the law specifies a ceiling in 2006 of copayments that do not exceed $1 for a generic drug or a preferred drug that is a multiple source drug, and $3 for any other drug. Copayment amounts are increased on an annual basis from these base amounts, as required by § 1860D–14(a)(4)(A) of the Act.

Additionally, under the law, specialized MA plans offering drug benefits to dual eligible individuals and pharmacies may exercise the option of reducing or eliminating copayments for dual eligible beneficiaries. Alternatively, States may elect to pay such copayments on behalf of these individuals.

Specifically, specialized MA plans (as defined in § 1859(b)(6) of the Act) offering benefits only to dual eligible individuals may choose to reduce or eliminate copayments for their members as a supplemental benefit. For all other plans, Part D copayments cannot be reduced or eliminated for dual eligible individuals by a non-specialized MA-PD plan unless reduced or eliminated for all other plan enrollees. However, we note that sections 1894(b)(1)(A)(i) and 1934(b)(1)(A)(i) of the Act preclude beneficiary cost sharing, including copayments, for PACE enrollees. We have included discussion of the conflicting MMA and PACE statutory copayment provisions in subpart T preamble language of this regulation.

Further, pharmacies may also waive or reduce cost-sharing requirements on behalf of a subsidy eligible individual, provided the waiver is not offered as part of any advertisement or solicitation, as specified in section 1128(B)(3) of the Social Security Act, as amended by section 101(e)(2) of the MMA.

Finally, the new Medicare drug benefit will replace significant State spending on dual eligible individuals' drug costs. States, in turn, may choose to use State dollars to pay for cost-sharing and provide supplemental drug coverage, although they will not receive a Federal match under Medicaid if they choose to do so.

Comment: One commenter questioned whether reduction of cost-sharing obligations by specialized MA plans (using premium rebate dollars) violates the uniformity of benefits provision.

Response: The reduction of cost-sharing obligations by specialized MA plans does not constitute a violation of the uniformity of benefits provision in the law, as long as the reduction is applied uniformly to all enrollees in the plan.

Comment: One commenter requested, for full-benefit dual eligible individuals, clearer guidance on ensuring that plans are providing the lesser of a copayment amount of $1 for a generic drug or preferred multiple source drug of $3 for any other drug, or the amount charged to other individuals with income below 135 percent of the FPL and resources not greater than 3 times the amount an individual may have and still be eligible for benefits under the SSI program. Specifically, the commenter requested guidance on dealing with noncompliance by plans and ensuring that non-institutionalized dual eligibles are informed of this provision.

Response: The regulation does clarify the first point raised by the commenter. In addition, we are currently working on an oversight process for noncompliance and will release further operational guidance on this issue.

Comment: One commenter suggested that adjustments made to cost-sharing amounts be rounded down to the nearest multiple of 5 cents or 10 cents (of the percentage increase in CPI), rather than rounded upward. The commenter cites that it is illogical to round upward and charge consumers more than their estimated spending limit.

Response: Rounding downward to the nearest multiple of 5 cents or 10 cents for any adjustment made to cost-sharing amounts would necessitate a legislative change because the methodology for making adjustments is stated in § 1860D–14(a)(4)(A)(ii) of the Social Security Act as ''adjustments in $1 and $3 cost-sharing amounts be rounded to the nearest multiple of 5 cents and 10 cents, respectively.'' Therefore, this change cannot be adopted.

Comment: One commenter sought clarification on the definition of out-of-pocket limits/thresholds, particularly if subsidy eligible are subject to copayments after reaching the out-of-pocket limit.

Response: For 2006, the premium and cost-sharing subsidy amounts for various subsidy eligible groups are as follows (Preamble, subpart P, Table P–2):

For 2006, the premium and cost-sharing subsidy amounts for various subsidy eligible groups are as follows (Table P–2):

FPL & Assets	Percentage of Premium Subsidy Amount (1)	Deductible	Copayment up to out-of-pocket limit	Copayment above out-of-pocket limit
Full-benefit dual eligible—institutionalized individual	100%*	$0	$0	$0
Full-benefit dual eligible– Income at or below 100% FPL (non-institutionalized individual)	100%*	$0	The lesser of: (1) an amount that does not exceed $1- generic/preferred multiple source and $3– other drugs, or (2) the amount charged to other full subsidy eligible individuals who are not full-benefit dual eligible individuals or whose incomes exceed 100% of the FPL	$0
Full-benefit dual eligible– Income above 100% FPL (non-institutionalized individual)	100%*	$0	An amount that does not exceed $2- generic/preferred multiple source and $5–other drugs	$0
Non-full benefit dual eligible beneficiary with income below 135% FPL and with assets that do not exceed $6,000 (individuals) or $9,000 (couples)	100%*	$0	An amount that does not exceed $2– generic/preferred multiple source and $5–other drugs	$0
Non-full benefit dual eligible beneficiary with income below 135% FPL and with assets that exceed $6,000 but do not exceed $10,000 (individuals) or with assets that exceed $9,000 but do not exceed $20,000 (couples)	100%*	$50	15% coinsurance	An amount that does not exceed $2–generic/preferred multiple source drug or $5–other drugs
Non-full benefit dual eligible beneficiary with income at or above 135% FPL but below 150% FPL, and with assets that do not exceed $10,000 (individuals) or $20,000 (couples)	Sliding scale premium subsidy (100%-0%) See attached chart	$50	15% coinsurance	An amount that does not exceed $2–generic/preferred multiple source drug or $5–other drugs

(1) Premium subsidy amount as defined in § 423.780(b)
*The percentage shown in the table is the greater of the low income benchmark premium amount or the lowest PDP premium for basic coverage in the region.

For 2006, the sliding scale premium and cost-sharing subsidy amounts for other subsidy eligible individuals are as follows:

FPL & Assets	Percentage of Premium Subsidy Amount(1)
Income at 135% FPL, and with assets that do not exceed $10,000 (individuals) or $20,000 (couples)	100%
Income above 135% FPL but at or below 140% FPL, and with assets that do not exceed $10,000 (individuals) or $20,000 (couples)	75%
Income above 140% FPL but at or below 145% FPL, and with assets that do not exceed $10,000 (individuals) or $20,000 (couples)	50%

FPL & Assets	Percentage of Premium Subsidy Amount(1)
Income above 145% FPL but below 150% FPL, and with assets that do not exceed $10,000 (individuals) or $20,000 (couples)	25%

(1) Premium subsidy amount as defined in § 423.780(b)

Comment: One commenter requested that MA organizations be allowed to obtain OIG advisory opinions that expressly permit them to reduce or waive premiums and cost-sharing for low-income members enrolled in MA plans.

Response: The law does not permit general/nonspecialized MA organizations to reduce or waive premiums and cost-sharing because these actions will violate bid integrity and uniform premium requirements.

Comment: A few commenters questioned whether a non-specialized MA plan can reduce cost sharing for its enrollees, as long as the reduction applies uniformly to all of its enrollees.

Response: The reduction would be classified as a supplemental benefit and cannot be included in the basic bid. The non-specialized MA plan may buy down the supplemental premium with beneficiary or rebate dollars. Reduction through the use of subsidy dollars is prohibited and inclusion of reduction costs in the basic bid or in allowable costs for purposes of reinsurance or risk sharing is also not permitted.

Comment: One commenter requested specification that plans cannot use an alternative benefit design to charge cost-sharing to low-income beneficiaries that exceeds the amounts set out in the regulation.

Response: Plans may not use alternative benefit designs to charge cost-sharing that exceeds the applicable $1/$3 and $2/$5 amounts set in the law. In the case of the other subsidy eligible individuals, they may not be charged cost sharing that exceeds 15 percent coinsurance for covered part D drugs obtained between the deductible and out-of-pocket threshold. The Part D plans may establish an alternative cost sharing structure with cost-sharing tiers based on an expected coinsurance of 25 percent. If a subsidy eligible individual enrolls in the plan with an alternative cost sharing structure, the beneficiary is responsible for the cost-sharing under the plan for a particular drug up to 15 percent, with our paying the difference if any. For example, if under a plan a covered part D drug has coinsurance of 10 percent, the beneficiary is responsible for the full 10 percent. If under a plan a covered part D drug has coinsurance of 20 percent, the beneficiary is responsible for 15 percent and CMS for 5 percent, provided this design is actuarially equivalent.

5. Administration of Subsidy Program (§ 423.800)

In the proposed rule we discussed establishing a process to notify the Part D sponsor that an individual is both eligible for the subsidy and the amount of the subsidy. Because we had not yet developed such a process, comments were invited concerning notification to the Part D sponsor that an individual is eligible for a subsidy and the amount of the subsidy.

Similarly, we requested comments on the proposed requirement that the Part D sponsor notify us that premiums or cost-sharing have been reduced and the amount of the reduction. We were also considering the process for reimbursing the Part D sponsor for the amount of the premium or cost-sharing reductions. Finally, we requested comments on how to best reimburse subsidy eligible individuals for out-of-pocket costs relating to excess premiums and cost-sharing incurred before the date the individual was notified of his or her subsidy eligibility but after the effective date the individual became a subsidy eligible.

We also requested comments on how to deal with premiums and cost sharing paid by charities or other programs, for example, the Ryan White program or State Pharmacy Assistance Programs, on behalf of an individual during a period when he or she is determined to be subsidy eligible. We specifically requested comments on whether Medicare should treat these programs for purposes of premium or cost sharing reimbursement as we would other employer-sponsored insurance programs in which Medicare is a primary payer for purposes of coordination of benefits. In addition, we requested comments on whether beneficiaries should be responsible for reimbursing any cost sharing or premiums paid on their behalf by another program or charity.

In accordance with section 1860D–14(c)(2) of the Act, reimbursement to Part D plans may be computed on a capitated basis, taking into account the actuarial value of the subsidies and with appropriate adjustments to reflect differences in the risks actually involved. (Refer to Subpart G of this rule for a discussion of interim payments and final reconciliation payments.)

Subsidy amounts under section 1860D–14 of the Act are counted toward the out-of-pocket threshold at section 1860D–2(b)(4)(C)(ii) of the Act. Part D plans will be responsible for tracking the application of the low-income subsidy amounts as described in § 423.100.

Comment: Many commenters expressed concern about the lack of a specified timeframe in which we must notify plans that enrollees are eligible for a subsidy, raising concerns that if there were lengthy periods between enrollment in a Part D plan and notification of subsidy eligibility, low-income beneficiaries would have to pay prohibitive costs and they may not use their Part D benefits. Some commenters suggested that we be required to notify plans within 24 hours after an application for the subsidy is approved. One commenter suggested that we should provide a daily tape match to Part D plans that provides the low-income subsidy enrollee identifier. One commenter expressed concern about retroactive determinations of low-income subsidy eligibility and the burden this could place on a MA organization that would have to refund premium and cost-sharing amounts paid by a member before either the member or the MA organization was informed of the member's low-income subsidy eligibility. The commenter suggested that we limit the period of retroactivity of low-income subsidy eligibility determination to no more than three months. One commenter asked for specific guidance on the data exchange requirements for a Part D plan. One commenter believed that the proposed rule did not adequately explain how Part D plans are to determine which beneficiaries are enrolled in the low-income subsidy. One commenter asked if the notification of the Part D plan would occur after a full-benefit dual eligible individual enrolls in a plan. Finally, one commenter asked if we could also notify SPAPs when notification is sent to Part D plans about low-income subsidy eligibility.

Response: We do not have authority to direct SSA to determine an individual's eligibility for the low-income subsidy within a given time period. In further operational guidance,

we will work with States to ensure timely State determinations of subsidy eligibility. As general guidance, we expect that States will determine subsidy eligibility within time periods that are at least consistent with the processing of State Medicaid applications. Retroactive eligibility is only an issue if an individual is enrolled in a Part D plan, and subsequently applies for and is determined eligible as a full-benefit dual eligible individual. For instance, if an individual is enrolled in a Part D plan and decides not to apply for the low-income subsidy, he or she may have retroactive subsidy eligibility if the individual later qualifies for Medicaid. By virtue of being entitled to full benefits under Medicaid, the individual will automatically be eligible for the low-income subsidy. In this case, subsidy eligibility will extend back to the start date of Medicaid eligibility, which could be three months earlier if the individual would have qualified for Medicaid during the three-month retroactive period. In such cases, the individual will be reimbursed for the extra cost sharing he or she otherwise would not have paid as a full subsidy eligible individual. This would also apply to individuals under a Medicare Savings Program as a SLMB or QI (but not as a QMB, because QMBs cannot receive retroactive benefits under the Medicaid statute). In further operational guidance, we will specify how these reimbursements will be made. For QMBs and other individuals who are enrolled in a Part D plan, and later apply and are determined eligible for low-income subsidy assistance, consistent with the statute, their eligibility would be effective on the first day of the month in which they applied for the low-income subsidy.

We will address the method of notification of Part D plans and will explore issues involving notification to SPAPs in future operational guidance.

Comment: Two commenters suggested the need for additional clarification about the manner in which plans must notify us on the amount of the subsidy reductions received by beneficiaries. One of these two commenters suggested we provide a methodology while the other commenter suggested that Part D sponsors have up to 60 days to inform us that the reduction in premium and cost-sharing has been implemented and that implementation should be effective no later than the first day of the second month following the month in which the low-income determination was sent by us to the Part D sponsor. The commenter further suggested that there should not be any special or separate notice that the Part D sponsor must send to CMS to indicate that the reduction in premium or cost-sharing has been implemented noting that this notification will be part of the monthly membership transaction file that Part D providers send to us.

Response: We will issue further operational guidance on the notification methodology that Part D plans must use. However, we will expedite notification to plans that its enrollee is a subsidy eligible individual. In addition, we similarly expect Part D plans to confirm that the reductions in premiums and cost-sharing have been implemented by plans in a timely fashion.

Comment: One commenter expressed concern that the rule does not explain how reimbursements will be made to Part D plans. Another commenter expressed concern that pharmacies will impose the cost-sharing reduction at the point-of-sale for low-income subsidy individuals. The commenter suggested we develop an explicit regulatory requirement to ensure such reductions occur at the point-of-sale. The commenter suggested we add a pass-through requirement to the final regulation.

Response: This comment is addressed by the regulation at § 423.329(d)(2). The interim payments referenced in section § 423.329(d)(2)(i) are made in anticipation of low income subsidies that will reduce beneficiary cost-sharing at the point of sale. The final payments in § 423.329(d)(2)(ii) will reimburse plans for adjustments made at the point of sale. There is no need for an additional pass-through requirement, since plans will only be reimbursed for subsidies that actually were used to reduce beneficiary cost sharing at the point of sale.

Comment: Commenters expressed concern about the methodology that will be developed to implement reimbursement for cost-sharing on a capitated basis. One commenter asked that Part D plans have the opportunity to work with us as it develops a methodology, while another commenter noted that reimbursement for low-income subsidies on an aggregated capitation basis—rather than on an individual member basis—would make calculation of individual subsidies difficult for purposes of counting them toward TROOP as required by the statute. One commenter recommended that Part D sponsors offering Part D plans that serve a significant number of American Indians/Alaska Natives not have available to them the option of having the cost-sharing subsidies reimbursed to them on a capitated basis.

Response: Subsection (d) of § 423.800 was inadvertently included in the proposed rule and has been removed. This is addressed in § 423.329(d)(2). Plans will be reimbursed for subsidies that actually were incurred to reduce beneficiary cost sharing at the point of sale. Interim estimated payments related to plan assumptions may be included with monthly capitated payments to assist plans with cash flow, and later reconciled to actual incurred costs. Although we initially will pay the low-income subsidy on a claims-paid basis, we reserve the right to pay on a capitated basis as allowed by 1860D–14(c)(2). Further information on payment methodology will be issued in separate guidance.

Comment: Commenters raised concerns about the reimbursement of cost-sharing expenses incurred by subsidy eligible individuals before they have been notified of their eligibility but after the date the subsidy eligibility is effective. Several commenters expressed concern that low-income enrollees cannot afford to pay cost-sharing even with the expectation that these out-of-pocket costs will eventually be reimbursed and recommended, as an alternative, that we adopt a presumptive eligibility system. Alternatively, these commenters suggested that the regulations provide that beneficiaries may present their notice of approval for the subsidy to their pharmacy and that pharmacies would accept this notice as adequate to relieve the beneficiary from making a copayment. One commenter expressed concern that plans would violate the requirement to reimburse these costs unless more stringent compliance requirements are adopted in the regulations, including a requirement that plans have a 10-day period for reimbursement after the date a beneficiary's subsidy is effective. Another commenter suggested strengthening the reimbursement requirement by explicitly stating that Part D plans must make these reimbursements on their own initiative without requiring beneficiaries to affirmatively seek the reimbursement and that these reimbursements must be made 15 days after the eligibility has been received by the plans. One commenter requested that we permit SPAPs, which may pay the cost-sharing for individuals who are subsequently determined to be subsidy eligible, to be reimbursed for their contributions.

Response: Individuals may incur out-of-pocket costs from premiums and cost-sharing before eligibility determinations and notification to plans are made.

The rule requires plans to directly reimburse the beneficiary, according to

the data it has kept on the beneficiary's incurred and paid expenses. We will then reimburse the plan for these expenses. We will have in place a mechanism to pay plans directly for the incurred and paid expenses. We will issue further operational guidance on this issue.

Programs like the Ryan White AIDS Drug Assistance Program or SPAPs may pay the premiums and cost-sharing for beneficiaries until the low-income subsidy eligibility determinations are made. The rule requires plans to reimburse these programs for payments made after the effective date of the eligibility determination. Therefore, we have revised § 423.800, new subsection (d), to reflect this change.

Comment: One commenter recommends that Part D plans be required to reimburse State programs and charitable organizations that pay cost sharing on behalf of the Part D beneficiaries who are later found to be low-income subsidy eligible individuals.

Response: We have clarified in the final rule that plans must reimburse organizations paying cost-sharing on behalf of such individuals, any out-of-pocket costs relating to excess premiums and cost-sharing paid before the date the individual is notified of subsidy eligibility and after the date subsidy eligibility is effective.

Q. Guaranteeing Access to a Choice of Coverage

1. Overview (§ 423.851)

Subpart Q implements the provisions of sections 1860D–3, 1860D–11(g), 1860D–12(b)(2), 1860D–13(c)(3) and 1860D–15(g) of the Act. In this section, we address a beneficiary's right to have access to a choice of at least two Medicare options for prescription drug coverage; the requirements and limitations on fallback plan bidding; review and approval of fallback prescription drug plans; contract requirements specific to fallback plans; and the determination of fallback plan enrollee premiums and CMS payments to those plans.

2. Terminology (§ 423.855)

a. Eligible Fallback Entity

In § 423.855 we state that an eligible fallback entity is defined for a given contract period and is an entity that meets all the requirements to be a PDP sponsor, (except that it does not have to be a risk-bearing entity) and does not submit a risk bid under § 423.265 for any prescription drug plan for any PDP region for the first year of that contract period. We also state that an entity will be treated as submitting a risk bid if that particular legal entity is acting as a subcontractor for an integral part of the drug benefit management activities of a PDP sponsor (or an entity applying to become a non-fallback PDP sponsor) that is submitting a risk bid; however, the same is not true if the entity is a subcontractor to an MA organization offering an MA-PD plan (or a subcontractor to an entity applying to offer an MA-PD plan).

Comment: A commenter asks that we not allow under any circumstances for the pharmacy benefits management (PBM) component of the fallback plan to be the same entity contracted with either as an MA-PD or a risk PDP in the same area. The commenter stated that to do so would reduce competition in the area, which could ultimately reduce beneficiary choice and access to drugs. Another related comment stated that under the current definition and contracting requirements described in the preamble and proposed regulation that it may be possible for two legally independent, but affiliated PDP sponsors to submit bids in the same region and undercut the clear intent of the statute requiring that plans be offered by different organizations in order to meet the access requirements.

Response: Section 1860D–3(a) of the Act requires that each Part D eligible individual have access to a choice of at least two plans in the area in which they reside. Additionally, the statute makes it clear that the beneficiary access requirement is not satisfied for an area if only one entity offers all the qualifying plans in the area. We will be closely monitoring PDP sponsors, MA organizations and their subcontractors to ensure that the same legal entity is not operating both plans in a fallback area. We note that there is no prohibition against a PBM operating as a subcontractor to an MA-PD plan as well as being a sponsor of a fallback PDP. We also note that a PBM can operate as a subcontractor to all kinds of PDPs, including fallback PDPs, and to MA-PDs in any region. There is also no prohibition against an MA organization offering both an MA-PD plan and a fallback plan in the same region.

In the proposed rule we incorrectly stated at 69 FR 46670 that MA organizations offering MA-PD plans could not simultaneously offer fallbacks. We clarify in this final rule our belief that such a reading would not comply with the clear language of sections 1860D–12(b)(2) of the Act which governs contracts with PDP sponsors and not MA organizations offering MA-PDs or with section 1860D–11(g)(2)(B) of the Act which speaks only in terms of prescription drug plans, and not MA-PD plans. We will be diligent in reviewing applications in order to exclude entities that have been set up to serve no other function than to circumvent the statute. An entity will not be considered separate and distinct if it is merely the instrumentality, agency, conduit, or adjunct of the other entity. However, to the extent that other legitimate legal arrangements are negotiated in the marketplace to facilitate the offering of Part D risk plans, we will not preclude such arrangements. We have not made any further changes to the definitions of PDP sponsors or eligible fallback entities to further restrict qualifications in response to these comments.

Comment: Many commenters asked that governmental entities be able to sponsor fallback PDPs in order to provide for a smooth transition of prescription drug coverage from Medicaid or other Federally-matched programs. Some asked that Medicaid agencies be considered as potential fallback plan sponsors. Several commenters asked whether the definition of an eligible fallback entity should be modified so that an SPAP can serve as the fallback plan for SPAP clients in the event that the fallback option must be implemented because not enough PDPs or MA-PD plans express interest in service in a State (all other beneficiaries would enroll with the Part D fallback provider).

Response: We are unable to accept these suggestions because under section 1860D–41(a)(13) of the MMA, governmental entities are not eligible to become PDP sponsors. This is consistent with the MMA transfer of responsibility for providing prescription drug benefits for dual eligibles from State programs to the Medicare program (under § 1935(d)(1) of the Act), and is set up for the most part so as not to supplant other government funding for prescription drug benefits (under section 1860D–24(c)(2) of the Act). As modified in § 423.4 and discussed in subpart A of this preamble, the definition of PDP sponsors includes sponsors of fallback plans.

Comment: One commenter suggested that in order to encourage traditional PBMs to serve as ''risk bearing'' entities, we should only allow pharmacy benefit administrators (PBA) to serve as fallback plans. According to the commenter, these entities serve as traditional administrators of prescription drug programs, rather than the PBM entities that have evolved from the PBA model, and this PBA model for the fallback plans would prevent the conflict of interest that exists today when a PBM

owns and operates its own mail order facility.

Response: Although we appreciate the intent behind this comment to avoid conflicts of interest that could theoretically result in higher costs for the Part D program, we believe that restricting eligible fallback plan entities to only pharmacy benefit administrators would be unnecessarily restrictive and inconsistent with the statutory definition provided in section 1860D–11(g)(2) and described in § 423.855. The statute does not limit the type of entities that can apply to meet the requirements to be either PDPs or MA-PDs, and we do not think there is any benefit to doing so. On the contrary, our goal is to do everything possible to maximize participation in the Part D program by any and all qualified entities in order to maximize beneficiary access to a choice of private plans and competition among these plans. Therefore, we have not modified the definition of eligible fallback entity, other than to clarify that it is a form of PDP plan, and have adopted it as proposed.

In the preamble to the proposed rule we interpreted the bidding restrictions to mean that if an organization wins the fallback bidding, that is, signs a fallback contract, it is effectively barred under § 423.265(a)(2) from bidding as a risk plan in that region for 4 years—for the 3-year contract term, it is barred everywhere, and in the 4th year, it is barred from bidding as a risk plan in that region. As we described in the proposed rule, this is because eligible fallback entities are restricted to only those entities that have not submitted an at-risk bid, or agreed to serve as a subcontractor to an entity that has submitted an at-risk bid to sponsor a PDP. As a result of this restriction in bidding, eligible fallback entities must decide not to submit either a full-risk, or limited-risk bid in any region (either as a primary sponsor or as a subcontractor for a PDP sponsor) in order to be eligible to be a fallback prescription drug plan in any region. If an organization is awarded a fallback contract and ''offers a fallback plan'', it is effectively barred under § 423.265(a)(2) from bidding as a risk plan in that region for 4 years—for the 3-year contract term, it is barred everywhere, and in the 4th year, it is barred from bidding as a risk plan in any region in which it offered a fallback plan. A fallback contractor is arguably offering a fallback plan even if it is only ''on standby'' to do so.

In the proposed rule we also suggested an alternative interpretation of what it means to ''offer a fallback plan'' in a region for purposes of section 1860D–12(b)(2)(C) of the Act, that is, not just signing the contract, but also actually offering prescription drug benefits to enrollees after a fallback service area has been identified. With the second interpretation, if the fallback contract was not activated and no plan was offered during year 3, the entity could be eligible to bid at risk for year 4.

Comment: We received several comments on our interpretation of our authority in this area. One commenter asserted that we do not have the statutory authority to bar a fallback entity from at risk bidding for up to 4 years. Another commenter supported the alternative interpretation of what it means to ''offer a fallback plan'' in a region. This commenter agreed with CMS that the alternative interpretation is ''reasonable and consistent'' with the statutory intent ''to prevent plans from converting their enrollment under a fallback contract to enrollment under an at-risk plan''. They also suggested that if a fallback plan were not activated in year one or year two of the contract cycle, it should be able to submit a risk bid for years two and three, respectively. They encouraged us to adopt this interpretation in the final rule—believing it to be in the best interests of the program in that it will provide for better competition if more entities are encouraged to participate in Part D, whether as potential fallback plans or PDPs.

Response: We appreciate this comment and agree that this interpretation furthers the goal of facilitating competition by allowing former fallback contractors to enter the risk bidding a year sooner (assuming they did not actually provide a fallback plan in year 3 of the contract cycle). We do not agree, however, that a fallback contractor should be released from its three-year contract and, therefore, free to submit a risk bid any earlier than year 4. If we were to permit this, we would be undermining the safety net provided by the three-year contract cycle that exists to ensure timely access to fallback coverage in the event that a sufficient number of risk plans were to withdraw from the market to create a fallback service area during or after years 1 or 2. Moreover, we would also be undermining the attractiveness of risk bidding by eliminating an important disincentive to stay out of the market in year one. Thus, an entity that is awarded a fallback contract—even if it is only on standby—may not submit a risk bid for the 3 years that it maintains its fallback contract. For example, a fallback contractor for the period 2006–2008 may not submit a risk bid for any of those years (even if the fallback contractor is merely on standby for that entire period). In addition, if the sponsor offers a fallback plan in regions 1 and 2 for 2008, then such sponsor is prohibited from risk bidding in such regions for 2009. The sponsor may, however, submit risk bids for regions other than regions 1 and 2 for 2009 (although if it does so, it may not seek a fallback contract for the period 2009–2011). In addition, if the sponsor was on standby for all of 2008, but never actually offered a fallback plan in 2008, the sponsor may submit a risk bid for any region for 2009 (but again, if it does so, it is prohibited from seeking to become a fallback contractor for the period 2009–2011). Therefore, we have adopted the provisions in § 423.855 and § 423.265(a)(2) that provide these limitations as proposed.

Comment: Numerous commenters asserted that the contracting restrictions and other (unspecified) requirements to become an eligible fallback plan are too severe, and that they believe we will not have any organizations stepping forward to become fallback plans.

Response: We agree the requirements for fallback plans are more severe than for full risk plans. We have intentionally made these requirements stricter than for risk-bearing plans because we believe this is an important strategy to maximizing participation in the competitive bidding program and to limit the attractiveness of participating as a fallback PDP for those plans that could participate on an at-risk basis. Our goal is to have either full or limited risk plans provide MA-PD and PDP prescription drug coverage in all regions. To that end, one of our selection criteria will likely be an appraisal of whether the fallback entity's pharmacy benefit management subcontractor is also participating as a subcontractor under risk plan offerings. The implementation of the fallback plan is viewed as a last resort—as its name implies—a plan to ''fall back'' on in the event a choice of two qualifying drug prescription plans is unavailable in a service area or region. We are aiming to design our bidding process so that fallback plans are not required at all, that is, to do everything possible to facilitate full-risk plans and to provide for limited-risk plans in a particular region if full-risk plans are not available. In fact, if any fallback plans are needed, the Congress requires us to submit an annual report with recommendations for further limiting the need for such plans and maximizing future participation by limited risk plans.

b. Fallback Prescription Drug Plan (Fallback Plan)

In the proposed rule under § 423.855 we stated that a fallback prescription drug plan is a PDP offered by an eligible fallback entity that provides only actuarially equivalent standard prescription drug coverage, as well as access to negotiated prices, including discounts from manufacturers, and that meets other requirements as specified by CMS.

Comment: Several commenters stated that we should amend the phrase 'actuarially equivalent standard prescription drug coverage'' with the phrase 'defined standard coverage' to reflect the clear intent of the Congress to limit the benefit offered by a fallback plan. Others urged us to make sure the final regulation is clear about what structures such as premiums or cost sharing can be different and about what protections must be in place to ensure that consumers are clearly informed of the differences and are protected against unfair practices.

Response: We agree that the statute requires fallback plans to offer standard coverage, but we point out that it makes a distinction between two types of coverage that are both considered ''standard''. For purposes of administering the Part D benefit we must maintain the distinction between defined standard coverage and actuarially equivalent standard coverage as described in § 423.100. We continue to think that beneficiaries and taxpayers may be able to get better value from actuarially equivalent packages that employ all of the cost and utilization management tools, particularly co-payment tiering, to drive to the most cost-effective utilization on the part of beneficiaries and the best price concessions from manufacturers, so we certainly will not preclude such offerings. However, we cannot say with impunity that PDPs offering defined standard coverage could not offer equal value through other formulary management tools and competitive negotiations with manufacturers. Consequently, we have modified § 423.855 to reflect that fallback PDPs may offer either defined or actuarially equivalent standard benefits. We do not believe this flexibility in any way impedes PDP plans from offering competitive plans that beneficiaries would prefer. We also note that we will be closely reviewing fallback plan formularies and benefit designs, as well as cost, quality and utilization management programs to ensure that they are reasonable and appropriate for a region in which beneficiaries do not have alternative plans from which to choose.

Comment: Several commenters recommended that we require that all price concessions be passed through to the beneficiary. One commenter also recommended that we not allow any pricing differentials on what is paid to pharmacies for reimbursement of the dispensing fee or ingredient costs. They also believe the fallback plan should be required to adequately reimburse pharmacies with appropriate dispensing fees and an appropriate product cost reimbursement.

Response: We agree with the commenters that fallback plans must pass through all price concessions that are known and available at point-of-sale to the beneficiary and, furthermore, must operate under conditions of complete price transparency in general. All other price concessions obtained (as discussed in detail in subpart G) must be reported to CMS and subtracted from paid claim amounts upon reconciliation. We note that some portion of these latter price concessions are passed through to the beneficiary in the form of lower premiums, but another portion is not and is passed through solely to the Medicare program in the form of lower program expenditures. It would be impractical to require that all price concessions be passed through to the beneficiary at the point of sale because certain price concessions can only be calculated retrospectively.

Nonetheless, we require that fallback plans pass through all price concessions that are known at the time of the sale in the point-of-sale price, because we do not believe that section 1860D–11(g)(5)(A)(i) of the Act allows us to reimburse fallback plans for any amount in excess of actual costs incurred. Therefore, fallback plans may not claim any amount in excess of the discounts and dispensing fees obtained from participating pharmacies as drug claim costs. All returns on investment must be negotiated as part of the management fees and performance measures. We note that this policy differs somewhat from our requirements for risk plans. We believe that risk plans will be motivated to pass through as much discount as practicable at the point-of-sale due to price competition, and we will encourage this through our Price Compare website. Even if they do not, however, they are paid prospectively and are in compliance with § 1860D–2(d)(1)(B) of the Act and § 423.104(g)(1) of this rule, so long as all price concessions are reported and deducted from claims costs in the reinsurance and risk corridor final payment processes. Fallback plans, on the other hand, are paid on the basis of 1860D–11(g)(5)(A)(i) of the Act and § 423.871(e)(1) of this rule, and our payments must be limited to the actual costs of covered Part D drugs provided to the fallback plan enrollees. Since fallback plans will submit their claim costs to us for direct reimbursement, we require that these claims represent actual point-of-sale costs. We have added a definition of actual costs to § 423.855 and modified § 423.871(e)(1) to clarify this interpretation.

As for the recommendation to prohibit pricing differentials among fallback plan contracts with network pharmacies, we do not believe that such a requirement would be consistent with the goal of creating a competitive market for prescription drugs and obtaining the best possible prices for beneficiaries and the Medicare program. We also do not believe that there is any prohibition on fallback plans contracting with subset(s) of preferred pharmacies, just as risk plans may; such subsets of preferred pharmacies may indeed have different pricing arrangements. Although we agree with the commenter that fallback plans should adequately reimburse pharmacies through appropriate dispensing fees and product cost reimbursement, we note that this result must be obtained through competitive price negotiations and that we may not interfere in such negotiations by attempting to define or require ''appropriate'' fees.

Comment: Several commenters asked that certain PDP requirements be extended to fallback plans. For instance, one commenter argued that the same out-of-network requirements applicable to PDPs should apply to fallback plans, and others suggested that they should be required by regulation to coordinate benefits with SPAP's in the same manner as must PDPs, or that they should comply with all the access and quality standards applicable to PDPs and MA-PD plans, including all grievances and appeal procedures.

Response: We agree and wish to clarify that a fallback plan is a special type of PDP and as such must meet all of the requirements established for Part D plans, including prescription drug plans, in these regulations, except as otherwise specified by CMS in this subpart or in separate guidance. In some cases, the statutory provisions applying to fallbacks will be such that to apply the requirements of PDPs to fallbacks would create a conflict in the statute. For example, fallback plans obviously could not be required to submit bids under section 1860D–11(b) of the Act, since fallbacks are paid on a different basis from risk contractors. Similarly, fallback contractors will not be required

to report information necessary for calculating reinsurance, because fallbacks do not receive any reinsurance payments. In these cases, where there is an apparent conflict in the statute, this subpart, or in our guidance, we would not require fallback plans to meet the requirements of PDPs. However, where there is no conflict, we believe that fallback plans should be considered PDPs and have amended the definition of PDP in subpart A to include a fallback plan. Thus, for example, a fallback plan will be required to meet all of the requirements for beneficiary protections under subpart C that apply to other Part D plans. In addition, fallbacks would be subject to most of the provisions in subpart K governing the terms of the contract and procedures for termination. However, a fallback plan would not be subject to the same licensure and solvency requirements that apply to PDP sponsors under subpart I. Fallback plans would be required to have regional networks that meet the access requirements specified in § 423.120, including meeting the Tricare standards for retail pharmacies at the State level, but they would not necessarily have to meet the Tricare standards at the local level of the eventual fallback service area, as this particular area could not have been foreseen. We have amended the definition of fallback plan in § 423.855, and the definitions of PDP and PDP sponsor in § 423.4, accordingly.

c. Qualifying Plan

Under § 423.855, a qualifying plan is defined as either a full-risk or limited risk prescription drug plan (PDP) or an MA-PD plan that provides basic coverage, or an MA-PD plan that provides supplemental coverage for no additional charge to the beneficiary. Specifically, if the MA-PD plan coverage includes supplemental prescription drug coverage, then in order to meet the definition of a ''qualified plan'' the MA-PD must be able to apply a premium rebate under Part C of Medicare as a credit against the supplemental coverage premium, leaving no cost to the beneficiary for the supplemental coverage. MA-PD plans must also be open for enrollment and not operating under a capacity waiver in order to be counted as a qualifying plan in an area. Similarly, we have modified § 423.855 to clarify that a PDP must not be operating under a restricted enrollment waiver, such as those that may be granted to special needs plans or employer group plans, in order to be counted as a qualifying plan in an area. No comments were received on these provisions, and they will be adopted as proposed.

3. Assuring Access to a Choice of Coverage (§ 423.859)

a. Access Standards

In § 423.859(a) we state that we will ensure that each Part D eligible individual has available a choice of enrollment in at least two qualifying plans offered by different entities in the geographic area in which he or she resides. Therefore, beneficiaries in an area must have a choice of two plans that provide basic coverage (or an MA-PD plan that provides supplemental coverage for no additional charge to the beneficiary). However, to meet the access test, different sponsors must offer the two qualifying plans, and at least one of the plans must be a PDP. There were no comments on these statutorily-based requirements and we are adopting § 423.859(a) as proposed.

b. Fallback Service Area

In § 423.859(b) we state that if before the start of a contract year (or at any other time) we determine that Part D eligible individuals in a PDP region do not have available a choice of enrollment in a minimum of two qualified plans as described in § 423.859(a), we will establish a ''fallback service area.'' Thus, a fallback service area is any area within a PDP region in which we have determined that Part D eligible individuals do not have available a choice of enrollment in two qualified plans, at least one of which is a prescription drug plan. Three examples of the application of a fallback service area follow:

- Example 1—We would establish a fallback service area in an area where an MA regional PPO plan is offered but no PDP is offered in the region. Since beneficiaries in the region would only have the choice of a MA-PD and not a stand-alone PDP, we would define the area as a fallback service area.
- Example 2—A fallback service area would also be designated if only one PDP is offered in a region, but in some or all parts of the region neither a regional (PPO) MA-PD plan nor a local MA-PD plan are available to beneficiaries. Since beneficiaries would not have a choice of two qualifying plans, we would define the areas within the region that only have access to the PDP, and not an MA-PD plan, as fallback service areas. As a result, it would be possible for only certain areas (counties) within a region to be designated as fallback service areas.
- Example 3—A fallback service area would also be designated in any area in which only one entity offered all qualifying plans, even if that sponsor offered two PDPs, or one PDP and one MA-PD plan with basic coverage, covering the entire region.

Comment: One commenter stated that a fallback plan should at a minimum be Statewide.

Response: In the MMA the Congress directed CMS to form Medicare Advantage regions of not less than 10 and no more than 50 encompassing the 50 States and the District of Columbia, and to create PDP regions that are consistent with these to the extent practicable. Discussion of the analysis and comments on the PPO and PDP regions has been published separately. However, in the event that we determine that only sections of a region are fallback service areas, we are prohibited by law from allowing the fallback plan to service the entire region, no matter its size. We recognize that this policy may result in fallback service areas that are much smaller than the regions on which the contracts are based. Our compensatory strategy is to encourage national or other large-scale fallback contracts in order to maximize operational efficiencies while operating under this sort of uncertainty.

c. Waivers for Territories

Section § 423.859(c) of this regulation makes Medicare beneficiaries residing in the U.S. territories—which include American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, and the U. S. Virgin Islands—eligible to enroll in Part D. We have the authority to waive any Part D requirements, including the requirement that access to two qualifying plans is available in each service area, as required to ensure access to qualified prescription drug coverage for Part D eligible individuals residing in the U.S. territories. In addition, entities wishing to become prescription drug plans in the territories may request waivers or modifications of Part D requirements that facilitate their operation in those areas.

In the proposed rule we suggested a number of Part D requirements that we were considering waiving and requested comments on these and any other potential waivers that would facilitate the offering of Part D coverage in the territories. The only comments received for the territories concerned the design of the regions, and these have been addressed in separate guidance. As a result, we retained the broad waiver authority in § 423.859(c) without modification, and will continue to conduct research to determine how best to facilitate Part D coverage in the territories. For risk-based applicants, we anticipate we would provide a table identifying requirements for waivers, and applicants would have to provide a

rationale for how a waiver would facilitate risk-based access in the territories. We would review each waiver, and if it is approved, it will apply to all similarly situated risk plans in the territories. Waivers of the bid requirements will not be entertained. Similarly for Fallback applicants, if there is a need for any of these, we would entertain waiver requests. Additionally, we will modify the payment incentive and performance guarantee arrangements as may be necessary to ensure fallback participation in the territories.

4. Submission and Approval of Bids (§ 423.863)

In § 423.863 we establish a separate bidding process for fallback plans distinct from the risk bidding process addressed in § 423.265 of our regulations, and state that the solicitation, timing and format requirements for this process will be provided in separate guidance.

Comment: A commenter asserts that neither the MMA nor the proposed rule address whether a PDP applicant approved by CMS may withdraw its application without any adverse consequences to the PDP applicant if a fallback plan is invoked in the same region. The commenter recommends that this option should be available if a plan does not wish to compete against a fallback plan.

Response: We fundamentally do not think that risk plans need to be concerned about competing against a fallback plan. Risk plans will have the competitive advantages of corporate marketing and brand recognition and the ability to offer more varied benefit designs (including supplemental benefits), as well as being offered to all enrollees in a region—not just to those in fallback service areas. We are also anticipating that efficient risk plans may have the opportunity to earn higher levels of profit. While there is a possibility that a fallback plan could enter a region if there is only one PDP risk plan, our strategic approach to encourage the offering of risk plans should also make them attractive to beneficiaries relative to fallback plans. And while we do not believe we have the authority to prevent a risk bidder from withdrawing its bid prior to entering into a PDP contract, we expect risk-based applicants to participate in the solicitation process in good faith, with the full expectation of participating in the regions for which they apply regardless of the anticipated presence of a fallback in that region. Accordingly, we intend to scrutinize applications and bids.

In § 423.863(b) we state that, except as otherwise noted, the provisions of § 423.272 apply for the negotiation and approval of fallback PDP contracts. We state that if access requirements have not been met after applying § 423.272(c), we will contract for the offering of a fallback PDP in that area, and that all fallback service areas in any PDP region for a contract period must be served by the same fallback plan. Fallback plans must be prepared to provide Part D services at the same time as risk plans, and in the event of mid-year changes, we will approve a fallback PDP for any new fallback service areas in a PDP region in a manner so that the fallback plan is offered within 90 days of notice. Under no circumstances may we contract for only one fallback PDP for all fallback service areas in the 50 States, the District of Columbia, and the territories.

Comment: One commenter pointed out that according to § 423.863(b)(5), in the event of mid-year changes we must approve a fallback prescription drug plan so that the fallback is offered within 90 days of notice. The commenter is concerned that this leaves open the possibility that beneficiaries could be without a PDP for a period of up to 90 days, and urges us to clarify that fallback plans must enter into a mid-year market as soon as practicable.

Response: We share the commenter's concern with ensuring access and continuity of care for beneficiaries in the unlikely event of either a risk plan or fallback prescription drug plan failure. We will make every effort to eliminate this possibility through our selection criteria that will involve scrutiny of financial and business stability, and will favor firms with national capacity. In addition, we will select fallback plans, in part, on their operational capability to be up and running quickly. We believe it would be a very rare occurrence to need a fallback plan in mid-year for a reason that could not be foreseen in time to have an alternate fallback plan in place, and thus we cannot foresee a circumstance in which there would be the possibility of a gap in access to a PDP. (Contract provisions in § 423.509 and § 423.510 require a 90-day notice of intent to terminate a plan. In 423.508, if a contract is terminated by mutual consent, the sponsor and CMS will work out an appropriate time frame to ensure time to secure a fallback plan.) In cases where a new fallback would be invoked mid-year due to plan withdrawal, beneficiaries might face different cost sharing and different formularies, but they would be eligible for an SEP and would be allowed to choose the MA-PD or PDP in the area (if there is one) instead of the new fallback plan. In the unlikely event of this occurrence, our goals will be to explain any differences to affected beneficiaries, and to limit disruption as much as possible.

Comment: One commenter stated that our suggestion in the proposed rule that we expected to award two fallback contracts for the entire country, assuming fallback contracts are needed, is arbitrary and does not serve the best interests of either beneficiaries or CMS.

Response: Because we now believe that two may not be sufficient to competitively provide for fallback coverage should it be necessary, we plan to award as many contracts as needed to provide potential fallback services. However, we still plan to have only a very limited number. We anticipate awarding a sufficient number of fallback contracts to ensure that any designated fallback area(s) are provided for at the start of the program, as well as later in the event of plan closure or failure. However, we do not anticipate awarding so many as to dampen the incentive for potential fallback plans to offer excellent customer service and competitive drug prices. We also plan to pursue every opportunity to ensure the option of at least two risk plans in every area, and do not anticipate the need to activate fallback plans.

In the preamble to the proposed rule we stated that in general we would enter into contracts with fallback plans using Federal acquisition rules on a timetable ensuring that such contracts were in place at the same time as prescription drug plans would otherwise be offered. However, in regulation we more correctly stated that we would use competitive procedures (as defined in section 4(5) of the Office of Federal Procurement Policy Act (41 USC 403(5)) to enter into a contract under this paragraph, and that the provisions of section 1874A(d) of the Act with regard to limitation of liability for Medicare contractors for payments on behalf of Medicare would apply. Thus the fallback plans must be competed, and their terms and conditions may be negotiated. Because fallback plans will be subject to competitive procedures, we have clarified subpart N to make clear that those appeals procedures would not apply to fallback plans or fallback entities.

Comment: We received comments asking that an alternative to the ''indefinite delivery'' type contracting be considered, including the use of cost plus fixed fee contracts.

Response: We do not believe the fallback contracts will be Federal Acquisition Regulations (FAR) contracts

per se, even though we plan to use the FAR competitive procedures to enter into fallback contracts. Section 1857(c)(5) of the Act, which is incorporated by section 1860D–12(b)(2)(B) of the Act, authorizes us to exercise the authority granted to the Secretary under Part D of Title XVIII without regard to provisions of law or regulations relating to the making, performance, amendment, or modification of contracts of the United States, as we determine is inconsistent with the furtherance of the purposes of Title XVIII.

Based on this authority, we proposed that for risk contractors, the contracts would not be written or entered into in accordance with the FAR or the Departmental acquisition regulations set forth in title 48 of the CFR. In addition, in the Medicare Advantage context, the MA contracts have not been considered to be FAR contracts and have not contained FAR provisions within them. We believe that it would be in furtherance of the purposes of Title XVIII to maintain consistency among the Medicare Advantage, risk, and fallback contracts to the extent possible. Therefore, as with both the risk and Medicare Advantage contracts, the fallback contracts will not contain many of the FAR or HHS-specific provisions automatically included in many government contracts.

In addition, because the contracts would not be written under the FAR or 48 CFR provisions, we do not believe it is accurate to refer to the standby contracts as indefinite duration, indefinite quantity (IDIQ) contracts—which is a term used under the FAR. Nonetheless, we expect to have umbrella provisions, which provide the necessary flexibility to deploy a fallback plan during a contract year in the event of a risk plan failure. Although the fallback contracts will not be written in accordance with the provisions of the FAR or 48 CFR, and will not look like typical ''FAR contracts,'' as we stated in the proposed rule at 69 Fed. Reg.46734, unlike both risk and MA contracts, we will enter into fallback contracts using the Federal acquisition rules on a timetable to ensure that the contracts are in place on time (that is, at the same time as the risk plans would otherwise be offered).

In anticipation of the approach discussed above, we intend to time the fallback solicitation process so that we can actively encourage participation in risk contracting and minimize the need for fallback plans while ensuring they are available if necessary. To this end, we intend to begin the fallback solicitation process after the risk plan solicitation process. We may also conduct a second risk plan solicitation (for applications) only for areas we determine to be likely fallback areas. Final fallback bids under this process would be due shortly after the risk bids are due with fallback contracts awarded in the fall. Further details on the fallback plan solicitation process will be provided in separate guidance.

In the preamble to the proposed rule we referred to the non-interference provision of the MMA and noted, for our negotiations with potential fallback plan sponsors, that we could not interfere with negotiations between drug manufacturers and pharmacies and PDP sponsors, and could not require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs. However, we noted that at the same time the revenue requirements standard in 5 USC 8902(i), discussed in subpart F of the preamble, require us to ascertain that the bid ''reasonably and accurately reflects the revenue requirements for benefits provided under that plan.'' Therefore, we concluded that while we may not set the price of any particular drug, or require an average discount in the aggregate on any group of drugs (such as single-source brand-name drugs, multiple-source brand name drugs, or generic drugs), we will take appropriate steps to evaluate whether the bid is reasonably justified. As specified in 5 USC 8902(i), we have the authority to take steps to ensure that benefits are ''consistent with the group health benefit plans issued to large employers,'' in order to ensure that the bid amounts submitted are comparable to those available on the private market. For example, if the price reference points appear to be particularly high (or low), we may request an explanation of the bidders' pricing structure, and the nature of their arrangements with manufacturers to ensure that there is no conflict of interest leading to higher bids. We also proposed to negotiate price-related performance targets with fallback plans, consistent with current market practices in which commercial plan sponsors negotiate price-related reference points with PBMs. We said we would also consider potential contractors based on their bids for administrative functions like claims processing.

Comment: We received a few comments that did not support our analysis of our negotiating authority. One commenter specifically recommended that we clearly indicate in the final rule that we will not set price benchmarks, create incentive payments, or otherwise interfere with the price structures for Part D drugs, whether provided through fallback plans or not.

Response: As stated in the proposed rule, we believe that section 1860D–11(g)(5)(B)(i) of the Act makes clear that the Congress contemplated taking prices into account in calculating incentive payments for fallback entities. Moreover, even though the performance measures and the potential incentive payments will be defined in advance, the determination of actual incentive payments will be made at the end of the contract period, and thus does not represent interference in the bidding process.

As is the case with risk bids, we continue to believe we have the authority to negotiate for fallback plans in four broad areas: administrative costs, aggregate costs, benefit structure, and plan management. We will evaluate administrative costs for reasonableness in comparison to other bidders. We will examine aggregate costs to determine whether the revenue requirements for the defined standard or actuarially equivalent standard prescription drug coverage as defined in § 423.100 are reasonable and equitable. We will be interested in steps that the plan is taking to control costs, such as through measures to encourage use of generic drugs, therapeutic interchange to preferred brand-name drugs, and formulary compliance. We will be interested in reviewing the formulary to ensure that it is appropriate for a region in which beneficiaries do not have alternative plans from which to choose. We will examine and discuss any proposed benefit structures or changes to benefits in later years, particularly with regard to any potentially discriminatory features. Finally, we will review performance metrics and discuss any identified issues with regard to plan management, such as customer service. No changes will be made to § 423.871 in response to these comments.

Comment: One commenter supported our position that we have the authority to negotiate with plans to ensure a good price for beneficiaries, and if the price reference points appear to be particularly high (or low), to request an explanation of the bidders' pricing structure, and the nature of their arrangements with manufacturers to ensure that there is no conflict of interest leading to higher bids. The commenter urged us to apply these same authorities to plans in non-fallback situations, as well as to fallback plans, and notes these ''pricing dangers'' may also occur in areas where there is no fallback plan, but just one MA-PD and one at-risk PDP.

Response: We appreciate the support of our position and agree that similar, although not identical, controls are required for evaluation of risk plan bidding. Since risk plans are by definition at risk for ineffective cost management, there is less need for us to set targets in order to incentivize reasonable and appropriate cost controls. Please refer to our discussion of risk plan bid negotiation in subpart F, as well as to our guidelines on risk bid submission published separately.

Comment: Numerous commenters wrote in about performance measures for fallback plans. Some expressed their approval of our intent to base incentives on various performance measures. Some commenters suggested specific measures such as: using cost per days supply instead of cost per prescription to ensure an apples-to-apples comparison, and including more specific measures of customer service such as: speed and efficiency in handling enrollee calls, timeliness and accuracy of communication materials to enrollees, comprehensiveness and accuracy of business support to pharmacies, prescribers and CMS, retail pharmacy network access, and mail service pharmacy performance.

However, the majority of commenters had serious doubts about the number, and kinds of performance measures we proposed. Some were worried there were too many proposed performance plan measures, and several believed that we were suggesting that the final rule was going to allow negotiated discounts for prescription drugs to be the sole performance measure for a fallback plan. Other commenters said they believed that fallback plans should not be expected to put their management fees at risk due to factors beyond their control, or for measures that are not mutually agreed upon with CMS, and others said that drug price discounts should not be used as a performance measure at all.

Response: We appreciate the supportive comments, and especially the suggestions for specific performance metrics we could utilize. We also agree that fallback plans should not have their management fees put at risk due to factors beyond their control. We have identified a number of performance measures that are used in the private sector as performance guarantees for which management fees are put at risk and we intend to adopt these practices to ensure best practices in benefit management.

Despite the comments arguing against the use of performance incentives tied to price discounts, we will be placing performance clauses in the contracts with fallback entities that tie performance payments to the fallback plan's ability to secure lower drug prices for beneficiaries and lower costs for Medicare. We note that in the absence of performance guarantees or incentives, fallback plans are no-risk cost-based arrangements that are reimbursed by Medicare for costs (including administrative fees and negotiated profit) incurred. In future guidance we will provide a number of measures that would encourage an efficient entity to bid on a fallback plan contract (because it believes it can meet the performance metrics), and also give a successful bidder an incentive to provide quality services to its beneficiaries at the best possible price (because it would have the opportunity to earn greater profits). We note that this increased profit opportunity is the result of performance incentive payments and not the retention of any spread between negotiated prices with pharmacies and the target pricing proposed in the fallback contract bid.

As stated in § 423.871(d), as part of the payment process for fallback plans authorized by section 1860D–11(g)(5) of the Act, we will assess the performance of plans with regard to specific performance measures and tie this performance to an incentive payment. Incentive payments may be either performance guarantees (with downside risk to management fees) or performance incentives (with upside potential for additional profit). These measures will include, but are not limited to, measures for cost containment, quality programs, customer service, and benefit administration (including claims adjudication). ''Cost containment'' refers to processes in place to ensure that costs to the Medicare Prescription Drug Account and to enrollees are minimized through mechanisms such as generic substitution. The term ''quality programs'' refers to drug utilization review processes in place to avoid occurrences such as adverse drug reactions, drug over utilization and medical errors. The term ''customer service'' refers to processes in place to ensure that the entity provides timely and accurate filling of prescriptions and delivery of pharmacy and beneficiary support services. We will be surveying enrollees of fallback plans to assess customer satisfaction with plan services. The terms ''benefit administration and claims adjudication'' refer to processes in place to ensure that the entity provides efficient and effective benefit administration and claims adjudication, such as accurately programming and updating its benefit administration information systems, and providing timely and accurate claims adjudication.

We believe the suggested performance standards are reasonable and largely consistent with private sector best practices. As the potential performance guarantees and incentives mentioned above illustrate, we will select (and will continue to refine) measures that focus on key indicators of the many aspects of prescription drug benefit management that are important to us and to beneficiaries. These measures will be updated and revised to reflect opportunities to ensure that best practice is reflected in each fallback PDP contract year.

Comment: One commenter indicated support for the concept of paying for performance, but expressed concern that the proposed regulations would subject only fallback plans (and not at-risk PDPs or MA-PDs) to performance standards that would rate these plans on their success at cost containment. The commenter argued that under this approach the fallback plans would have a greater incentive to make formulary choices based on the amount of discount they receive from manufacturers, rather than on the most appropriate and cost-effective clinical treatments. If this were to occur, it could put beneficiaries enrolled in fallback plans—including those who have no other real options—at a significant disadvantage. The commenter recommended that performance standards for all Part D plans need to balance both cost containment and access to clinically appropriate medications.

Response: The MMA was designed in large part to foster a competitive market place by making every effort to encourage at-risk plans to contract with us, thereby creating competition among plans and choice for beneficiaries. We believe that both cost containment and quality performance will be logical outgrowths of plans competing for beneficiaries in the same area. Contract provisions outlined under (subpart K) § 423.505 and performance measures provided under § 423.871(d) are all designed to protect the beneficiary and are a condition of contracting with CMS. Nonetheless, we too believe that fallback PDPs, which are paid costs, may not always have the same incentives as at-risk plans to negotiate aggressive discounts and otherwise minimize net costs, as opposed to net reimbursement. Consequently, the point of the performance guarantees is to bolster the incentives to undertake those activities aggressively. We understand, for instance, that if we were to base performance incentives on rebates

obtained, this would create an incentive to steer patients toward drugs that receive higher rebates from manufacturers, rather than toward drug choices that optimize both therapeutic outcomes and cost effectiveness for the patient and the payer. Consequently, when evaluating costs, we will avoid metrics such as average rebate level or average rebate per script (as we suggested in the proposed rule) in favor of better measures of net cost to the program.

Comment: We received several comments regarding fallback plan quality programs. One suggested we change the language from over- and under-utilization to ''appropriate use''. One commenter wanted us to include a statistically significant sample of MTMP enrollees to identify medication management. Another suggested that in addition to reducing medication errors and avoiding adverse drug events, fallback PDPs should offer quality programs on prescription drug therapy that include adherence and persistency programs.

Response: We appreciate these comments and share the commenters' goals of ensuring comparable and appropriate quality assurance programs in fallback plans. As noted already, fallback plans are subject to all of the requirements for PDPs and other Part D plans (except as otherwise noted in this subpart or in separate guidance) and readers are referred to subpart D for discussion of related comments and responses on quality requirements and initiatives. We have modified § 423.871(d)(1)(ii) to reflect the requirements to monitor for appropriate utilization.

In the preamble to the proposed rule we stated that in contrast to plans that contract on a risk basis, fallback entities will be paid for covered Part D drugs on the basis of cost, and thus these entities will have less of an incentive to negotiate low drug prices. Consequently, because the statute directs us to pay management fees that are tied to performance measures, and directs that there must be a measure for costs, we said we were considering tying the performance payments of fallback entities to the average discounts they are able to negotiate, including discounts from manufacturers. We noted that this type of incentive contracting is found in the commercial pharmacy benefit management market today. We requested comments on alternative reference points or alternative methodologies that could promote competitive pricing.

Comment: We received a number of comments around using AWP as the price reference point for negotiated prices. Numerous commenters supported our use of a price benchmark and believe it represents due diligence on the part of the agency to ensure that beneficiaries and the Medicare program are not penalized with high prices in areas in which there are no choices among plans. Some recommended that we use AWP as a reference point to measure the cost containment by fallback plans. Others agreed with our expressed concern that the use of a fluctuating benchmark like AWP was in some ways problematic.

Response: Despite its frequent fluctuations and inherent vulnerability to manipulation, the AWP remains the primary measuring stick for drug costs. We will therefore be incorporating it into our performance targets, but we will also be looking at other indicators or proxies for financial performance, such as rates of generic substitution, that will provide other perspectives on cost management.

Comment: One commenter recommended that we clarify that ''actual costs'' incurred to provide the drug benefit include administrative costs, and not simply actual drug costs.

Response: We appreciate the recommendation to clarify these terms in regulation. The actual costs referenced in § 423.871(e)(1) refer to the actual costs incurred by the fallback plan for the acquisition of drugs, and are net of administrative expenses. Administrative costs, including return on investment, should be included in the computation and negotiation of management fees. We have added the definition of actual costs to § 423.855 and modified § 423.871(e)(1) to clarify these terms.

Comment: Several commenters urged us to eliminate the requirement that fallback entities apply direct or indirect remuneration as an ''offset'' to actual costs incurred by the fallback entity.

Response: We do not believe that we have the authority to reimburse fallback contractors for costs at a rate above their actual acquisition costs. In § 423.308 we state that ''*Actually paid* means that the costs must be actually incurred by the sponsor and must be net of any direct or indirect remuneration (including discounts, chargebacks or average percentage rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers) from any source (including manufacturers, pharmacies, enrollees, or any other person) that would serve to decrease the costs incurred by the sponsor for the drug.'' In the proposed rule we also explained (for allowable costs for risk plans) that we understand that today a significant volume of price concessions are not applied in the context of point of sale claims data, but rather in periodic accounting adjustments, and that they are frequently reported along with administrative fees paid by the manufacturer. We are aware and concerned that, in some cases, plan sponsors may accept lower administrative costs or receive services at less than market value in lieu of some or all of the price concessions. We are concerned that this practice may result in improper shifting of costs in order to inappropriately maximize cost reimbursements. We intend to monitor these arrangements closely to ensure that actual costs are not improperly inflated. We are also concerned that these accounting and business practices would be incompatible with the requirement to disclose all price concessions for purposes of determining actual costs and we, therefore, are proposing to require that the true cost of all price concessions be segregated from administrative fees in all records. We require that all price concessions passed through to the plan sponsor or beneficiary in any form be subtracted when calculating actual costs. Again, we have added the definition of actual costs to § 423.855 and modified § 423.871(e)(1) to clarify this policy.

Comment: One commenter requested that we extend the confidentiality protections of the Medicaid rebate statute to all negotiated pricing information submitted to, or reviewed by, CMS under Part D, including information obtained under subparts F, G, K, Q, and R of the proposed rule.

Response: We received several comments regarding extending the confidentiality provisions of the Medicaid rebate statute to Part D. As discussed in subpart F of this preamble, Part D bid information that determines payment is protected under section 1860D–15, since the bid information is used to actually pay the sponsors (if, for example, it is an estimate of reinsurance, or it supports the actuarial value of the bid). We believe this same protection applies to the information submitted in response to a fallback plan solicitation or as part of the cost reconciliation process. We also do not believe we have the authority to extend the confidentiality provisions of the Medicaid rebate statute where the Congress has not authorized us to do so. The Congress has been quite clear when it wishes the Medicaid rebate statute to apply. For example, in section 1860D–

2(d)(2) of the Act, the Congress specifically stated that certain aggregate negotiated price concessions described in that provision would be protected under section 1927(b)(3)(D)—the Medicaid rebate confidentiality provisions to which the commenter refers. Similarly, section 1860D–4(c)(2)(E) of the Act applies the Medicaid rebate confidentiality provisions to disclosures made under that provision. Finally, section 101(e)(4) of the MMA amended section 1927(b)(3)(D) to specifically add to that section the information disclosed under sections 1860D–2(d)(2) or 1860D–4(c)(2)(E). Therefore, we do not believe the Medicaid rebate confidentiality provisions would apply, except where the Congress specifically indicated they should. For further information regarding the Disclosure of Information provision, please refer to subpart G, § 423.322. Please refer to subparts F and G for discussion of comments and responses related to confidentiality of pricing information submitted with the bid and upon reconciliation.

Section 423.871(f) of the regulation implements section 1860D–15(d) and (f) of the Act. Under these provisions the Secretary is authorized to collect any information necessary to carry out section 1860D–15 of the Act, but information ''disclosed or obtained pursuant to the provisions of [section 1860D–15] may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out [section 1860D–15 of the Act].'' We have clarified that information disclosed to determine Medicare payment or reimbursement to the fallback entity may be used by the officers, employees and contractors of HHS (including OIG) only for the purposes of, and to the extent necessary in, determining payment or reimbursement, and we have modified § 423.871(f) accordingly. We also note, however, that this restriction does not limit CMS or OIG authority to conduct audits and evaluations necessary to ensure accurate and correct payment and to otherwise oversee Medicare reimbursement to fallback entities, or to conduct other statutorily-authorized quality, research, and oversight functions. Nor does this restriction necessarily limit the ability of others with independent authority to collect data using their own authority. As we did in subpart D of this preamble, we interpret sections 1860D–15(d) and (f) of the Act as limiting the use of information collected under the authority of that section. If information is collected under some other authority, however, we do not believe that section 1860D–15 of the Act would limit its use—because the information would not be collected ''pursuant to the provisions'' of section 1860D–15 of the Act. QIOs have independent authority to collect data, and to fulfill their responsibilities. To the extent QIOs need access to data from the transactions between pharmacies and Part D sponsors, these data could be extracted from the claims data submitted to us. We refer readers to subpart D for a more extensive discussion of this issue.

5. Rules Regarding Premiums (§ 423.867)

In § 423.867 we proposed that the monthly beneficiary premium charged under a fallback prescription drug plan offered in all fallback service areas in a PDP region must be uniform (except as provided with regard to any enrollment penalty, low-income assistance, or employer group waivers under § 423.458(c). It must equal 25.5 percent of an amount equal to our estimate of the average monthly per capita actuarial cost, including administrative expenses as calculated by the Chief Actuary, under the fallback prescription drug plan of providing coverage in the region. In calculating administrative expenses, we said we would use a factor based on similar expenses of prescription drug plans that are not fallback prescription drug plans. No comments were received on these statutorily determined provisions and they will be adopted as proposed.

In § 423.867(b) we proposed that fallback plans would not receive any applicable late enrollment penalties since they do not bear risk for increased expenses attributable to individuals to whom the penalty applies. We required that monthly beneficiary premiums for enrollees in fallback prescription drug plans be deducted from Social Security benefits (as provided in § 422.262(f)(1)) or in any other manner provided under section 1840 of the Act. Both § 422.262(f)(1) (as provided under sections 1854(d)(2)(A) and 1840 of the Act provide for the collection of monthly premium through the withholding of benefit payments. For those beneficiaries for whom Federally based monies are not available, section 1840(e) allows for premiums to be ''paid to the Secretary at such times, and in such manner, as the Secretary shall by regulations prescribe''.

In the proposed rule we interpreted the reference to section 1840(e) as requiring direct payment to us when Federal benefit withholds were not available. We stated: ''Premiums from beneficiaries enrolled in fallback plans would not be collected by the plan. Instead, these premiums would be withheld from social security checks (or from other benefits as permitted under section 1840 of the Act). Beneficiaries who do not receive social security checks or otherwise have premiums deducted from other benefits or annuities would pay us directly.'' We have clarified that we have the authority to require that premiums be collected by fallback plans, and to deduct such amounts from payments due to fallback plans in the case of any individual who does not receive such benefits or annuities, or who receives insufficient benefits or annuities to cover the monthly premium. We believe this procedure is more familiar to beneficiaries and to plans, and allows the plan to be in closer touch with the beneficiary's enrollment status. Therefore, we have modified § 423.867(b) to reflect this clarification.

6. Contract Terms and Conditions (§ 423.871)

In § 423.871 we state that the terms and conditions of contracts with eligible fallback entities offering fallback prescription drug plans will be the same as the terms and conditions of contracts for other Part D plan sponsors, with the following exceptions:

- The contract term for a fallback prescription drug plan will be for a period of 3 years (except as may be renewed after a subsequent bidding process). However, a fallback prescription drug plan may be offered for any year within the contract period only if that area is a fallback service area for that year.
- An eligible fallback entity with a contract under this part may not engage in any marketing or branding of a fallback prescription drug plan. This refers to marketing activities promoting the plan and its sponsor to Part D eligible beneficiaries as addressed in § 423.50 of this rule. Section 423.50 includes in the definition of marketing materials: membership communication materials, such as membership rules, subscriber agreements, handbooks and wallet card instructions, letters about contractual changes, changes in premiums, benefits, plan procedures, and membership or claims processing activities. It also refers to required dissemination of information on approved plan characteristics to enrollees as required in § 423.128 of our proposed rule. The prohibition on marketing and branding means that in none of these required activities or materials may the fallback plan sponsor

use its corporate identity to brand the fallback plan; only references to the approved name of the fallback plan or Medicare may be used. Beneficiary education and outreach to employers potentially interested in providing supplemental coverage will remain solely our responsibility.

- Payment will be based on reimbursement for actual costs (taking into account price concessions) of covered Part D drugs provided to Part D eligible individuals enrolled in the plan, and management fees tied to the performance measures that we establish including but not limited to those for cost containment, quality programs, customer service, and benefit administration (including claims adjudication).
- Each contract for a fallback prescription drug plan must require an eligible fallback entity offering a fallback prescription drug plan to provide us with the information that we determine is necessary to carry out the fallback plan payment provisions, and calculate accurate payments, including, but not limited to, all documentation relating to including 100 percent of drug claims, costs, rebates and discounts, and disclosure of all direct and indirect remuneration as offsets to the claim costs.
- We can amend the contract at any time, as needed, to reflect the exact regions or counties to be included in the fallback service area(s).
- Competitive procedures (as defined in section 4(5) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(5)) will be used in fallback plan contracting.
- Other contract terms will be specified during the bid solicitation process.

We note that like all Part D plans, fallback prescription drug plans must abide by all Federal and State laws regarding confidentiality and disclosure of beneficiary health information, including the obligation of fallback prescription drug plans as HIPAA covered entities to comply with the HIPAA Privacy Rule.

Comment: One commenter asked us to clarify that the service area of a fallback plan will not be changed except by mutual agreement of the parties.

Response: Under umbrella contracts, service area applies to two different aspects of the contract: one is where the fallback plan is actually operating a plan in any given year, and the other is the service area to which the umbrella provisions pertain, meaning the total potential service area. A fallback plan would be required to provide service as determined necessary by CMS in any additional area covered under the umbrella terms but not beyond that service area.

Comment: One commenter recommended that we publish in advance of bidding any proposed performance standards that we intend to use under the proposed fallback contract. The commenter also recommended that provisions be included in § 423.871 to ensure that any performance standards, as well as the requirements and process to establish that the standards have been met, cannot change during the term of a contract.

Response: In accordance with § 423.871, we may specify other contract terms during the bid solicitation process. The performance standards we intend to use under contracts will be provided in the fallback solicitation documentation prior to bidding. [Competitive procedures (as defined in section 4(5) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(5)] will be used in fallback plan contracting and potential fallback plan sponsors will need to compete on these performance measures. Under Part D plan contract terms and conditions, as described in § 423.516, we agree not to implement any significant regulatory requirements for a Part D plan other than at the beginning of the year.

7. Payment to Fallback Plans (§ 423.875)

As provided in § 423.875, the amount payable under approved fallback prescription drug contracts would be the amount determined under the specific contract negotiated for each such plan under § 423.871(e). In the proposed rule we proposed some alternative payment mechanisms, including draw down accounts and prospective payments, as well prospective or retrospective rebate allocation methodologies.

Comment: One commenter recommended that we use a prospective payment approach, and asked for more detail on how that system would work.

Response: We published separately the proposed guidelines on payment methodologies to Part D plans. Further guidance will be included in the fallback plan solicitation documentation. Our goals are to avoid any undue burden to fallback plans and at the same time develop a method of payment that requires a limited amount of adjustment.

R. Payments to Sponsors of Retiree Prescription Drug Plans

1. Introduction

Subpart R implements section 1860D–22 of the Act, which provides for subsidy payments to sponsors of qualified retiree prescription drug plans. Sponsors of qualified plans can receive an annual subsidy equal to 28 percent of specified retiree drug costs.

We received 87 comments on subpart R in response to the August 2004 proposed rule. Below we summarize the major proposed provisions in the subpart and respond to public comments. (For a detailed discussion of our proposals, please refer to the proposed rule (69 FR 46736).)

2. Options for Sponsors of Retiree Prescription Drug Programs

The enactment of Title I of the MMA has provided sponsors of retiree prescription drug plans with multiple options for providing drug coverage to their retirees. In the preamble of the proposed rule, we reviewed the various options available to sponsors. We believe the availability of these various options will encourage sponsors to continue to assist their retirees in having access to prescription drug coverage. For the benefit of the sponsors, we again summarize the options below.

Generally, employers and unions who offer drug benefits to their retirees (and their dependents) who are eligible for Medicare Part D can choose to:

(1) Continue to provide prescription drug coverage through employment-based retiree health coverage. If such coverage is at least actuarially equivalent to the standard prescription drug coverage under Part D (as defined in § 423.104 of the final rule), the sponsor is eligible for a special Federal subsidy for each individual enrolled in the sponsor's plan who is eligible for Part D but elects not to enroll in Part D;

(2) Contract with a prescription drug plan (PDP) or Medicare Advantage-prescription drug (MA-PD) plan to offer prescription drug benefits to retirees who are eligible for Medicare. Alternatively, the retiree plan sponsor itself could apply to be a Part D plan for its retirees. Such plan may consist of ''enhanced alternative coverage'' (as defined under § 423.104(f) of the final rule), offering drug coverage that is more generous than the standard prescription drug coverage under Part D (as defined under § 423.104 of the final rule); or

(3) Provide separate prescription drug coverage that supplements, or ''wraps around,'' the coverage offered under Part D plans in which the retirees (and their Medicare eligible dependents) enroll.

The first option is the subject of this subpart R. The latter two options, which involve the employer or union's retirees (and their dependents) enrolling in Part

D, were discussed in the preamble of the proposed rule for subpart J, § 423.454(b)

We note that if employers or unions elect to sponsor enhanced alternative coverage under Part D or provide separate supplemental coverage that wraps around Part D, this will affect the point at which their retirees (and their dependents) are eligible for catastrophic drug coverage, which will have consequences for the participants, the sponsors, the plans, and the Medicare program. As specified in subpart C of the final rule, individuals enrolled in a Part D plan are eligible for catastrophic drug coverage after they incur out-of-pocket drug costs in the amount specified under § 423.104(d)(5)(iii) of the final rule. Under the reinsurance provisions at § 423.329(c), Medicare will reimburse Part D sponsors 80 percent of their gross costs for providing catastrophic coverage (excluding administrative costs and reduced by any discounts, rebates, and similar price concessions). Only drug costs paid by a Part D enrollee, or on behalf of a Part D enrollee by another individual, a charitable organization or a qualified State Pharmacy Assistance Program but excluding insurers, government-funded health care programs, group health plans, and similar third party arrangements, would count toward the annual out-of-pocket threshold. We refer to those drug expenditures that count toward the out-of-pocket threshold as ''true out-of-pocket (TrOOP) expenditures.''

Under these rules, sponsors who provide retirees (and their dependents) enhanced alternative coverage in effect delay the point at which an individual's total drug spending will trigger catastrophic coverage, since participants in the plan will have lower cost-sharing, and thus have lower out-of-pocket costs. Similarly, when employers or unions sponsor supplemental coverage that wraps around Part D coverage, there will be an increase in drug expense that must be incurred before catastrophic coverage is triggered, since drug costs paid for by such plans do not count toward the out-of-pocket annual limit. By delaying the provision of catastrophic coverage, these plans lower the cost of Part D to the Federal government by lowering our reinsurance payments.

As discussed above, under MMA, sponsors of retiree prescription drug plans can provide coverage that supplements or ''wraps around'' the Part D standard benefit in two ways. First, plan sponsors can purchase integrated supplemental coverage directly from a specific Medicare prescription drug plan (PDP) or Medicare Advantage plan that includes prescription drugs (MA-PD). Second, plan sponsors can maintain a free-standing plan which is not tied to a specific PDP or MA-PD and is meant to supplement any of the Part D plans that Medicare-eligible retiree plan participants enroll in.

We also note that the choice between integrated and separate supplemental coverage has operational implications for plan sponsors. If the sponsor purchases integrated coverage through a PDP or MA-PD, the enrollment of retirees in Medicare Part D will be handled by the PDP or MA-PD. Under this approach, the dispensing pharmacy will only need to undertake one transaction to the PDP or MA-PD; there would not be separate standard Part D and supplemental coverage transactions. In contrast, when sponsors provide coverage through a separate plan, they (or their plan administrator) will only handle enrollment for their free-standing coverage; retirees will be responsible for enrolling in Part D coverage of their choice. We are sensitive to the concerns of plan sponsors regarding the operational challenges of coordinating separate plans with Part D plans. Therefore, we are exploring approaches that stakeholders may be able to use to coordinate benefits at point-of-sale among these plans through the use of a single point of contact for coordination of benefits and facilitation of TrOOP calculation at the Part D plan..

CMS has a program that can assist plan sponsors and administrators with identifying Medicare eligible individuals covered under their plans. This is a process called the Voluntary Data Sharing Agreement (VDSA) process. Plan sponsors that enter into VDSAs will be better prepared for enrolling their retirees into either integrated supplemental coverage through a Part D plan, establishing a separate plan to supplement or ''wrap around'' Part D coverage, or applying for the retiree drug subsidy. There is no requirement that any employer enter into a VDSA; it is strictly a voluntary process. (For more information on VDSAs, go to the website at *http://www.cms.hhs.gov/medicare/cob/employers/emp__vdsa.asp*). Other existing CMS programs permit group health plans and other secondary payers to sign agreements to receive Medicare paid claims data for the purpose of calculating their secondary payment liability.

When an employer or union elects to sponsor retiree coverage through a Part D plan, the employer, union or entity seeking to offer or administer such coverage may submit written requests to us for permission to waive requirements under Part D that hinder the design of, offering of, or enrollment in an employer-sponsored group prescription drug plan (as defined under § 423.454) or a MA-PD plan offered exclusively to the sponsor's retirees and their spouses and dependents. We believe these waivers will facilitate efficient administration and integration of sponsor-provided enhanced alternative coverage with other retiree health benefits offered by the sponsor. For example, the PDP or MA organization could request permission to restrict enrollment in its Part D plan to the retiree plan sponsor's retirees (and their dependents). Similarly, should the plan sponsor wish to enroll its retirees (and their dependents) in its own plan, with enrollment limited to such individuals, the sponsor could apply to be a Part D plan sponsor organization offering a PDP or MA-PD plan, and request such waivers as necessary. Further guidance on waivers will be provided to assist sponsors in evaluating this option.

We encourage plan sponsors to carefully review each option and determine which one is most beneficial to the sponsor and its retirees. We believe that the variety of options will encourage sponsors to retain drug coverage for their retirees.

3. Definitions (§ 423.882)

The final subpart R rules provide definitions that are critical to understanding how the retiree drug subsidy functions. We received comments regarding only a few of the proposed definitions under subpart R: group Health Plan, qualifying covered retiree, allowable retiree costs, and sponsor. We also amended the definition of gross covered retiree plan-related prescription drug costs based upon comments received in response to the definition of a covered Part D drug in § 423.100 in subpart C, and added a definition of sponsor agreement in response to comments received on the proposed rule.

A. *Group Health Plan*: In general, the subsidy is paid for allowable retiree costs in a sponsor's group health plan. The statute and the proposed regulations incorporated the definition of Group Health Plan that appears in section 607(1) of the Employee Retirement Income Security Act (ERISA), 29 U.S.C. 1167(1). (This is also the definition used in the health care continuation of coverage provisions of ERISA, as added by the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA).) The statutory definition, incorporated in the proposed regulations, also specifically includes

plans maintained for their employees by the Federal Government, plans maintained by State or local governments, and church plans exempt from Federal taxes, even if they are not subject to ERISA or COBRA requirements.

In the preamble to the proposed rule we said we intended to model our rules on the COBRA regulations (26 CFR § 54.4980B–2, Q.6) that apply for determining the number of group health plans sponsored by an employer or a union, which is important for purposes of applying the actuarial equivalence test. Under the COBRA rules, all health benefits provided by a single employer constitute one group health plan, unless it is clear from the instruments governing an arrangement or arrangements that health care benefits are being provided under separate plans, and the arrangement or arrangements are operated pursuant to such instruments as separate plans. The COBRA rules also provide that if a principal purpose of establishing separate plans is to evade any requirement of law, then the separate plans will be considered a single plan to the extent necessary to prevent the evasion. To the extent that the COBRA rules require that an arrangement be considered a single group health plan, the sponsor must follow special rules for determining actuarial equivalence described in section 4(b)(3) of this subpart of the preamble below.

Comments: Several plan sponsors, health plans, and employer advocacy groups suggested that we adopt the rules in the COBRA regulations for determining the number of plans sponsored by an employer or union, but remove the requirement that the arrangements be operated as separate plans. Some plan sponsors wanted the flexibility to differentiate between various groups of retirees within a single plan without compromising their plan's eligibility status. (For example, some sponsors separate their retirees according to years of service, family status, location, retirement date, coverage level, contribution structure, etc.) An actuarial association agreed that we should give employers and unions the flexibility to define plans and move away from a single plan definition to allow multiple benefit options to be included within a plan.

An employer advocacy group discouraged us from requiring a separate filing, other than the attestation of actuarial equivalence, to satisfy any documentation requirement for plan definition purposes. A beneficiary advocacy group approved the use of the COBRA rules for determining the number of plans, but suggested limits on how actuarial valuation rules should be applied if there are multiple drug benefit options.

Response: For the purposes of subpart R, the term group health plan will mean plans that meet the definition of group health plan in ERISA section 607(1), 29 U.S.C. 1167(1), including plans established or maintained for its employees by the Government of the United States, by the government of any State or political subdivision, or by an agency or instrumentality of the foregoing; plans established or maintained under or pursuant to one or more collective bargaining agreements; and plans established or maintained for its employees (or their beneficiaries) by a church or by a convention of churches which is exempt from tax under section 501 of the Internal Revenue Code. Provided they meet the definition of group health plan in ERISA section 607(1), those arrangements are treated as group health plans even if the plans are not subject to ERISA or COBRA. Sponsors should use the rules in the COBRA regulations and other guidance issued by the Treasury Department and Internal Revenue Service for determining the number of group health plans offered by a plan sponsor. However, as discussed in § 423.884, the final rule generally gives a sponsor with different benefit options (including different cost-sharing arrangements) within a single group health plan a significant degree of flexibility to choose whether to measure actuarial equivalence and receive subsidy payments for aggregated benefit options or to apply the rules separately for each benefit option.

Comments: A business advocacy group recommended that defined contribution accounts such as Health Reimbursement Accounts (HRAs), Health Savings Accounts (HSAs), Archer Medical Savings Accounts (MSAs) and Flexible Spending Arrangements (FSAs) be considered group health plans for purposes of qualifying for the retiree subsidy. In addition, they recommended that sponsors establishing account-style plans that credit amounts during an individual's active service toward retiree benefits have the discretion to allocate payments between medical and drug costs for purposes of the actuarial equivalence test.

Response: The final rule clarifies that Health Reimbursement Arrangements (HRAs) (as defined in Internal Revenue Service Notice 2002–45, 2002–28 I.R.B. 93, and Internal Revenue Ruling 2002–41, 2002–28 I.R.B. 75) and health Flexible Spending Arrangements (FSAs) (as defined in Internal Revenue Code (IRC) section 106(c)(2)) are treated as group health plans given the nature of these arrangements, including that they generally are treated as health plans by employers and unions subject to ERISA. The term group health plan generally will not include health savings accounts (HSAs) (as defined in IRC section 223) or Archer MSAs (as defined in IRC section 220), unless these accounts are treated as part of a group health plan under ERISA rules. While HSAs and Archer MSAs may not be group health plans, any high deductible plans that sponsors provide in connection with HSAs and Archer MSAs are group health plans.

However, regardless of whether an account-type arrangement is a group health plan, the nature of such a plan raises certain challenging questions for purposes of the retiree drug subsidy program. For example, how should the value of the prescription drug coverage available through an account be determined if the account can be used to pay for prescription drug coverage and other benefits? Will beneficiaries be able to adequately compare that arrangement to benefits available through Part D, particularly if the account stands alone and is not offered in conjunction with other types of coverage (such as high-deductible plans)? How can it be determined whether these arrangements are creditable coverage for purposes of implementing the late enrollment penalty in § 423.46?

We intend to offer further guidance on these issues and on what types of account-based arrangements can be considered for the subsidy.

Drug costs paid or reimbursed from funds in an HRA, which is generally funded solely by the employer, do not count as an incurred drug cost for purposes of the True Out-of-Pocket (TrOOP) rules, while drug costs paid or reimbursed from funds in other types of accounts, which can be funded by the employee, do count towards TrOOP. (See subparts C and J of this preamble (Coordination of Benefits), for a more detailed explanation of the rules for calculating TrOOP expenditures.)

B. *Qualifying Covered Retiree*: The statute defines qualifying covered retirees as Part D eligible individuals, who are not enrolled in a Part D plan but who are covered under a qualified retiree prescription drug plan. The statute indicates that qualifying covered retirees include Part D eligible individuals who are spouses and dependents of covered retirees. The proposed rule used the statutory definition without further clarification.

Comments: An association of actuaries requested that the final regulations clarify whether a qualifying covered retiree, under the retiree drug subsidy calculations, includes an employee who is receiving coverage following a disability and who is also entitled to Medicare Parts A or B on account of that disability (and therefore eligible for Part D). One employer advocacy group suggested that disabled Medicare-eligible individuals under age 65 be considered retirees for subsidy purposes, and that employers might drop coverage entirely if we decide not to allow it.

An employer advocacy group encouraged us to deem persons with End Stage Renal Disease (ESRD) as qualified retirees for purposes of the subsidy, because these individuals might receive lower drug coverage without such designation.

A government association sought clarification on the status of domestic partners who are Part D eligible individuals and their eligibility as qualifying covered retirees' dependents, for purposes of calculating the retiree drug subsidy.

Response: For the purposes of subpart R, the term qualifying covered retiree means a Part D eligible individual who is: (1) a participant or the spouse or dependent of a participant; (2) covered under employment-based retiree health coverage that qualifies as a qualified retiree prescription drug plan; and (3) not enrolled in a Part D plan. In general, sponsors will have flexibility to determine whether an individual is a retiree, and to determine who are dependents of retirees based on the coverage rules under the plan. However, a participant is presumed to not be a retiree if the person is receiving health coverage based on current employment status as determined under the Medicare Secondary Payer (MSP) rule (§ 411.104 of this chapter) (regardless of whether such rules apply to the sponsor). We believe this approach gives reasonable flexibility to sponsors in terms of defining who is a retiree or dependent for purposes of the subsidy provisions. Under this definition, for example, sponsors generally can treat a person who is entitled to Medicare based on disability as a retiree for these purposes; sponsors can treat as a dependent any person to whom the sponsor is providing coverage in connection with a qualified covered retiree even if the person is not the retiree's dependent for Federal or State tax purposes; and they can treat as retirees self-employed persons and other individuals who previously provided services to the sponsor of the group health plan on a contractual, rather than employment, basis.

End Stage Renal Disease (ESRD) beneficiaries who are not active workers meet the definition of a qualifying covered retiree if they do not enroll in Part D. Accordingly, sponsors can count for purposes of the retiree drug subsidy the allowable retiree costs of ESRD beneficiaries, including those costs incurred in the first 30 months of eligibility when the sponsor's plan is primary to Medicare.

Comments: Comments from employers, employer advocates and government entities informed us that the retiree drug subsidy program not only affects retirees of the sponsors, but also the possible dependents of non-Medicare eligible workers or retirees who will be eligible for Medicare and therefore covered by the reporting requirements.

Response: In response to the comments regarding non-Medicare eligible, active employees who have dependents who are Medicare Part D eligible individuals, the sponsor would not be eligible to claim the subsidy for the dependents because the covered worker is not in a retiree status. For covered retirees who are not themselves Part D eligible individuals, but who have dependents who are Part D eligible individuals, the sponsor would be able to claim the dependents' eligible prescription drug expenses under the subsidy.

C. *Gross covered retiree plan-related prescription drug costs*: The proposed rules defined this term as ''non-administrative costs incurred under the plan for *covered Part D drugs* during the year ... including costs directly related to the dispensing of *covered Part D drug*''. Section 423.100 of the final rule now makes a distinction between a ''covered Part D drug'' and a ''Part D drug.'' A ''Part D drug'' is a drug that may be covered under Part D pursuant to section 1860D–2(e) of the Act and a ''covered Part D drug'' is a Part D drug that is in a Part D plan formulary. For purposes of calculating the appropriate drug costs for the retiree drug subsidy, sponsors of retiree prescription drug plans may count costs incurred for any drug that can be covered under Part D. Accordingly, we have changed the definition of gross covered retiree plan-related prescription drug costs to mean non-administrative costs incurred under the plan for *Part D* drugs during the year ... including costs directly related to the dispensing of Part D drugs.

D. *Allowable Retiree Costs*: The proposed rule defined Allowable Retiree Costs as gross covered retiree plan-related prescription drug costs between the cost threshold and cost limit that are actually paid by either the qualified retiree prescription drug plan or the qualifying covered retiree (or on the retiree's behalf), net of any manufacturer or pharmacy discounts, chargebacks, rebates, and similar price concessions.

Comments: Several beneficiary advocacy groups wanted us to adopt a definition of allowable retiree costs that included only the employer's financial contribution to retiree drug coverage, not any of the payments made by the retiree. They believe that including contributions from the retiree could result in ''improper cost shifting.''

Response: There is no statutory authority to exclude retirees' payments in the definition of allowable retiree costs. The statute specifies that retiree drug subsidy payments are made for gross covered prescription drug costs paid by or on behalf of a qualified covered retiree. Thus, as long as coverage meets the actuarial equivalence standard, costs paid by the retiree will be included along with sponsor payments under the plan in determining retiree drug subsidy payment amounts.

Comment: An association of actuaries found it difficult to understand what we are is defining as gross costs to be used in determining allowable retiree costs, but this might be due to a simple terminology difference, so they suggest we provide examples to clarify what costs should be used.

Response: The statute indicates that gross covered retiree plan-related prescription drug costs are costs incurred under the plan, not including administrative costs but including the costs directly related to the dispensing of Part D drugs. The final rule retains the basic statutory definition. We may (if needed) issue further guidance to clarify what costs constitute gross covered retiree plan-related prescription drug costs.

Comment: A government entity found the term price concessions problematic because, as used in its contract with a pharmacy benefit manager (PBM), that term refers to confidential and proprietary information. Also, rebates are included in the pricing quoted to the PBM, and are not an identifiable line item that can be easily subtracted to determine allowable retiree costs.

Employer groups requested that we distinguish what will be included in the definition of price concessions for the purpose of calculating allowable retiree costs.

Specifically, the groups provided a number of comments on why price concessions relating to performance guarantees and point-of-sale discounts

should not be included in allowable retiree costs.

They claim that including such price concessions when calculating allowable retiree costs would require a large, nearly impossible administrative burden. Performance guarantees or incentives, as well as point of sale discounts, lower the price of the prescription drug in a manner that would make it burdensome for the sponsor to determine the gross allowable costs. Thus, the employer groups argue that, in the instance where performance guarantees and point-of-sale discounts occur, reporting the actual cost to the sponsor as the gross cost should be sufficient.

Response: The statutory provisions of the MMA specify that allowable retiree costs may include only costs actually paid by the sponsor or by or on behalf of a qualifying covered retiree, and that rebates, chargebacks and average percentage rebates must be subtracted from those costs. To comply with the statute, the final regulation retains the requirement that these and similar price concessions be taken into account in determining allowable retiree costs.

We anticipate providing any additional clarification that is required for price concessions in further guidance. However, pending such guidance, performance guarantees that are not predicated on actual drug costs incurred, but rather on matters such as customer service performance standards or identification card delivery, are likely not the types of price concessions that need to be taken into account in determining allowable retiree costs. Moreover, to the extent point-of-sale discounts and other price concessions are passed through to the beneficiary and plan at the point-of-sale for a given drug expense, the allowable retiree costs and gross covered retiree plan-related prescription drug costs for the expense would be equal, and the point-of-sale discounts and other price concessions would not have to be further subtracted from these costs when a sponsor calculates allowable retiree costs as defined in § 423.882.

Comments: For sponsors with fully insured plans, a health industry association and insurers ask that we provide sponsors with the flexibility to have the retiree drug subsidy calculated based on the sponsor's premiums, using reasonable actuarial methods to determine what portion of the premium is allocated to gross covered prescription drug costs of qualifying covered retirees within the cost threshold and cost limits. Commenters support that position by arguing that employers and unions purchasing insurance do not pay actual incurred drug costs; they pay a premium based on expected costs, which may be pooled with a broader group of employers and unions. In a given year, an employer's or union's retirees may incur drug costs that are more than or less than the premium paid. They expressed concern that if drug costs actually paid by the insurer rather than premiums paid by the employer or union were the measure for subsidy payments, for any given retiree the employer or union would be getting a subsidy payment that is likely higher or lower than the allowable cost actually incurred by the employer or union (via the premium) for that retiree.

As noted, the commenters propose using reasonable actuarial methods to determine a percentage of the premium that approximates what was paid for Part D-eligible retirees within the cost thresholds and cost limits. They also request being allowed to perform these calculations on an aggregate basis for all employers and unions with a specific retiree drug plan, since the experience for the employers and unions is pooled when determining premiums.

Another fully insured plan sponsor recommended that if the plan sponsor contracts with an at-risk health plan, the retiree drug subsidy should be a flat payment based upon the amount paid instead of adjusted for actual experience and requested clarification as to how we anticipate the subsidy to be integrated with fully insured plans.

Response: The statute specifically requires that a subsidy payment be based on allowable retiree costs attributable to gross covered retiree plan-related prescription drug costs, which are actual prescription drug costs incurred under the plan (not including administrative costs but including costs directly related to the dispensing of Part D drugs) for a qualifying covered retiree. In general, we believe the statute envisions that the incurred costs are costs actually paid by the insurer for each qualifying covered retiree. However, we also recognize the concerns that were raised in the comments. Therefore, in lieu of submission of the cost data under § 423.888(b)(2), the sponsor and insurer may choose instead to have data submitted in the following manner. If an sponsor chooses monthly, quarterly or interim annual payments as described in § 423.888(b)(5), the interim subsidy payments made during the year can be based on a determination by the insurer using reasonable actuarial principles that allocates a portion of the premium costs charged to the sponsor (excluding administrative costs, risk charges, etc., but including premium costs that the sponsor requires the retiree to pay) to the gross covered prescription drug costs incurred for a sponsor's qualifying covered retirees between the cost threshold and the cost limit. If the insurer determines premiums based on the pooling of a sponsor's experience in a given policy, the insurer will be permitted to make such determination based on the aggregate experience incurred under the policy for the sponsor's qualifying covered retirees. However, a revised cost determination must be submitted to us (within the same time frame that year-end data is required under § 423.888(b)(4)) that reflects the actual allowable retiree costs attributable to gross retiree plan-related prescription drug costs within the cost limit and cost threshold that were incurred under the plan for each of the sponsor's qualifying covered retirees. Thus, we must receive data described in § 423.888 that indicates the extent to which actual gross costs and allowable costs for a sponsor's qualifying covered retirees were more or less than the sponsor's previously-allocated premium costs. We will accept data submitted directly by the insurer. Upon receiving this data, we will adjust the payments made for the plan year in question in a manner to be specified by us.

Comment: Several plan sponsors wanted clarification that subsidy payments go to the plan sponsor, not the insurer.

Response: The statutory language is clear that the retiree drug subsidy is paid to the plan sponsor.

Comment: Commenters suggested that we provide guidance on whether the prices negotiated with sponsors of qualified retiree prescription drug plans are exempt from the Medicaid best price calculation.

Response: In section 1927(c)(1)(C) of the Act, best price is defined as the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, non-profit entity, or governmental entity within the United States. Among the exemptions listed in the statute are any prices charged which are negotiated by a qualified retiree prescription drug plan as defined in section 1860D–22(a)(2) of the Act. Therefore, prices negotiated between a qualified retiree prescription drug plan sponsor and a manufacturer will not go into the Medicaid best price calculation.

E. Sponsor:

The proposed regulations state that sponsor means plan sponsor as defined in ERISA (29 U.S.C. 1002(16)(B)), which is an employer in the case of an

employee benefit plan established or maintained by a single employer or an employee organization (for example, trade union) in the case of a plan established or maintained by an employee organization. In the case of a plan established or maintained by two or more employers or jointly by one or more employers and one or more employee organizations, ERISA defines the sponsor as the association, committee, joint board of trustees or other similar group of representatives of the parties who establish or maintain the plan. The MMA modifies the definition when the plan is maintained jointly by one employer and one employee organization; if the employer is the primary financing source, sponsor means only the employer.

Comments: A governmental organization indicated that plans such as its own are exempt from ERISA and therefore may not fall within the strict definition of an ERISA plan. This plan believes that Congressional intent was to include plans like it, and requests that we include a provision to allow governmental plans offering a qualified retiree prescription drug plan to receive the retiree drug subsidy.

A State government entity expressed concern over the definition of sponsor and whether or not it would be included under the Part D final regulations even though it is not covered under ERISA. A national association of public employee retirement systems indicated its preference that the final regulations not contain a definition of plan sponsor, or if they must, that the definition of plan sponsor defer to applicable State and local laws and regulations. The association suggested this because they think that imposing a definition in the final regulations could have unintended impact on State and local laws.

Response: As noted above, the definition of a group health plan includes plans sponsored by Federal and State government plans and their political subdivisions, agencies and instrumentalities. Thus, we agree that under the MMA, States and other governmental organizations can potentially qualify as sponsors. We believe the definitions for sponsor and for group health plan as stated in the proposed rule clearly indicated this. We believe a more specific definition of a sponsor in the final rule that takes into account the various types of sponsor arrangements that may exist would be problematic. We will consider issuing additional guidance to sponsors based on their particular facts and circumstances.

F. Benefit option:

In response to comments we received on applying the actuarial equivalence test to individual plans (summarized in the discussion of actuarial equivalence in section 4(b)(3) of the preamble, below), we have added in the final rule a definition of benefit option, which we define as a particular benefit design, category of benefits, or cost-sharing arrangement offered within a group health plan.

4. Requirements for qualified retiree prescription drug plans (§ 423.884)

(a) Overview

(1) General Requirements

In the proposed rule, we outlined the general requirements for applying for the retiree drug subsidy, including the submission of an attestation of actuarial equivalence and the disclosure notices to beneficiaries. We requested comments on the most effective methods of conducting outreach as well as prospective venues for conducting the outreach.

Comments: Several commenters emphasized that it was critical that we provide guidance on the retiree drug subsidy process as soon as possible in light of the fact that enrollment is to begin in 2005. Several comments requested that we publish the final rule by December 31, 2004 and issue guidance before that date.

Response: We respect the prospective sponsors' need to have guidance on the retiree drug subsidy as soon as possible due to the complexity and timing of the process. In addition to promulgating this final rule and issuing other guidance as quickly as possible, we will continue to conduct outreach to various groups to educate the stakeholders on the requirements for applying for the retiree drug subsidy.

(2) Privacy and Confidentiality

The HIPAA Privacy Rule at 45 CFR part 160 and subparts A and E of part 164 (''Privacy Rule'') applies to ''covered entities,'' which include group health plans and health insurance issuers, as defined in 45 CFR 160.103. Third party administrators would be business associates, as defined in 45 CFR 160.103, of group health plans. Sponsors would not become covered entities by sponsoring a plan. Sponsors typically do not perform administrative activities for their group health plans and therefore do not have access to the claims information or similar protected health information (PHI) we require in this regulation to support the retiree drug subsidy payment. Much of the data that we would need to support the retiree drug subsidy payments, as outlined above, would be PHI held by group health plans, health insurance issuers, or third party administrators on behalf of group health plans.

As indicated in the proposed rule, we believe that we have the authority to mandate the disclosure of the PHI in accordance with our oversight authority under section 1860D–22(a)(2)(B) of the MMA, and covered entities on behalf of individuals eligible for benefits under Part A or Part B can comply with the mandate (without first obtaining specific authorization from individuals) pursuant to ''the required by law'' provisions of the Privacy Rule (45 CFR 164.512(a)). We have added a paragraph, § 423.884(b) to clarify that a disclosure to us by a group health plan or health insurance issuer is required by law when necessary for the sponsor to comply with this subpart.

As noted above, typically group health plans and issuers or third party administrators acting on behalf of group health plans, have PHI that CMS requires for the submission of cost and claims data for payment of the retiree drug subsidy pursuant to § 423.888(b)(2) and other sections. In these situations, it may be unlawful, under the Privacy Rule, for PHI to be shared with the sponsors. Therefore, for purposes of this subpart, the sponsor must have a written agreement with the group health plan or health insurance issuer, as applicable, regarding disclosure of records, and the plan or issuer must disclose to us, on the sponsor's behalf, the information necessary for the sponsor to comply with this subpart. Sponsors of self-funded plans with access to such data will be able to either provide this data to us themselves or have a group health plan or insurer provide the data to us on their behalf. We asked for comments on the impact this transfer of data will have on the plan sponsors, group health plans, issuers and third party administrators.

Comments: An business consulting firm indicated that employers do not collect Medicare information on their retirees because of HIPAA privacy concerns and that requiring employers to store this data will add a great deal of administrative complexity and cost. A pharmaceutical company recommended that we require that only total aggregate cost data (not broken out by individual retirees) be submitted to us for payment purposes in order to protect patient privacy. An employer advocacy group agreed that we have the authority to mandate disclosure of PHI for retiree drug subsidy purposes and requested that we clarify that individual authorization not be required for such disclosure. A human resource

management association also agreed that we have the authority to mandate disclosure of PHI and requested that we clarify that the disclosures will not violate State privacy statutes.

Response: As noted above, employers will not be required to collect or maintain Medicare data on their retirees for purposes of collecting the retiree drug subsidy. They can direct their group health plans or health insurance issuers, as well as third party administrators (or other business associates), to submit the required protected data to us on their behalf. We agree that individual authorization will not be required for the disclosure of the data to us since the disclosure is required by this regulation for purposes of payment of the retiree drug subsidy.

The HIPAA Privacy Rule preempts a contrary provision of State law except in specific circumstances, such as if the State law is more stringent-that is, more protective of privacy-than the Privacy Rule. (See 45 CFR Part 160, subpart B). Therefore a sponsor, or an issuer, plan or third party administrator on behalf of a sponsor, may need to comply with State privacy laws as well as the HIPAA Privacy Rule in disclosing information to us.

Comments: Several pharmaceutical companies requested that we extend the confidentiality protections under the Medicaid rebate law to data submitted to us under § 423.888.

Response: We agree that the rebate information being disclosed to us is confidential. We believe that protections provided under other sections of the regulation will ensure this. We anticipate issuing further guidance regarding this issue.

(b) Actuarial Attestation

In order to be eligible for a subsidy, the coverage of a sponsor's qualified retiree prescription drug plan must be at least actuarially equivalent to the standard Part D coverage. The sponsor will have to annually submit to us an attestation that its coverage meets this requirement. We discuss below the methodology and the standards for the sponsor submission of the actuarial attestation.

1. Timing, Who Can Submit, and Public Access to Data

(a) We proposed to require that the attestation be submitted to us before September 30, 2005 for the calendar year 2006 and at least 90 days before the beginning of the calendar year (or plan year, depending on whether the final rule used a plan year approach) for subsequent years. We also proposed to require that an attestation be submitted to us at least 90 days prior to the effective date of any material change to the drug coverage of the plan that impacts the actuarial value of the coverage.

Comments: Among the comments that we received, a business consultant requested that we shorten the time period for submission of the actuarial attestation to 30 days prior to the start of the year because most employers and unions do not know their final plan design 90 days in advance. An actuarial consultant, on the other hand, indicated that the 90 day timeframe was reasonable and sufficient to accomplish the objectives of the MMA. We received comments from several employer groups recommending that we not require subsequent annual attestations from sponsors that had not implemented any changes in their retiree drug coverage since the previous submission of the attestation for the plan.

Response: In the final rule, we require that the attestation be submitted 90 days before the start of the plan year and by September 30, 2005 for plan years ending in 2006 (see our discussion of plan year vs. calendar year under § 423.888), unless an extension request has been filed by the date under rules specified by the Secretary. We also require the filing of attestations 90 days prior to the effective date of any material change. We believe this process provides us sufficient time to review the attestation and to notify the sponsor of any problems (for example, attestation not signed by a qualified actuary), yet is flexible enough to permit extensions in necessary cases.

The final rule retains the requirement that sponsors submit a new actuarial attestation on an annual basis, even if a sponsor has not implemented any changes to its retiree coverage since the previous submission of the attestation for the plan. The thresholds for Part D coverage will change each year and this may impact whether the sponsor's plan is actuarially equivalent.

Comment: A beneficiary advocacy group indicated that a requirement of 90 day advance notice to beneficiaries of any change that will render coverage no longer actuarially equivalent is an important protection.

Response: To be consistent with the policy on creditable coverage and reflect statutory requirements, the final rule requires that sponsors provide notice to beneficiaries prior to any change that will render coverage no longer creditable. See the discussion in subpart B of the preamble for further guidance on creditable coverage notice requirements. Advance notice regarding changes in actuarial equivalence is not required by the MMA, and we decline to impose that requirement in the final rule. See also our response to the following comment.

Comment: Several union and beneficiary advocacy groups recommended that we provide public access to the assumptions and methods used by sponsors for their attestations of actuarial equivalence. A union suggested that we develop a form, similar to the Department of Labor's 5500 form (used for ERISA disclosures), for sponsors to file with their attestations, which would then be accessible for public inspection. The unions and beneficiary advocates indicated that public access to this data would increase public confidence in the retiree drug subsidy program and would permit the retirees to monitor the sponsors' filings for accuracy. Business advocacy groups indicated that the Congress neither required employers or unions to disclose their actuarial equivalency calculations to anyone but us for audit purposes, nor gave individuals the right to challenge an employer's or union's actuarial equivalency determination. An actuarial consultant recommended that the attestation of actuarial equivalence and the application for the subsidy should be submitted and therefore disclosed to CMS only. The consultant indicated that the data submission and the application may have proprietary information embedded in it, as well as beneficiary data subject to privacy concerns.

Response: While we understand the rationale for requiring public disclosure of certain attestation data, we have concerns that requiring public disclosure of the assumptions and methods used for the actuarial attestation could inhibit the desire of sponsors and their service providers to file for the subsidy and to maintain their retiree drug benefits, for example, for fear of disclosure of proprietary data. We want to further study this issue to determine if there is a level of public disclosure of attestation data that will enhance beneficiary confidence in the retiree drug subsidy program but will not deter sponsors from filing for the subsidy and maintaining their retiree coverage.

(b) In the proposed rule, we require that the attestation be certified by the attesting actuary. We also required that the attesting actuary be a member of the American Academy of Actuaries.

Comments: We received several comments from small employers stating that we should accept attestations of actuaries with the insurance carriers or with third party administrators who can attest on behalf of the sponsor that the sponsor's retiree drug coverage is

actuarially equivalent to Part D. It was indicated that small employers may not have the resources to hire an actuary for the attestation.

Response: We agree that sponsors can submit attestations of actuaries employed by insurance carriers, pharmacy benefit managers or the third party administrators of their retiree drug plans. The attestation will be submitted in a form or forms approved by us in additional guidance. We expect to require the attestation to solely address the sponsor's plan and meet all requirements for the attestation.

Comment: One health care industry organization requested that due to the cost of an annual attestation, small employers should be allowed to submit an application, their eligibility list and plan benefit descriptions, provide us with two years of experience or premium data, and have our actuaries perform the attestation on behalf of their plan.

Response: The statute states that, as a condition of receiving the retiree drug subsidy, the sponsor must provide the attestation to us. As indicated above, a sponsor can have an outside actuary do the attestation and the attestation may be submitted directly by such outside actuary or by the plan sponsor to us pursuant to the procedures outlined in this final rule.

2. Establishing Actuarial Equivalency

In the proposed rule, we outlined three options for the actuarial equivalence standard. The first option was a single prong gross value test in which the plan design of the sponsor's retiree drug plan will be compared with the plan design of standard prescription drug coverage under Part D without taking into account the financing of the coverage. This test would generally require that the expected amount of paid claims (or plan payout) under the retiree prescription drug coverage be at least equal to the expected amount of paid claims under the standard Medicare Part D benefit. The second option involved using the ''gross value'' test as in option one but restricting the subsidy payment to no more than what the sponsor contributed towards the cost of the retiree drug coverage. The third option was a two-prong test in which the first prong is the gross value test as in option one, and the second prong is a net value test which takes into account the sponsor's contribution toward the financing of the retiree prescription drug coverage.

The proposed rule also discusses several variants for determining the value of the second prong of option three, the net value test. The lowest variant proposed is the average per capita amount that Medicare will expect to pay for the retiree drug subsidy. A second variant was the after-tax value of the retiree drug subsidy, since the subsidy is not subject to Federal income tax. The highest variant stated in the proposed rule would compare the gross value of the plan design reduced to account for the level of benefits financed by the beneficiary (that is, by subtracting out the retiree premiums) to the expected value of paid claims under standard prescription drug coverage under Part D minus the retiree's expected monthly beneficiary premium for the coverage. As we indicated in the preamble to the proposed rule, adopting a higher variant for the net value could arguably provide greater protection for beneficiaries against cost-shifting but also make it more difficult for sponsors to qualify for the subsidy. Conversely, adopting a lower variant would allow more sponsors to qualify for the subsidy but may discourage some employers and unions from increasing their contributions to reach the higher threshold level.

Comments: We received numerous comments on this standard. The vast majority of the comments, including those from both the business groups and beneficiary advocacy groups, supported the two-prong test (option three) as best serving our stated goals of maximizing the number of retirees that retain their employer and union retiree drug coverage and not creating windfalls to the sponsors. Several comments supported the single prong gross value test (option one) because they felt there was no legislative authority to require any other test. The comments were varied regarding the value of the second prong of option three, the net value test. The beneficiary advocacy and union groups generally supported the highest variant stated in the proposed rule, asserting that lower values would allow sponsors to shift additional costs to retirees while still qualifying for subsidy payments. They believe a higher variant would give sponsors a disincentive for such cost-shifting. Employer and business groups supported the lowest variant, the expected per capita value of the retiree drug subsidy. They expressed concern that higher thresholds would make fewer employers and unions eligible for the subsidy, and thus conflict with the critical goal of giving as many employers and unions as possible an incentive to retain their retiree coverage.

Several employer groups proposed an additional variant for the net value test. The subsidy provides an incentive to sponsors to continue providing retiree drug coverage rather than reduce coverage and provide benefits that supplement those provided under standard prescription drug coverage under Part D. Therefore, in determining whether the drug coverage provided under a sponsor's group health plan is of sufficient value to qualify for the subsidy, the employer groups argued that the sponsor's coverage should be compared to the value of the standard prescription drug coverage that a retiree would receive if the retiree had both the Part D coverage and the sponsor's supplemental coverage. This approach will have the effect of delaying the point at which the individual can qualify for catastrophic coverage under Part D, which is only available when an individual's true out-of-pocket (TrOOP) expenses exceed a specified threshold. Because beneficiary out-of-pocket drug costs reimbursed through group health plans are excluded from TrOOP, the existence of employer or union coverage that reimburses retirees for some of their out-of-pocket drug costs would mean it would take longer for the beneficiary to qualify for catastrophic coverage under his or her Part D plan, and the value of the Part D coverage to the retiree therefore would be less.

These same groups also proposed that we allow sponsors to use the expected per capita value of the retiree drug subsidy as a proxy for this test since, by their calculation, both tests result in approximately the same value for Part D.

Response: While the single prong gross value test will maximize the number of beneficiaries retaining their employer and union-based drug coverage, it will be the most likely of all the options to create windfalls to the sponsors. The second option raised in the proposed rule using the gross value test as in option one but restricting the subsidy payment to no more than what the sponsor paid into the retiree drug coverage has the advantages of eliminating windfalls and being simple to describe and operationalize. However, we had questions about the adequacy of the legal basis underpinning that policy, and we did not receive any comments that would help alleviate those legal questions.

Accordingly, we agree with the majority of the comments that the two-prong test (option three) accomplishes our goals of maximizing the number of beneficiaries retaining employer and union-based retiree drug coverage while not creating windfalls to sponsors. Thus, our final regulations state that in order to qualify for the retiree drug subsidy, a sponsor's plan must meet the gross value test (which is equivalent to

the test used in determining whether coverage is creditable prescription drug coverage under § 423.56), and an additional test that takes into account retiree premium payments.

Balancing the various policy goals and statutory restrictions in determining the appropriate way of valuing standard prescription drug coverage (to which sponsors should be comparing their coverage under the net value test) is a difficult challenge. The more stringent we set the standard, the fewer the number of sponsors that will qualify for the subsidy, which will likely have an adverse impact on the future availability of retiree drug coverage. However, a higher value is less likely to create windfalls to sponsors. In addition, as noted above, we believe the applicable statutory provisions under section 1860D–22(a)(2)(A) of the Act impose some constraints on the methods that can be used in determining actuarial values for this purpose.

We believe the most appropriate way of balancing these competing issues is to establish in the final rule that employment-based retiree drug coverage satisfies the actuarial equivalence standard if its actuarial value (as determined after reducing the gross value of the benefit by expected retiree premiums) is at least equal to the net value of defined standard prescription drug coverage under Part D (as determined after reducing the gross value of the benefit by the expected monthly beneficiary premiums), with the net value of the defined standard prescription drug coverage reflecting the impact of employer or union-sponsored prescription drug coverage that would supplement the beneficiary's defined standard prescription drug coverage. As explained previously, the existence of coverage supplemental to the standard prescription drug coverage would postpone the point at which the retiree would receive catastrophic coverage under defined standard prescription drug coverage (as defined under § 423.100). This would have the effect of decreasing the expected amount of paid claims under the defined standard prescription drug coverage, and thus would decrease the actuarial value of the coverage.

We agree with commenters that it is reasonable to take this approach given that many employers and unions will be deciding between continuing to provide retiree drug coverage as a primary payer for retirees (and accept a subsidy), and coordinating their retiree drug coverage with Part D (with the sponsor becoming a secondary payer for Part D drugs). Sponsors are likely to consider the impact of their supplemental coverage on the value of the Part D benefit for their retirees (for example, reducing the value of the reinsurance subsidy for catastrophic coverage) in their calculations. We believe that using this approach will help maximize the number of Medicare beneficiaries that retain their employment-based retiree coverage.

Because § 423.100 defines the term ''standard prescription drug coverage'' under Part D to mean either defined standard prescription drug coverage or actuarially equivalent standard coverage, we clarify that sponsors must use defined standard coverage (and not actuarially equivalent standard coverage) as the fixed point of comparison for applying the actuarial equivalence standard.

We disagree with commenters who suggested that we lack the legal authority to adopt a two-prong net actuarial equivalence. We believe our two-prong net actuarial equivalence best reflects Congressional intent. Under section 1860D–22(a)(2)(A) of the Act, the sponsor of employment-based retiree health coverage is entitled to the retiree subsidy only if the sponsor provides us with an attestation that the ''actuarial value of the prescription drug coverage under the [sponsor's] plan ... is at least equal to the actuarial value of standard prescription drug coverage.'' As discussed above, were we to interpret this statutory provision as only allowing an actuarial equivalence standard that compares the gross value of the prescription drug benefits provided under the sponsor's plan to the gross value of the benefits provided under standard prescription drug coverage, sponsors who contribute little or nothing toward the cost of their retirees' prescription drug coverage would receive a windfall. We do not believe the Congress intended to provide subsidies to sponsors when the sponsor's retirees pay all or most of the plan premium for prescription drug coverage. The conference report to the MMA explains that the purpose of the retiree subsidy is to help employers retain and enhance their prescription drug coverage so that the current erosion in coverage would plateau or even improve. (See H.R. Conf. Rep. No. 108–391, at 484 (2003)). This erosion in employer-sponsored prescription drug coverage reflects the rising financial burden for sponsors who finance, in substantial part or in whole, the cost of such coverage. (See ''Current Trends and Future Outlook for Retiree Health Benefits: Findings from the Kaiser/Hewitt 2004 Survey on Retiree Health Benefits'') As suggested in the Conference report, providing a subsidy to these sponsors would lower their financial cost of providing retiree prescription drug coverage, thereby decreasing the likelihood a sponsor will terminate such coverage. However, providing a subsidy to sponsors that bear little or none of the cost of providing retiree prescription drug coverage but instead shift the cost of such coverage to retirees would do little to reverse this trend. We believe we have an obligation to interpret the statute in a manner that would avoid the absurd result of providing a windfall to sponsors that bear little or none of the cost of their retiree prescription drug coverage, thereby giving effect to the Congress' likely intent.

We also believe our interpretation reflects a permissible reading of the statute. We believe the statute affords us significant discretion in adopting a methodology to determine actuarial equivalence under Part D, including for purposes of the retiree subsidy. First, we interpret section 1860D–11 of the Act as allowing us to establish more than one process for assessing the actuarial value of prescription drug coverage. Section 1860D–11(c)(1) of the Act states that the Secretary ''shall establish processes and methods for determining the actuarial valuation of prescription drug coverage, including—(A) an actuarial valuation of standard prescription drug coverage under section 1860D–2(b).'' We believe the use of the plural terms ''processes'' and ''methods'' authorizes us to adopt a methodology for determining actuarial equivalence for purposes of the retiree subsidy that differs from the methodologies used to determine actuarial equivalence under other sections of this Part, such as the determination of whether alternative coverage is creditable prescription drug coverage under § 423.56 of the final rule.

Second, we believe our interpretation of the actuarial equivalence requirement under section 1860D–22(a)(2)(A) of the Act to take into account the sponsor's financial contribution finds support under section 1860D–2(c)(1) of the Act. Section 1860D–2(c)(1) of the Act establishes a multi-step test for comparing the actuarial value of alternative prescription drug coverage to standard prescription drug coverage. In the first step under section 1860D–2(c)(1)(A) of the Act, the Secretary looks only at plan design and ensures that the actuarial value of the total coverage provided under the alternative prescription drug coverage is at least equal to the actuarial value of standard prescription drug coverage.'' In the second step under section 1860D–2(c)(1)(B) of the Act, however,

government financing is taken into account. Section 1860D–2(c)(1)(B) of the Act provides that the ''unsubsidized value of the [alternative] coverage must be at least equal to the ''unsubsidized value of standard prescription drug coverage.'' The unsubsidized value is determined by subtracting the government reinsurance and direct subsidies provided under section 1860D–15 of the Act from the total value of the alternative prescription drug coverage. While this is the inverse of how sponsors will determine the actuarial value of prescription drug coverage provided under their plans and standard prescription drug coverage for purposes of this subpart, it does demonstrate that the Congress believed that a determination of the actuarial value of prescription drug coverage could take into account the financing of the coverage.

We also note that there is precedent for us taking into account financing in determining the value of coverage. For example, in accordance with section 1854(e) of the Act, currently premiums are included in the comparison of beneficiary liability for cost sharing under a MA plan to the cost-sharing required under original fee-for-service Medicare, although we note that premiums will not be included in this comparison beginning in 2006.

Comment: We received several comments from employer groups and actuarial consultants requesting that we not issue a fixed numerical value for the net value test and allow sponsors to calculate a value based upon their own claims experience. Some commenters had requested advance indication of safe harbors relating to minimum benefit designs that would meet the requirements for actuarial equivalence to ease the uncertainty associated with the various filing processes and increase the likelihood of filing success.

Response: We agree with commenters requesting that we not issue a fixed numerical value for the net value test and instead will require sponsors to calculate the value of the prescription drug coverage provided under the sponsor's plan and defined standard prescription drug coverage under Part D based upon their own claims experience for plan participants or their spouses or dependents who are Part D eligible individuals. Section 1860D–22(a)(2) of the Act requires sponsors to provide an attestation of actuarial equivalence ''with respect to a Part D eligible individual who is a participant or beneficiary under'' the sponsor's plan. We believe requiring sponsors to base their actuarial valuation on these individuals' claims experience best reflects the true value of the prescription drug coverage under the plan, as compared to the defined standard prescription drug benefit, for those individuals. However, we recognize that not all sponsors will have sufficient claims data to support a reasonable calculation of the actuarial value of prescription drug coverage under the sponsor's plan and defined standard prescription drug data based on actual claims data. We will allow these sponsors to utilize alternative normative databases in accordance with CMS guidance.

We will issue further guidelines on the appropriate methodology for the actuarial equivalence test in line with the standard outlined above. The guidelines will include simplified actuarial methods that could be used to qualify for the retiree drug subsidy. We believe these simplified methods will be particularly useful for sponsors that may have difficulty measuring the impact of their benefit design on the value of defined standard prescription drug coverage because the design differs significantly from the defined standard prescription drug coverage.

For example, we anticipate that if there is an out-of-pocket maximum in the sponsor's plan (that is less than the out-of-pocket threshold under § 423.104(d)(5)), sponsors will be able to disregard the value of Part D catastrophic coverage that would be provided if participants enroll in defined standard prescription drug coverage under Part D. We also anticipate developing and publishing simplified actuarial methods for comparing a sponsor's plan with the defined standard prescription drug benefit that includes the actuarial impact of any supplemental employer or union coverage.

Comment: We received one comment from an association of church plans stating that we should allow sponsors to use the single prong gross value test to determine whether their coverage is actuarially equivalent to Part D if the sponsors will certify that the retiree drug subsidy payment will go into a trust for the benefit of the beneficiaries in the plan.

Response: If we allowed certain sponsors to use the single prong gross value test for the actuarial equivalence standard in applying for the retiree drug subsidy, there would be no guarantees of prohibiting windfalls to those sponsors. Accordingly, the two prong standard, as defined in the final rule, shall apply to all sponsors who apply for the retiree drug subsidy.

3. Applying the Actuarial Equivalence Test to Plans with Multiple Benefit Designs and Cost Sharing

As noted above, the proposed rule proposed to use the COBRA regulations as a model for determining how many group health plans a sponsor provides and which benefit options are included within a single health plan. Under those rules, all benefit options offered by a sponsor would be treated as a single group health plan unless through its documents and operations, the sponsor treats them as separate plans. Under the proposed rule, sponsors would then be required to determine actuarial equivalence for each plan as a whole. That is, a plan would be actuarially equivalent if, on average, the actuarial value of retiree drug coverage under the sponsor's employment-based retiree health plan were at least equal to the actuarial value of defined standard prescription drug coverage under the actuarial standards described above.

Comments: While several employer groups agreed with our use of the COBRA definition of a plan as a model for determining what benefit options are included within an employer's group health plan, they indicated that sponsors need additional flexibility to distinguish among retirees with different arrangements within a single plan for the purpose of determining actuarial equivalency. They felt that sponsors should be given the discretion to aggregate all retirees in a single plan as a whole or to apply the test to each individual benefit option within a plan. An association of actuaries commented that, if we give employers and unions the flexibility to define plans, then employers and unions will presumably do so in a way that will maximize their subsidy payment. However, a beneficiary advocacy group questioned whether, if an aggregate average is allowed across multiple options for purposes of the test, payment could be made on the basis of incurred costs in a drug option that does not meet the actuarial equivalence standard on its own. The same group suggested using the enrollment numbers to determine a weighted average across multiple options in order to protect retiree's interest.

Response: We believe section 1860D–22(a)(2)(A) of the Act is subject to two reasonable interpretations: under the first interpretation the actuarial equivalence standard would be applied to the group health plan as a whole, and under the second interpretation the actuarial equivalence standard would be applied for each benefit option (including separate cost-sharing

arrangement) within a single group health plan. At this point in time, we elect not to choose between these two reasonable interpretations of the statute. The final rule provides sponsors with flexibility by allowing them to choose whether to apply the net prong of the actuarial equivalence test for each benefit option, or to apply the net prong of the actuarial equivalence test on an aggregated basis for all benefit options within a group health plan that satisfy the gross test and creditable coverage standard of § 423.56. This flexibility will accommodate sponsors that have a wide variety of benefit options for their retirees. However, each benefit option in the sponsor's plan must independently satisfy the gross prong of the actuarial equivalence test. The gross test is equivalent to the actuarial equivalent standard applied for purposes of determining whether a group health plan is creditable prescription drug coverage. As explained in subpart B, the actuarial equivalence standard for creditable prescription drug coverage is separately applied to each benefit option in the sponsor's group health plan. We do not believe it would be appropriate to provide sponsors a subsidy under this subpart for qualifying covered retirees enrolled in a benefit option that is not creditable prescription drug coverage. Therefore, the final rule provides that sponsors must apply the gross prong of the actuarial equivalence standard to each benefit option for which the employer seeks to receive a retiree drug subsidy.

4. Applying the net test to plans with integrated drug and non-drug premiums.

Comments: One commenter noted that it was unlikely that retiree health plans would include a separate identifiable premium for drug benefits and that an estimate of the portion of the total premium relating to the drug benefits would have to be made prior to doing a net value calculation on actuarial equivalency. An employer consultant firm commented that employers and unions should have wide latitude to restructure, redesign, or otherwise limit or improve benefits and the employer's or union's contribution thereto. A human resource management association requested that the final rule clarify that employers and unions may determine how such amounts are to be allocated based on sound actuarial principles.

Response: We agree that sponsors (both those with insured benefits and those with self-funded benefits) generally should have flexibility to design premium structures that are most appropriate for their employees and retirees. We also recognize that many employers and unions offer medical and drug benefits as an integrated package providing support to the beneficiaries and supplementing their current Medicare Parts A and B coverage, and in addition have included the drug benefit since Medicare has not previously provided coverage for outpatient prescription drugs. Accordingly, in many respects for those employers and unions that decide to take the retiree drug subsidy, this subsidy will help maintain retiree health coverage, including both medical and drug benefits.

The final rule provides maximum flexibility to sponsors in allocating the premium between the medical and drug benefits for the purpose of determining the actuarial equivalence of the drug benefit. By doing so, we are not allowing for a windfall subsidy payment to the sponsors since, in order to meet the net test for actuarial equivalence test and qualify for the retiree drug subsidy, the sponsors will have to make a substantial financial contribution towards the retiree health coverage.

(c) Sponsor Application for Subsidy Payment and Required Information

In the proposed rule, we proposed to require that a plan sponsor who wishes to be paid the retiree drug subsidy must annually submit to us a subsidy application, actuarial attestation, and a list of qualified covered retirees, no later than 90 days prior to the beginning of the plan year. For a subsidy to be paid for 2006, we proposed that the application be submitted no later than September 30, 2005. Plans that begin coverage in the middle of a year would have to submit the application 90 days prior to the date the coverage begins. Sponsors that establish new plans after September 30, 2005 would have to submit the application no later than 150 days prior to the start of the new plan.

Comments: Plan sponsors, actuarial consultants, business consultants and health care industry advocates indicated that there was a need for an extension beyond the September 30, 2005 due date for the submission of the retiree drug subsidy application, attestation and the list of qualifying covered retirees. Many felt that while they could provide the application prior to September 30, 2005, they might not be able to provide an attestation as they might not have made the final plan design determination and have the final list of qualified beneficiaries until 30 days prior to the start of the plan year. Another comment from an employer advocacy association recommended that we shorten the advance submission of an attestation for new plans from 150 days prior to the effective date of coverage to 90 days prior to the effective date.

Response: We reviewed public comments on the effect that the application data requirements and the impact that the timeframe of the application deadlines will have on plan sponsors. In order for plan sponsors to receive a subsidy payment for January 2006, the final rule generally retains the requirement that all plan sponsors (regardless of their plan year) apply for the subsidy payment no later than September 30, 2005. We believe this is necessary to reduce confusion and uncertainty for retirees and for employers and unions that may be claiming a subsidy for a retiree enrolling in Part D coverage when the initial enrollment period for the new program opens in November 2005. However, to accommodate sponsors that are unable to obtain all necessary data in time, we will allow sponsors to obtain an extension under procedures and conditions we establish. In general, the procedures will include a requirement that sponsors file the extension request prior to September 30, 2005, and have the extension application include the names of retirees for whom the sponsor believes it may be claiming subsidy payments in 2006. For future years we will require that plan sponsors apply for the subsidy no later than 90 days prior to the start of their plan year, unless an extension has been filed with us and granted by us under procedures we establish. For sponsors that institute retiree prescription drug coverage after September 30, 2005, we will require that these sponsors submit an application, attestation, and all of the necessary data as outlined in § 423.884(c)(2) at least 90 days prior to the start of the new plan for the first plan year. (We agree that the advance attestation submission for new plans need not be 150 days.)

We feel that we need this 90 day period to review the retiree drug subsidy application and contact the sponsor if any further information is needed. However, we will accept updates to the application up to the beginning of the plan year. As provided for in § 423.884(c)(6) and discussed subsequently, additional periodic updates relating to eligibility data are also required during the year.

We also intend to build in safeguards in the Part D application process for beneficiaries to decrease the instances in which a sponsor attempts to claim a subsidy payment for an individual who (unknown to the sponsor) has enrolled in a Part D plan. We would expect such safeguards to include a process that could enable retiree plans to obtain

relevant information before the individual's Part D enrollment takes effect. For further discussion on enrollment protections, see § 423.36 of the subpart B preamble.

Comments: Plan sponsors, health plan advocates, carriers, insurers and administrators raised numerous other issues regarding the retiree drug subsidy application. They asked for clarification on who is responsible for signing the subsidy application. Plan sponsors and an employer advocacy association requested confirmation that the plan sponsor may act with the assurance that the plan is qualified for the subsidy upon submission of its signed completed application and a signed attestation to us so that they may communicate plan information to its retirees and their dependents sooner. A taxpayer advocacy association felt that we need to enhance the certification requirements of § 423.884 and § 423.888 to reflect what is required in § 423.505(l). That provision requires certification by the CEO, CFO or an individual delegated the authority to sign on behalf of one of these officers, or who reports directly to the officer of the accuracy, completeness and truthfulness of all the information related to the enrollment data, claims data and payments.

Response: The final rule requires that the application be signed by the sponsor or by an authorized representative of the sponsor. A sponsor or its authorized representative must certify that the information on the application is true and accurate to the best of its knowledge and belief. The final rule does not specifically require that certifications for subsidy payments meet the same standards as § 423.505(l). However, we will be providing further guidance on the terms and conditions of the application.

Comment: The proposed rule indicated that the application would require the sponsor to comply with a number of specific requirements (including the terms and conditions for receiving retiree drug subsidy payments) and that the application would constitute an agreement between the sponsor and CMS (the sponsor agreement). Several employer advocacy groups requested clarification regarding whether, upon submission of a signed application, the sponsor may act with the assurance that the sponsor is qualified for the retiree drug subsidy.

Response: Although we intend to streamline the application process as much as possible, the mere submission of a subsidy application does not qualify an entity to receive subsidy payments. The sponsor cannot assume it is eligible for a subsidy payment until we (or our subsidy contractor) review the sponsor's application and provide written notification regarding the sponsor's eligibility to receive a subsidy payment. (We have clarified this in the regulation text by adding a definition of ''sponsor agreement'' at § 423.882.)

Comments: We were asked to clarify the application process for those sponsors with multiple tax identification numbers.

Response: For a sponsor that includes separate entities with multiple tax identification numbers, the final regulation allows them to determine the appropriate tax identification number and other appropriate information (such as contact data) to include as outlined in the data requirements for that application.

Comments: Several plan sponsors, business consultants, insurers/carriers and health care industry advocates indicated that they do not collect the health insurance claim (HIC) or Social Security numbers of their retirees and their dependents, which we proposed to require as part of the application process in the proposed rule, due to privacy issues and historical business practices. They said this requirement could create an administrative burden for them. They also raised concerns about the ability to identify qualifying covered retirees, given uncertainty about whether some people (particularly dependents) are entitled to Medicare Part A or B and not enrolled in Part D.

Response: We believe that it is necessary to require the data as outlined in the proposed rule to establish the sponsor's eligibility for the retiree drug subsidy and to verify the qualified retirees and their dependents (as defined in § 423.882) that are enrolled in the sponsor's plan. Further, based on discussions with stakeholders, we believe sponsors and their vendors should be able to track the data elements that we require in this section. However, we understand that some sponsors may not collect the HIC numbers of their Medicare retirees; thus the final rule requires that either the HIC number or the social security number of qualifying covered retirees be provided. We strongly urge, however, that sponsors provide both the HIC and social security numbers of their qualifying covered retirees if they collect both in order to reduce the potential for error and to increase the confidence range of the submitted data.

We recognize that determining whether a person (particularly a dependent) is eligible for Part D may pose some difficulty for certain sponsors. However, sponsors are able to enroll in voluntary data sharing agreements (VDSAs) with us that would allow sponsors to submit a list of retirees and covered dependents prior to submitting an application for the retiree drug subsidy and have us determine which retirees and dependents are qualified covered retirees. More information about the CMS Employer Voluntary Data Sharing initiative can be found at *http://www.cms.hhs.gov/medicare/cob/employers/emp__vdsa.asp*. We may also explore other approaches that could be used to provide necessary information to sponsors.

Comments: A health care industry association and outside vendors who provide eligibility and claims data to plan sponsors and who will be submitting data to us for enrollment and payment under the subsidy stated their concerns about the False Claims Act. They requested that we clarify their potential liability and possible relief from liability for data submitted that was provided by them.

Response: The False Claims Act provides a remedy for false claims submitted to the Federal government if a person or entity ''knowingly'' submits a false claim, or knowingly causes another to submit a false claim. Section 901 of the MMA expressly states that nothing in the title dealing with Medicare contractor reform shall be construed to compromise or affect existing legal remedies for addressing fraud or abuse, and we believe it is clear that the law is intended to apply for the retiree drug subsidy program. However, innocent mistakes and errors do not result in liability under the Act. Rather, the False Claims Act imposes liability on a person or entity which acts with actual knowledge of the false claim; acts in deliberate ignorance of the truth or falsity of the information; or acts in reckless disregard of the truth or falsity of the information (31 U.S.C. § 3729(b)(1–3)). Thus, the False Claims Act's liability provisions were not intended to apply to a merely inadvertent reporting error or an innocent mistake by a sponsor. We note that parties have a continuing obligation to disclose to the government any new information indicating the falsity of the original statement.

A sponsor, or its authorized representative requesting the subsidy on behalf of the sponsor, must certify that the information on the application is true and accurate to the best of its knowledge and belief. Thus, as noted above, innocent mistakes in the application, as opposed to intentional misstatements or statements made with deliberate ignorance of or reckless

disregard for the truth, will not result in False Claims Act liability, unless the sponsor (or its authorized representative) subsequently fails to inform the government of information indicating the falsity of the original statements.

Comments: Plan sponsors, business consultants, insurers/carriers and plan administrators asked us to clarify the frequency and manner in which updates will be required. They recommended that they provide periodic enrollment updates to us as they identify qualified retirees and their dependents that become eligible for Medicare. Additionally, comments suggested allowing sponsors to file updated information during the year following the September 30 deadline, and to allow sponsors to submit new census data only if there are no material changes to the plan.

Response: The final rule requires periodic updates of beneficiary data as outlined in § 423.884(c)(6) to keep our database accurate and reduce the possibility of overpayments or underpayments.

To reduce the lag time between the occurrence of a change in the enrollment and the adjustment of the subsidy payment, and to minimize situations in which a sponsor is attempting to claim a subsidy payment for someone who has enrolled in Part D, the final rule requires a monthly update by all sponsors of the enrollment data, regardless of the subsidy payment frequency (unless we specify a different frequency in other guidance). Such data shall be provided in a manner we specify.

In general, sponsors will be expected to provide to us on a periodic basis the changes, additions and deletions to their enrollment data. To ensure development of a procedure that is most administratively feasible for sponsors and CMS, we will consider the possibility of permitting the submission of entire enrollment files. We anticipate issuing further guidance on the frequency and the manner of the enrollment updates.

Table R–1, containing the key dates involved in the sponsor retiree drug subsidy application process is included at the end of this section.

TABLE R–1
KEY DATES

Publication of Final Rule	January 2005
Application for Retiree Drug Subsidy Due Date for All Sponsors seeking the Retiree Drug Subsidy for plan years which end in 2006, regardless of whether they operate on a calendar year	No later than September 30, 2005, unless an extension request is filed with CMS prior to the due date
Attestation of Actuarial Equivalence Due Date for all Sponsors seeking the Retiree Drug Subsidy for plan years which end in 2006	No later than September 30, 2005, unless an extension request is filed with CMS prior to the due date and granted by CMS
Retiree drug subsidy Program Begins	January 1, 2006
For plans operating on a non-calendar year basis—Application for Retiree Drug Subsidy Due Date for Sponsors seeking the Retiree Drug Subsidy for all subsequent years	90 days prior to beginning of each plan year (that is, for plan years which begin in 2006 and end in 2007 and for each plan year thereafter), unless an extension request is filed with CMS and granted by CMS.
For plans operating on a calendar year basis—Application for Retiree Drug Subsidy and Attestation of Actuarial Value Due Date for Sponsors seeking the subsidy for all subsequent years	September 30, 2006 (for 2007) and each September 30 thereafter for subsequent years, unless an extension request is filed with CMS and granted by CMS
Application for Sponsors that institute coverage after September 30, 2005	90 days prior to the start of the new plan
Notice to CMS of mid-year plan changes that materially affect actuarial valuation	90 days prior to the plan change
Notice to enrollees of plan changes that result in the plan no longer providing creditable coverage	Prior to the plan change.

(d) Surety bond

We sought comment on whether to require a surety bond type of instrument or preferred creditor status as part of the enrollment process in order to address situations related to businesses that may terminate or experience bankruptcy prior to completion of a final reconciliation.

Comments: CMS received comments from private and governmental plan sponsors that this will be an unnecessary cost and burden to them and especially problematic for governmental entities.

Response: After review of the comments we have determined that since all subsidy payments will be made by us after submission of cost data, the degree of risk to us in connection with the year-end reconciliation process is not significant enough to justify requiring a surety bond type of instrument or preferred creditor status certification, particularly given that many plan sponsors and administrators are subject to other laws and contractual obligations that should provide protections.

(e) Creditable Coverage and Notification

Section 1860D–22(a)(2)(C) of the Act specifies that in order for a sponsor's plan to meet the definition of a qualified retiree prescription drug plan, the sponsor must provide for disclosure of whether coverage is creditable prescription drug coverage in accordance with the proposed requirements set forth under proposed § 423.56 of the final rule. This includes, for example, providing advance notice to beneficiaries in the plan of any material change that causes their coverage to no longer be creditable prescription drug coverage. The rules for providing notices of whether coverage is creditable prescription drug coverage are described in subpart B, including the rules for coverage sponsored by an employer or union not claiming the subsidy.

5. Retiree drug subsidy amounts (§ 423.886)

As outlined in the final regulations, § 423.886 governs the subsidy amount a sponsor of a qualified retiree prescription drug plan receives for each qualifying covered retiree that is enrolled with the sponsor in a given year. The sponsor is eligible to receive a retiree drug subsidy payment for each qualifying covered retiree equal to 28 percent of the allowable retiree costs that are attributable to the gross costs that exceed the cost threshold and do not exceed the cost limit. Section 1202 of the MMA amends the Internal Revenue Code of 1986 to provide that these subsidy payments will be exempt from Federal tax. Further guidance on the Federal tax treatment of the subsidy will be under the auspices of the U.S. Department of the Treasury.

Debts owed to us that are generated by an overpayment of the subsidy to a sponsor, including collection of interest, administrative costs, and late payment penalties will be governed by regulations at 45 CFR Part 30, subpart B.

Comments: Many tax-exempt plan sponsors including governmental plans commented that the tax-exempt nature of the subsidy payments means that taxable plan sponsors can receive a subsidy that is approximately 35 percent higher in value than what the tax-exempt sponsors can receive. They requested that we address this disparity in the final rule for Part D to make sure all plan sponsors are treated equally. An employer advocacy group also asked for clarification on how the subsidy should be calculated for allowable costs that are attributable to gross retiree costs that exceed the cost threshold and do not exceed the cost limit.

Response: The statute does not allow us to provide additional retiree drug subsidy payments based on tax-exempt status. As for the calculation of subsidy payments, the final rule clarifies that the statute requires the subsidy payment to be calculated by first determining gross retiree costs between the cost threshold and cost limit, and then determining allowable retiree costs attributable to such gross retiree costs. As noted elsewhere, allowable retiree costs are based on gross retiree costs actually paid under the plan (or by or on behalf of the retiree), with rebates and other price concessions subtracted from these gross retiree costs.

Comments: Employers and beneficiary advocacy groups also commented on additional provisions regarding the plan sponsor's use of the subsidy once received. Beneficiary advocacy groups suggested that since employers and unions are allowed to shift costs of retiree plans to retirees by way of premium contributions and cost-sharing, beneficiaries should be entitled to a fair portion of the subsidy amount received by the plan sponsor. Employer groups and business consultants commented that once an employer or other plan sponsor qualifies for the retiree drug subsidy, we have no authority to regulate that employer's or union's or plan sponsor's utilization of the subsidy.

Response: The statute does not impose restrictions on how the sponsors use the subsidy. However, beneficiaries may have rights provided under other laws or by contract.

6. Payment Methods, Including Provision of Necessary Information (§ 423.888)

a. *Plan Year Versus Part D Coverage (Calendar) Year*

Under section 1860D–22(a)(3)(B) of the Act, the cost threshold and cost limits that determine the amount of the subsidy are calculated for ''plan years that end in'' 2006 and subsequent calendar years. However, section 1860D–22(a)(3)(A) of the Act refers to the subsidy amount for a qualifying covered retiree for a ''coverage year,'' that is defined as calendar year. Thus, we believe that, in the context of section 1860D–22 of the Act, we have the interpretive authority to require that the subsidy determinations be made either on a calendar year or plan year basis. In the proposed rule, we proposed to have the rules apply on a calendar year basis because Medicare already operates on a calendar year basis.

Comments: In considering whether sponsors will use plan year or calendar year in calculating the retiree drug subsidy amount, comments varied among private health care companies and health care industry associations. One such entity commented in favor of utilizing a calendar year schedule for simplicity. Others prefer having the flexibility to choose between a calendar year and a plan year that a sponsor may currently be operating in. Employer advocacy associations and actuarial consulting groups suggested giving sponsors flexibility, especially if it means allowing sponsors to choose between plan year and calendar year. A government entity commented in favor of plan year, and discussed utilizing a pro-rata method for determining the subsidy amount for the initial year of a plan using a non-calendar year.

Response: In determining whether sponsors will be required to use plan year or calendar year, we took into consideration the large number of comments in favor of flexibility. We also recognized the costs that plan administrators and sponsors might face if they maintain records for plan purposes based on a period that differs from the calendar year, but are forced to establish a different system that maintains records on a calendar year basis solely for purposes or the retiree drug subsidy program. Finally, we considered costs associated with administering the program by CMS or a subsidy contractor. In response to these considerations, the final rule uses the plan year approach. Thus, if a plan's records are maintained on a calendar year basis, it enables sponsors to calculate retiree drug subsidy payments on that calendar year basis. If a plan's records are maintained based on a year that differs from the calendar year, sponsors can determine those calculations on the non-calendar year basis.

Sponsors of non-calendar plans will use the cost threshold and cost limit for the calendar year in which the plan year ends for purposes of determining subsidy payments. Thus, for example, a sponsor claiming subsidy payments for the plan year running from July 1, 2007 through June 30, 2008 would use the cost thresholds and cost limit amounts published for 2008 in determining subsidy payments. If the sponsor requests payments on a monthly or quarterly basis, adjustments and reconciliations for prior payments will have to be made once the cost threshold and cost limitation for the relevant year have been published.

Subsidy payments are determined based on the plan year that ends in a given calendar year, using the same rule in determining whether a sponsor's plan is actuarially equivalent to Part D raises a challenge. It might require that the sponsor submit an actuarial attestation for a given plan year before the deductible, initial coverage limit, and other elements of the defined standard prescription drug coverage have been determined for the corresponding calendar year. To address that concern, the final rule allow sponsors to use the actuarial value of the standard prescription drug coverage under Part D for the calendar year in which the sponsor's plan year begins, provided the attestation is submitted to us no later than 60 days after the publication of the coverage limits for defined standard prescription drug coverage for the upcoming calendar year. If the attestation is submitted beyond 60 days after the publication of the coverage limits for defined standard prescription drug coverage for the upcoming year,

then the new coverage limits should be used for the attestation.

Note that our decision to allow sponsors to use non-calendar year plans as the basis for the retiree drug subsidy payment should not have an impact on, or impede, the timing of the beneficiaries' right to drop their employer or union coverage in favor of Part D if they choose. For example, beneficiaries should have the option to coordinate obtaining Part D coverage during open enrollment periods and dropping their retiree coverage in a way that avoids late enrollment penalties. Beneficiaries may also have special enrollment periods relating to the loss of creditable retiree coverage. (See § 423.56.)

The use of a plan year approach also requires a transition rule for plan years that begin in 2005 and end in calendar year 2006. The proposed rule outlined three transition options. The first is to start counting gross prescription drug costs for prescriptions filled after January 1, 2006, and pay the subsidy only for claims incurred in 2006. The second option is to determine the subsidy amount based on claims incurred for the entire plan year but prorate subsidy payments to reflect the number of months of the plan year that fall in 2006. The third option is to determine subsidy amounts monthly for the entire plan year and then pay the full subsidy payments, but only for claims that are incurred in 2006.

Comments: Business advocacy groups recommended that the final rules allow employer and union flexibility to select among the three proposed transitions alternatives in determining the subsidy payment for 2006, based on their administrative capabilities and other considerations.

Response: For administrative simplicity, and given the nature of this rule, we believe it is reasonable to specify the particular transition option to be used. Option 1 would require that sponsors meet the cost threshold twice in 2006, a strict test that we believe is not absolutely required under the statute. In comparing transition options 2 and 3, we have concluded that option 3 provides the most equitable result that is consistent with the statute. Under Option 3, sponsors determine claims incurred in all the months of the plan year, including those that fall in 2005, for calculation of the cost threshold for a plan year that ends in 2006. However, subsidy payments are based solely on claims incurred on or after January 1, 2006.

b. Payment Methodology and Frequency

Section 1860D–22(a)(5) of the Act specifies that payments to plan sponsors are to be made in a manner similar to the payment rules in section 1860D–15(d) of the Act, which applies to payments made to PDP sponsors and MA organizations under Part D. We proposed a preferred approach to calculating and paying the subsidy. For each month starting with January 2006, the plan sponsor would certify by the 15th of the following month the total amount by which actual retiree-beneficiary gross drug spending exceeded the cost threshold yet remained below the cost limit. Medicare would pay 28 percent of the certified amount to the sponsor by the 30th of that month. Not later than 45 days after the end of the plan year, the plan sponsor would submit a final reconciliation (except for outstanding rebates) to us for payment by or, if applicable, to us. In the month in which they are received (or recognized), the appropriate share of any discounts, rebates, chargebacks, or other price concessions, along with any adjustments to the actual expenditures for prior months, are reflected. Any amounts owed the government would offset the subsidy payment for that month, and to the extent that the amount owed to the government would exceed any applicable monthly payment, the plan sponsor would pay this amount to us.

We proposed three possible alternatives to this option. The first alternative was for us to make a single payment after the close of the year. Sponsors would submit their cost data, including rebate data, by the start of the fourth month after the close of the plan year. A second alternative would be to make interim payments throughout the year based on the sponsor's estimate of claims, rebates and discounts (determined based on historical data), with a settlement after the end of the plan or calendar year. We would pay less than 100 percent of the subsidy payments that would be calculated from these estimates, given the uncertainties associated with these estimates. The third alternative would be to make lagged payments based on actual claims experience on a periodic basis throughout the year, with the subsidy payments being reduced by a specified percentage to reflect the sponsor's estimate of discounts, chargebacks and rebates. After the year ends there would be a settlement limited to reconciling estimated versus actual discounts, chargebacks and rebates. We also sought comment on the use of bi-annual, quarterly or monthly payment periods under these approaches.

Comments: Generally, comments supported a method that allows flexibility to select the methodology and timing of retiree drug subsidy payments and rebates each year. A number of commenters, including employer consultants and government employers encouraged a monthly payment system. Entities that supported alternative option 1 said that it would protect patient privacy, proprietary information between plans and manufacturers would be kept from potential exposure, and both administrative costs and data collection burdens would be reduced.

One State commenter supported alternative option 2, stating this method takes into account programs that are fully insured and use a Health Maintenance Organization (HMO) that does not segregate actual cost data by plan and is community rated. Additionally, advocates claim that option 2 would be more reasonable for small business because of the lighter administrative burden. Comments critical of the preferred option stated that the 15 day turnaround time for submitting monthly payment requests and the 45-day deadline for year-end reconciliation seemed rather tight, even for employers and unions who have PBMs with excellent administrative abilities.

A business consultant also commented that only the third alternative proposal actually accounts for drug costs of the group health plan on an accrual basis. The other methods appear to follow the cash flow of the plan but fail to recognize accrual accounting required for the plans. They felt that we neglected to consider more user-friendly methods that are proposed for other cost based entities, for example, fallback plans, which we proposed to pay through a debit account system. They felt that the second approach is acceptable because it sets prospective payments and provides for reconciliation, even though it arbitrarily pays less than what the parties agree upon as the prospective rebate.

Another employer advocacy association urged us to develop a point of sale subsidy payment system, and in the interim, provide the sponsors the flexibility to choose the payment methodology that is best for them.

Response: Unless and until such time technology, resources and other considerations would enable us to develop a point-of-sale payment system for the retiree drug subsidy program, the final regulation will provide other methods and frequency options to address the multiple requests for payment flexibility.

A sponsor may annually elect during the application process whether to receive payments monthly, quarterly, or

annually; that sponsor may change its election during the application process of a subsequent year. A sponsor choosing an annual payment method could avoid the need for interim data submissions, estimates and reconciliations, (discussed in more detail below), and may limit the administrative costs because data submissions are less frequent. However, sponsors that do not want to make multiple data submissions but also do not want to wait for subsidy payments until all rebate and other data is received will be able to make an interim annual payment request, with only one additional (final) reconciliation required at year-end.

Sponsors who choose the periodic method of payment must submit periodic requests for payment to us on the same schedule as the payments are to be received, at a time and in a manner specified by us. Final detailed cost data must be submitted no later than 15 months following the end of the plan year. We will make payments to the sponsor at a time and in a manner to be specified by us in future guidance.

In the final rule, we reserved the right to restrict the payment options available to sponsors in 2006 in case of any unforeseen operational impediments.

Comments: Actuarial consultants suggested that we develop approximate methods of determining individual drug spending, because of the difficulty of determining the actual costs and assigning a rebate to a specific person. An employer advocacy group suggested allowing employers and unions to choose their own methodology for reflecting rebates, in order to accommodate their own administrative capabilities and restrictions. A health care industry consultant indicated that group health plans would need to separate rebates by their applicability (individual retirees or entire group). An employer was concerned because they have a fully insured plan which factors rebates into the premium; they suggested that we accept the insurance carrier's attestation that the claims used in the subsidy calculation are net of rebates and other discounts, rather than require them to provide information the sponsor does not have. Another employer encouraged us to allow sponsors and PBMs to freely contract regarding rebate terms, and not require them to file PBM agreements of documentation of those negotiations.

A health care industry consultant recommended that we allow multiple methods for allocating rebates because a single method would unduly constrain health plans in future negotiations with manufacturers for price concessions. An employer suggested the most appropriate way to recognize rebates is to determine the average amount per rebatable prescription and apply it to the actual retiree drug utilization of the plan sponsor. Actuarial consultants and a health care industry association agreed with the suggestion to estimate rebates on a periodic basis to be included in subsidy payments, and then reconcile both rebates and subsidies at the end of the year. One industry association suggested an ongoing accounting of rebates to eliminate the need for reconciliation at the end of the year. They also asserted that the proposed 4 month period after the end of the year was not enough time to count the rebates.

An employer advocacy association proposed a two-phase settlement process for rebates, which would include a preliminary estimate at the end of the year and a final adjustment up to twelve months later; the association states that such a system would provide maximum flexibility and minimum administrative burden on the sponsor.

Response: If the sponsor chooses the monthly, quarterly or an interim annual method of payment, then in addition to the data requirements described below, the plan sponsor must provide an estimate of rebates (based on historical data) upon submission of data for payment. We believe the sponsor's submission of estimated rebates limits the amount of reconciliation at year end; is consistent with data capabilities of the sponsors; limits the extent to which we would be making overpayments during the year; and allows for monthly and quarterly subsidy payments in order to enhance cash flow of sponsors.

Sponsors choosing the monthly, quarterly or an interim annual method of payment will be required to provide an annual reconciliation to us that includes cost data segregated per qualifying covered retiree and actual rebates, discounts, or other price concessions received for the costs, unless we provide for different data requirements in future guidance. If rebates and other price concessions for a plan are not specifically allocated by a manufacturer to the drug spending of a particular qualifying covered retiree, a sponsor (or its designee) will be permitted to assign the price concessions to qualifying covered retirees using reasonable actuarial principles or other methods we may specify.

The reconciliation must take place within 15 months following the end of the plan year. If gross covered retiree plan-related prescription drug costs in a given plan year are reduced at the point-of-sale to reflect rebates, discounts or other price concessions and no additional price concessions for the costs are received for the year, then allowable retiree costs will equal such gross costs for the year. However, any rebates that are received retrospectively would have to be subtracted when a sponsor calculates retiree costs. As a result of the reconciliation, sponsors will, as applicable, repay any subsidy overpayments or be paid any subsidy underpayments in a manner to be specified by us.

If a sponsor chooses the annual payment method, the sponsor will be required to submit cost data per individual retiree, including rebate adjustment within 15 months following the end of the plan year. However, as noted in § 423.884 (c)(6), a sponsor who chooses the annual payment option must still provide updates of enrollment information to us on a monthly basis.

c. Data Collection

The plan sponsor will be required to submit cost data for each qualifying covered retiree. Regardless of what payment methodology is ultimately chosen for the retiree drug subsidy, we would need certain data from the sponsors in order to accurately calculate the amount of the subsidy to which the sponsor is entitled.

In the proposed rule, we requested comments on the level of detail of the cost data that would be submitted to us in order to receive the retiree drug subsidy payment. Option 1 would require that the sponsor submit the aggregate total of all allowable drug costs of all of the qualifying covered retirees in the plan for the time period in question. This aggregate cost would not be broken down to each qualifying covered retiree. Option 2 would require the sponsor to submit the aggregate allowable costs for each qualifying covered retiree for the time period in question. Option 3 would be to combine various elements of the first two options. The sponsor would be required to submit information with the specificity outlined in the second option for each of the first two years of the subsidy's availability. In the third and fourth years, the sponsor would submit its cost data in accordance with the first option. Option 4 would have been for the sponsor to submit the actual claims data for each qualifying covered retiree, though the proposed rule specifically rejected that option given privacy concerns.

Comments: Comments from employers, the healthcare industry, employer advocates and government entities request that we make data

collection and reporting requirements reasonable for plan sponsors. Commenters also stated that we must account for the fact that employers and unions do not customarily record some of the data requested, and third party administrators, insurers, PBMs and like entities also do not maintain all of the data elements required under the proposed rule. Further, comments suggested that we concentrate on attaining aggregate claims data.

Response: We agree that the requirements for submission of cost data should be reasonable and the least burdensome possible. At the same time, we have an obligation to create rules aimed at providing only the subsidy payments authorized by statute. As noted above, in balancing these objectives, the final rule provides that unless we imposes other data requirements in future guidance, when a sponsor chooses either the monthly, quarterly, or interim annual payment option, it must submit to us, at a time and in a manner specified by us, the aggregate gross covered retiree plan-related prescription drug cost data (as defined in § 423.882), as outlined in option 1, along with an estimate of the extent to which its expected aggregate allowable retiree costs will differ from the aggregate gross cost data (based upon expected rebates and other price concessions) for interim payments. However, the aggregate data must be reconciled within 15 months after the end of the plan year, and the sponsor would have to resubmit the total gross cost data segregated by individual retiree and actual rebate/discount/other price concession data and repay any subsidy overpayments (or be paid subsidy underpayments). (Specific detail about each claim would not be required.) Likewise, all sponsors who choose the annual payment option would have to submit the total gross cost data segregated by individual retiree and actual rebate/discount/other price concession data within 15 months after the end of the plan year for payment. We believe that these requirements are reasonable and least burdensome for the sponsors, yet provide the additional information needed by us in assessing the accuracy of payments. As outlined in our earlier discussion on allowable retiree costs, in section 3(C) of this subpart of the preamble, we will provide flexibility to sponsors of insured plans in the submission of interim cost data.

d. Record Retention for Audits

In the proposed rule, we stated that a plan sponsor will be required to maintain and provide access to sufficient records for our audits or audits of the Office of Inspector General (OIG) to ensure the accuracy of the attestation regarding actuarial value and the accuracy of subsidy payments made under this subpart. All records must be maintained for at least 6 years after the end of the plan year in which the costs were incurred.

Comments: Employers, employer advocacy associations and an employer business consultant commented that the data retention period should match the IRS/SSA/CMS data match program period of 3 years to ease the administrative burden on employers, unions, carriers and plan administrators. Employers indicated that if they switched carriers or administrators, it would be difficult to force them to retain records for at least 6 years. A taxpayer advocacy association recommended a 10-year time period, coinciding with the statute of limitations in False Claims Act cases. A governmental employer wanted us to mandate that carriers retain and provide the necessary data to the sponsor for the required period of time. In discussions with sponsors and employer advocacy groups, they indicated that they are required to retain 6 years of certain types of data for the Department of Labor (DOL) audits under ERISA.

Response: The final rule retains the 6-year record retention rule. We believe that 6 years is a reasonable because it is consistent with the period for retaining certain ERISA records and certain information related to the Health Insurance Portability and Accountability Act (HIPAA) administrative simplification rules. However, consistent with the commenters' concern that records would not be retained long enough, we are modifying the regulation text to specify that a sponsor (or its designee) must retain records longer than 6 years if they know that the records are the subject of an ongoing investigation, litigation, or negotiation regarding criminal or civil liability. In such cases, the obligation to retain records need not arise solely through a formal communication from CMS or OIG.

6. Appeals (§ 423.890)

Although the statute does not contain provisions for administrative appeals of the retiree drug subsidy amount, we believe that it is prudent policy to allow an opportunity for review of certain agency decisions issued in relation to this subpart. Examples of these decisions are as follows—

- A retiree prescription drug plan is determined not to be actuarially equivalent.
- An enrollee in a retiree prescription drug plan is determined not to be a qualifying covered retiree.
- A determination of the subsidy amount to be paid to a Sponsor.

Comments: Beneficiaries, beneficiary advocacy organizations and labor organizations requested that they have the opportunity for review and appeal of the retiree drug subsidy application and the payment determination so that they could assist us in verifying that the benefits provided and the payments made under the retiree drug subsidy program were proper and fiscally responsible. Plan sponsors, business advocates and health care industry vendors felt that only they should be allowed appeal rights because the application to receive retiree drug subsidy payments, the actuarial attestation and payment under the retiree drug subsidy program would not affect the benefits provided to beneficiaries under the plan. Plan sponsors and business advocates indicated that third parties, including beneficiaries, should not have standing to appeal our decisions. One employer advocacy association requested that we consider an appeals process that provides plan sponsors an opportunity to develop a detailed record concerning disputes for which they request reconsideration. The employer association also requested that if we determine that no such opportunity needs to be provided, require that its factual determinations relating to such disputes be decided on a de novo basis upon judicial review. They also requested that if an employer or union seeks to reopen a determination on its own, such a right should be unfettered as long as it is made within one year of final determination.

Response: We do not believe that the MMA gives participants or other third parties standing to appeal to us regarding retiree drug subsidy payment determinations. The MMA provides that the subsidy is to be paid to the sponsors if the sponsors meet certain conditions imposed on them. We recognize that participants and beneficiaries in a sponsor's plan have an interest in knowing whether their retiree drug coverage qualifies for the subsidy, and that we have audit responsibilities to ensure the accuracy of payments. But given the absence of any administrative appeals provisions in the statute and our need to also consider the potential burdens that could be posed on retiree health plan sponsors, we do not believe it would be prudent policy to provide administrative appeal rights to individual participants or third parties.

We believe that the appeals process that is outlined in the preamble to the proposed rule provides sufficient due process to protect the interests of the sponsors. To require that a detailed record be developed on appeal or to require de novo judicial review of the administrator's decision would create administrative costs for the retiree drug subsidy program and would be burdensome for us. As we indicated in the preamble of the proposed rule, there is no constitutional property right to the retiree drug subsidy. Because the subsidy payment is not an entitlement, there is no need to provide for an extensive appellate process that includes judicial review.

We also have not accepted one commenter's request that an employer receive an unfettered right to reopen a determination as long as it is made within a year of the final determination. As we stated in the proposed rule, at 69 FR 46750, the Supreme Court has ruled on reopening in the context of cost reports. In that case, the Court stated that the ''right ... to seek reopening exists only by grace of the Secretary,'' *Your Home Visiting Nurse Services, Inc.* v. *Shalala* 525 U.S. 449, 454 (1999), and that a reopening by the Secretary is not a ''clear nondiscretionary duty.'' Id. at 456–7. For these reasons we have decided to retain the rule that while a reopening may be requested by a sponsor, there is no right to reopening under the regulations. We have also amended the regulations to reflect the policy announced in the preamble of the proposed rule that a decision not to reopen is not subject to further review.

7. Change of Ownership (§ 423.892)

Sponsors who apply for a retiree drug subsidy payment would be required to comply with change of ownership requirements.

Comments: We received no public comments in this area that disputed the proposed provisions of change in ownership.

Response: In § 423.892, we would carry over the three situations that constitute change of ownership (CHOW) in § 423.551 of the final rule.

8. Construction (§ 423.894)

Sections 423.894(a) through § 423.894(d) are based on section 1860D–22(a)(6) of the Act, which outlines the employer and union options for providing retiree drug coverage and coordinating with Medicare under the MMA.

Comments: Beneficiary advocacy organizations were concerned that employers and unions will drop employer and union-based coverage if beneficiaries enroll in Part D coverage. Plan sponsors want clarification that if they file for the subsidy, they can tell beneficiaries not to enroll in Part D coverage.

Response: The final rule adopts the provisions as outlined in the proposed rule. Plan sponsors are not permitted to tell qualified retirees and their eligible dependents that they cannot enroll in Part D coverage. The MMA mandates that beneficiaries must be allowed to freely choose whether or not to enroll in Part D.

However, plan sponsors claiming the retiree drug subsidy must offer a prescription drug program that is actuarially equivalent to or better than defined standard prescription drug coverage. If a sponsor elects to apply for the retiree drug subsidy, it is also able to design its eligibility rules under its employer or union-based plan so that qualifying covered retirees and their dependents lose eligibility in the sponsor's plan if they enroll in a Part D plan. The sponsor shall give advance notice of this type of material change to plan participants as required by other notification regulations that govern their plan (that is, ERISA, State or local law).

S. Special Rules for States-Eligibility Determinations for Low-Income Subsidies, and General Payment Provisions

1. Eligibility Determinations (§ 423.904)

The MMA added a new section 1935 to the Act, ''Special Provisions Relating to Medicare Prescription Drug Benefit,'' which specifies the requirements for States regarding low income subsidies under the new part D benefit. In accordance with the statute, our proposed regulations at § 423.904(a) and (b) required States to make initial eligibility determinations for premium and cost sharing subsidies based on applications filed with the States, to conduct periodic redeterminations consistent with the manner and frequency that redeterminations are conducted under Medicaid, and to notify us of eligibility determinations and redeterminations once they are made.

As proposed in § 423.904(c), States would be directed to identify individuals who apply for the low-income subsidy who may also be eligible for programs under Medicaid that provide assistance with Medicare cost sharing and to offer enrollment in these programs. This requirement is consistent with existing obligations imposed on States when they make eligibility determinations for Medicaid. In § 423.904(d), we proposed requiring States to begin accepting application forms for the low-income subsidy no later than July 1, 2005. In § 423.904(d), we also proposed requiring States to make available application forms, provide information on the nature of and requirements for the subsidy program, and provide assistance in completing subsidy applications.

We also proposed requiring that States ensure that applicants or personal representatives attest to the accuracy of the information provided. In verifying application information, we specified that States may require the submission of statements from financial institutions and may require that information on the application be subject to verification in a manner the State determines to be most cost-effective and efficient.

In addition, § 423.904(d) directed States to provide us with necessary information to carry out implementation of the Part D program. This includes information such as income levels for other low-income subsidy eligible individuals under § 423.773 needed to permit Part D plans to determine the amount of sliding scale premium subsidy that a person will receive under § 423.780(b).

We developed uniform criteria for determining resources, income, and family size under the subsidy, which were reflected in the proposed definitions at § 423.772, and the proposed eligibility requirements at § 423.773.

We also stated that we were considering a number of options to ease the burden on States and to ensure, to the degree permissible under the MMA, a consistent eligibility determination process. We invited comments from States on this issue.

Comment: Several commenters suggested that § 423.904(a) be cross-referred to the entire subpart P rules.

Response: We agree with the commenters and have done so in this final rule.

Comment: Many commenters expressed concern that both SSA and States would be making subsidy eligibility determinations and stressed the need for coordinated policies and processes so that identical treatment is ensured, no matter where the applicant goes to apply for the subsidy. It was further suggested that CMS allow States to choose whether to make the subsidy eligibility determinations themselves or forward applications to SSA.

Response: As stated in our response to comments on § 423.774, the statute sets forth the requirement that eligibility for the low-income subsidy program will be determined by either the State Medicaid agencies or by SSA. Therefore, States

must have the ability to determine eligibility if someone requests a ''State'' subsidy determination.

While this obligation is imposed on States, States may encourage applicants to use the SSA low-income subsidy application process in order to reduce the administrative burden associated with sending notices and processing appeals and redeterminations. In other words, States may provide applicants with the SSA application which they will forward to SSA or provide access to a terminal for accessing the SSA application on line and SSA will perform the eligibility-processing role for these applications. However, as we noted in responses to comments in subpart P, States must have the ability to determine eligibility if someone requests a ''State'' subsidy determination. As part of this obligation, if the applicant files a ''State'' application, States are required to send notices of subsidy determinations, process redeterminations, and handle appeals. We are working on a process whereby States and SSA will be able to access timely information on the status of a beneficiary's application filed at either SSA or State offices. We expect to provide further information on this process through operational guidance. We also note that we have clarified the final rule in subpart P, based on similar comments made in subpart P in response to the proposed rule. Section 423.774 now requires that multiple applications not be permitted in cases where an individual has received a positive determination from either SSA or the State. In other words, an individual may not file a second application for the remainder of the eligibility period with the alternate agency if he or she has received a positive determination from the State or SSA. As stated in the response to comments in subpart P, this requirement is not intended to preclude an individual from reporting subsidy changing events in accordance with the determining agency's rules, but rather to prevent confusion that could arise if a State and SSA process duplicate determinations for the individual.

Comment: Some commenters stated that we should impose a time limit on how long States have to notify CMS of eligibility or redetermined eligibility determinations. Several commenters suggested we require States to notify CMS within 24 hours of making such determinations.

Response: We have decided not to impose a specified period on States to notify CMS of eligibility or redetermined eligibility determinations through regulation. Instead we intend to provide operational guidance to States, monitor the time period for determining subsidy eligibility, and take action as appropriate. In general, we expect that States will determine subsidy eligibility within time periods that are at least consistent with the processing of State Medicaid applications.

Comment: One commenter was concerned that States did not have the opportunity to comment on the model application.

Response: SSA published notice of the model application in the **Federal Register** on November 17, 2004 for public comment.

Comment: One commenter states that both SSA and the States should be required to use the same application for the low-income subsidy. Another commenter asked what form of application a State would be required to accept.

Response: We cannot mandate use of the same application form by States and SSA. Where a State finds that it can use the SSA application for the State's low-income subsidy eligibility determination process, we would encourage it to do so. However, as States might need to implement different verification strategies when they actually make the low-income subsidy determinations, they may have to design application forms specific to their determination process. States have expertise in the area of administering means-tested programs and will be developing their application forms based on that expertise. In addition, we will be working with States and SSA to assist States as they design and develop the optimum eligibility process for making low-income subsidy determinations.

Comment: One commenter was concerned about CMS' requirement for States to begin taking low-income subsidy applications by July 1, 2005 due to State concerns about staffing needs and necessary support systems.

Response: We continue to believe that allowing individuals to apply by July 1, 2005, will allow a more seamless transition of prescription drug coverage for individuals eligible for the low-income subsidy. If an individual needs to consider coverage of specific drugs by a particular Part D plan in making an enrollment decision, the greater time in advance of the new plan's coverage effective date allows individuals, doctors and other payers to assure a smooth transition of drug coverage.

In addition, we have clarified in this final rule that CMS will send notices of eligibility to all deemed subsidy eligible individuals. This should relieve States of the financial burden of sending notices to deemed subsidy eligible individuals. We will also educate Medicare beneficiaries, including dual eligibles, through a variety of methods about prescription drug coverage under the new Part D benefit.

Comment: One commenter also asked about the timeframe in which the State is to make the low-income subsidy eligibility determination. This same commenter also asked about the timeframe required for applications taken as early as July 1, 2005, in which eligibility determinations made after July 1st and prior to November 15, 2005, may need to be redone if there is a change in the applicant's circumstances.

Response: We expect that States will determine subsidy eligibility within time periods that are at least consistent with the processing of State Medicaid applications. Initial determinations of subsidy eligibility shall remain in effect for a period of up to a year and can be effective no earlier than January 1, 2006. As discussed in the response to comments in subpart P, changes in financial circumstances that could impact subsidy eligibility should be reported to the agency that processed the subsidy application, according to that agency's rules.

Comment: One commenter requested more detail on the process CMS will use to collect data from State Medicaid agencies.

Response: We will provide the data collection process to State agencies through operational guidance.

Comment: One commenter indicated its desire to avoid the need for beneficiaries receiving assistance from a SPAP to submit the same information on two different application forms: the SPAP eligibility application and the low-income subsidy application. The commenter would prefer to use only the low-income subsidy application for both the subsidy and SPAP eligibility.

Response: SPAPs will be free to use the application designed for the low-income subsidy, or a variation on the application, to determine SPAP eligibility.

Comment: A number of commenters suggested that States should not be permitted to impose additional documentation requirements on beneficiaries over and above what SSA requires, and asked that the language in § 423.904(d)(3) be revised to indicate that statements from financial institutions would be required ''only if the applicant or personal representative is unwilling to authorize the agency to contact the financial institution directly to obtain necessary information.''

Response: The simplified application developed by SSA, in consultation with CMS, is based on the principle of self-attestation. While we expect some information may be requested from applicants on an exception basis, based on responses to certain questions or based on inconsistencies from electronic data matches, we believe the majority of applicants who use the SSA form will not need to provide additional information beyond what is submitted and attested to in the application form.

We acknowledge that States may employ different verification strategies than SSA, if States actually determine the eligibility for the low-income subsidy. SSA has access to a variety of data sources to enable it to verify within acceptable tolerances the majority of income and resource information using electronic data matches. Again, we encourage States to utilize the SSA application process to the greatest extent possible. However, we cannot limit States' authority to require statements from financial institutions by providing that they may do so only if the applicant or personal representative is unwilling to provide authorization to contact the institution. States have the expertise necessary to determine what the best process is for obtaining necessary information.

Comment: A number of commenters suggest that individuals who apply at SSA offices for the low-income subsidy be screened and enrolled in Medicare Savings Programs. They argue that the obligation to screen and enroll should not be imposed solely on States. They also suggest that joint applications be developed for both programs to avoid requesting duplicate information and to streamline verification of income and assets for eligibility purposes.

Response: We received similar comments in reference to § 423.773 and § 423.774. As we indicate in the responses to those comments, we are working with SSA to design a process to provide subsidy eligibility determination to States for purposes of identifying individuals who apply at SSA and who may also qualify for Medicare Savings Programs under the State's Medicaid program. With this process, we hope to avoid situations in which an individual applies for a low-income subsidy at an SSA office, finds out that he or she has excess income or resources to qualify, and remains unaware that he or she may automatically qualify for a subsidy if the individual chooses to enroll in a State's Medicare Savings Program.

In addition, we also noted in response to other comments in § 423.773 and § 423.774 that the application for the low-income subsidy program must reflect the definition of income and resources outlined in this final rule. However, section 1935 (a)(3) of the Act obligates States to make a determination of a subsidy applicant's eligibility for Medicare Savings Programs and to offer them enrollment. States may develop a special addendum to the low-income subsidy application to address questions specific to Medicaid or Medicare Savings Programs eligibility in order to streamline the application process for these programs.

Comment: One commenter suggested that income and resources will not be verified as rigidly for the subsidy programs as for Medicare Savings Programs. The commenter indicated that the subsidy could be approved and the State could later, due to verification requirements for QMB, SLMB, or QIs, find that the subsidy was approved in error. The commenter suggests that there are no provisions for resolving this occurrence and argue for one standard to be used nationwide.

Response: Medicare Savings Programs represent a Medicaid benefit designed to offer low-income Medicare beneficiaries assistance with Medicare premiums and in some cases cost sharing. The low-income subsidy program is a Medicare benefit under part D. While eligibility for the two benefits may be based on similar methodologies for counting income and resources, they are not identical. Moreover, eligibility for the subsidy can be determined by SSA or States. While uniformity may be a desirable goal, verification methods may differ between the two programs. Verification for the low-income subsidy, for example, is based on the principal of self-attestation. Automation will be utilized by SSA, and we hope by States, to the greatest degree possible, with additional information requested on an exception basis.

Comment: Some commenters suggest the proposed regulations regarding State obligations to screen and offer enrollment in Medicare Savings Programs is inadequate. The commenters suggest that CMS specify what ''offer enrollment'' means. They argue that it should not be interpreted to imply that someone who presents himself at a State office to apply for the subsidy is informed that he can return at a later time to apply for a Medicare Savings Program.

A few commenters assert that the applicant must be offered the opportunity to enroll in a Medicare Savings Program during the same visit or contacted via phone or mail without having to provide further documentation or compelling the completion of additional forms. The commenters also suggest that it would be confusing if individuals first receive notices that they are ineligible for the subsidy and later receive notices from the State that they are eligible for a Medicare Savings Program. Again, commenters suggest that CMS align the income and resource rules for both programs under a single application.

Finally, a few commenters also suggest that CMS automatically enroll individuals in Medicare Savings Programs, with an opt-out provision.

Response: Section 1935(a)(3) of the Act specifically requires States to screen individuals applying for the low-income subsidy for eligibility for Medicaid Savings Programs and to ''offer enrollment'' to such individuals under the State plan. Under this provision, we expect that States will perform an initial assessment of whether an individual is likely to qualify for the State's Medicare Savings Programs, either based on the individual's application for the low-income subsidy taken at the State office or based on subsidy eligibility information provided to the State by SSA. The State should encourage the individual to complete the application and assist the individual in doing so. Given the fact that States administer the Medicaid program, and the fact that enrollment in Medicare Savings Programs could trigger estate recovery implications, we are not considering the commenters' suggestions for CMS to automatically enroll individuals in Medicare Savings Programs with an opt-out provision.

Comment: Some commenters suggested that in order to align the enrollment requirements between Medicare Savings Programs and the low-income subsidy, States should not be permitted to pursue estate recoveries against Medicare Savings Program beneficiaries.

Response: We do not have authority under the MMA to implement the commenters' recommendation to prevent States from pursuing estate recoveries against Medicare Savings Program beneficiaries.

Comment: Several commenters suggested that the low-income subsidy application process represents an opportunity to connect Medicare beneficiaries to food stamps and other programs that might provide assistance to them. The commenters suggest that CMS set up an eligibility process in the final regulation that allows low-income Medicare beneficiaries to be enrolled as seamlessly as possible in food stamps, as well as other State administered benefits for which they may qualify. The commenters also remarked that setting

up such a system would likely entail that CMS work collaboratively with SSA, USDA, and State agencies. A few commenters detail specific opportunities such as providing information about food stamps and other major benefit programs in any outreach materials that CMS, SSA and State Medicaid programs distribute; designing procedures that allow applicant information to be shared between SSA, State agencies, and CMS; collaborating with other Federal agencies, primarily USDA and SSA, on ways to enroll eligible applicants in all benefit programs; developing coordinated redetermination processes that are simple as possible for Medicare beneficiaries; and reimbursing SSA for the food stamps program's share of any costs associated with efforts to inform Social Security recipients of the availability of food stamps and other programs.

A few other commenters suggested that CMS ensure that applicants be given the choice of opting out of the other programs, noting that the complex income calculations under the different programs such as food stamps or Section 8 Housing could endanger an individual's ability to enroll in other assistance programs.

Response: We agree that the application process for the low-income subsidy represents an opportunity to improve coordination and awareness of other programs designed to assist low-income individuals. As part of outreach efforts for the low-income subsidy, we will consider encouraging awareness of other programs. However, we do not have the authority to align the eligibility systems of other programs in order to design a single application process for benefits beyond the low-income subsidy under Medicare Part D.

If SSA is the agency that determines subsidy eligibility, SSA's response may include a paragraph regarding the individual's potential eligibility for other programs like food stamps, SSI, and Medicaid, based upon the information SSA received when determining the low-income subsidy.

Comment: One commenter recommended CMS conduct a dynamic enrollment campaign targeted toward beneficiaries who have been determined eligible for subsidies during the pre-qualification process. CMS should also develop a one-step application/enrollment process that requires all prescription drug plans to include information about the availability of subsidies in their marketing materials and requires plans to include specific eligibility questions on enrollment forms.

Response: We will be working on a detailed education and outreach strategy over the next few months. We note, as explained in detail in subpart B, that while we encourage individuals to choose a plan that best meets their needs, full- benefit dual eligible individuals who apply and are found eligible for the low-income subsidy will be enrolled automatically in Part D plans if they fail to choose one. We will also facilitate enrollment in Part D plans of other subsidy-eligible individuals.

Comment: A few commenters asked whether a person screened and found eligible is required to enroll in a Medicare Savings Program as a QMB, SLMB, or QIl. Additionally, the commenter asked whether such enrollment is a condition of eligibility for the low-income subsidy program.

Response: Enrollment for those who qualify for a Medicare Savings Program is optional. The State cannot condition eligibility for the Part D low-income subsidy on the individual applying for the Medicare Savings Program.

2. General Payment Provisions (§ 423.906)

Section 1935(d) of the Act contains provisions on Medicaid coordination with Medicare prescription drug benefits. Specifically, in the case of a person who is eligible for Part D and also eligible for full Medicaid benefits, Federal Financial Participation (FFP) in State Medicaid expenditures is not available for Medicaid covered drugs that could be covered under Part D or for cost sharing related to such drugs. As a result, no Federal payment should be made under Medicaid for covered Part D prescription drugs for full-benefit dual eligible individuals.

We proposed in § 423.906(a) that States could receive the regular Federal match for administrative costs in determining subsidy eligibility. We also proposed, at § 423.906(c), that States may elect to provide coverage for outpatient drugs, other than Part D covered drugs, in the same manner as provided for full-benefit dual eligible individuals or through arrangements with the PDP sponsor or MA-PD.

Comment: One commenter asked that Medicaid coverage not expire for full-benefit dual eligible individuals until they voluntarily enroll in a Part D plan or until CMS or the State has automatically enrolled them in a plan. By changing the date on which Medicaid coverage ends, SPAPs would not be obligated to provide drug coverage during such a period without coverage.

Response: In accordance with section 1935(d) of the Act, in the case of a person who is eligible for Part D and also eligible for full Medicaid benefits, FFP is not available for Medicaid covered drugs that could be covered under Part D or for cost sharing related to such drugs. In these cases Medicare is the primary payer. We do not have the authority to delay the end date of Medicaid prescription drug coverage for such individuals. However, we will deem full-benefit dual eligible individuals as eligible for Part D low-income subsidies, and assign these individuals to a PDP, with the option to disenroll, so that there will be no breaks in coverage between Medicaid and the implementation of Medicare Part D in January 2006 for this population.

Comment: One commenter asked for clarification that FFP would also be available to State Medicaid programs to conduct the periodic eligibility redeterminations. The commenter also asked if work done by States and SPAPs to enroll beneficiaries in the Part D program would be claimable as Federal reimbursable services at the administrative FFP rate under Medicaid program costs just as low-income subsidy eligibility determinations costs are claimed. Finally, the commenter asked about claiming FFP for all administrative expenses associated with State Medicaid agencies or SPAPs administering a ''wrap around'' benefit.

Response: FFP is available to States at the normal Federal match rate to conduct redeterminations. However, because neither States nor SPAPs enroll beneficiaries in Part D plans no FFP is available in that regard. In addition, the statute does not allow for reimbursement for administering a State benefit that supplements, or ''wraps around'' Part D.

Comment: One commenter asked if a State could pay for and receive FFP for non-covered Part D drugs when a Part D plan's enhanced alternative coverage includes supplemental benefits such as coverage of non-covered Part D drugs. In such a case, the commenter asked whether the State Medicaid program wrap around coverage for dual eligible beneficiaries in such plans could continue and whether the State could receive FFP for these non-covered Part D drugs.

Response: In the scenario described, the plan's supplemental coverage of non-covered Part D drugs does not preclude Medicaid from wrapping around these non-covered drugs and receiving FFP for such coverage. However, to the extent that the Part D plan provides coverage for the non-covered Part D drugs, Medicaid could only wrap-around (pay for amounts not covered by the plan for those non-

covered drugs) the plan's coverage. FFP would not be available for amounts which the plan covers as supplemental coverage.

Comment: One commenter strongly recommends that CMS provide States with a template to take into account changes to the State plan that will result from implementation of Part D.

Response: We do not plan to create a template to take into account changes to the Medicaid program because of the implementation of Part D. However, States should be aware that any changes it makes to Medicaid payment, eligibility, or coverage because of the impact of the new benefit must be reflected in the State's plan. A State that does not amend its Medicaid State plan to reflect changes to its Medicaid program risks losing FFP.

3. Treatment of Territories (§ 423.907)

Low-income Part D eligible individuals residing in the territories are not eligible for premium and cost-sharing subsidies. However, in accordance with section 1935(e) of the Act, territories may submit a plan to the Secretary under which medical assistance is to be provided to low-income individuals for covered Part D drugs. Territories with approved plans will receive increased grants under section 1935 (e)(3) of the Act. Proposed § 423.907 contained the provisions explaining the territories' submittal of plans and the grant funding.

Comment: One commenter expressed concern that low-income Medicare beneficiaries in Puerto Rico will have no incentive (due to the rich prescription drug benefit through the Health Reform program), and no means, to enroll in a PDP because the low-income subsidy program is not available to the territories.

Response: While residents of the territories are not eligible for the low-income subsidy, the MMA provides that the territories receive an increase in the grants paid under section 1108 of the Act if the territory has a plan approved by the Secretary for providing medical assistance for Part D drugs. The territories may choose to use these funds to pay Part D premiums and cost sharing for low-income residents. The territories may also design their programs to wrap around the Part D benefit, thus providing an incentive for Medicare beneficiaries to enroll in the Part D program

Comment: One commenter asked that CMS not require the same financial and statistical reporting for the funds provided to the territories added to the grant under section 1108 of the Act so as not to make the grant administratively burdensome.

Response: Reporting requirements are administrative in nature and are not addressed in this regulation. We will work with the territories to design reports that provide CMS with sufficient information to establish accountability without creating overly burdensome reports.

Comment: One commenter believed that a multi-state PDP region including Puerto Rico will compromise the viability of the Medicare Part D program in that territory because of differences in language, culture, income, and cost structure between Puerto Rico and States.

Response: We appreciate the commenter's concerns. The actual designation of the regions has been announced by CMS and is listed on our website.

4. State Contribution to Drug Benefit Costs Assumed by Medicare (§ 423.908 through § 423.910)

Medicare will subsidize prescription drug costs for full benefit dual eligible individuals. However, in accordance with section 1935(c) of the Act, States and the District of Columbia will be responsible for making monthly payments to the Federal government beginning in January 2006 to defray a portion of the Medicare drug expenditures for these individuals. The percentage of State contributions to Medicare Part D funding is reduced over a ten-year period.

The statute directs, and we specified, in § 423.910(b)(2) that State payments will be made in a manner similar to the mechanism through which States pay Medicare Part B premiums on behalf of low-income individuals who are eligible for both Medicare and Medicaid, except that those payments will be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

As we proposed in § 423.908 through § 423.910 to calculate the monthly State contributions we would first calculate an amount we refer to as the projected monthly per capita drug payment. This amount is based in part on a State's Medicaid per capita expenditures for covered Part D drugs for Medicare beneficiaries eligible for full benefits under Medicaid for 2003, which is equal to the weighted average of gross per capita Medicaid expenditures for prescription drugs for 2003 for Medicaid recipients not receiving drugs through a managed care plan and the estimated actuarial value of prescription drugs benefits provided under a comprehensive Medicaid managed care plan for these individuals in 2003. The weighted average would be based on the proportion of individuals who, in 2003, did and did not receive medical assistance for covered outpatient drugs through a comprehensive Medicaid managed care plan.

The gross per capita Medicaid expenditures for prescription drugs for 2003 is equal to the average (mean) per person expenditures (including dispensing fees) for a State during 2003 for covered Part D drugs provided to Medicare beneficiaries receiving full benefits under Medicaid who are not receiving medical assistance for drugs through a comprehensive Medicaid managed care plan, based on data from the Medicaid Statistical Information System (MSIS) and other available data, as adjusted by an adjustment factor.

We would apply an adjustment factor to the gross per capita Medicaid expenditures for prescription drugs. The adjustment factor for a State would have to equal the ratio of the aggregate payments to the State in 2003 under rebate agreements under section 1927 of the Act to a State's 2003 gross expenditures for covered Part D drugs not received through a Medicaid managed care plan, based on data contained in the CMS–64 Medicaid expenditure report. We proposed to define 2003 as CY 2003 (January 1, 2003 through December 31, 2003). The gross per capita Medicaid expenditures for prescription drugs for 2003 will be reduced by this adjustment factor ratio.

The projected monthly per capita drug payment will be equal to 1/12 of the product of the State's Medicaid per capita expenditures for covered Part D drugs for Medicare beneficiaries eligible for full benefits under Medicaid for 2003 and a proportion equal to 100 percent minus the Federal medical assistance percentage (as defined in section 1905(b) of the Act) applicable to the State for the year for the month at issue. This amount will be increased by the growth factor for each year beginning in 2004 through the year for the month at issue. The growth factor for years 2004, 2005, and 2006 will be the average percent change from the previous year of the per capita amount of prescription drug expenditures (determined using the most recent National Health Expenditure (NHE) projections). The growth factor for 2007 and succeeding years will equal the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals for the 12-month period ending in July of the previous year as described in 423.104(d)(5)(iv). We will provide

further detail regarding the sources of data to be used and how the annual percentage increase will be determined via operational guidance to States.

The monthly State contributions for each year, beginning in January of 2006, will be the product of the projected monthly per capita drug payment, the total number of full-benefit dual eligible individuals for the State in the applicable month, and the applicable ten year phased-down factor for the year (see Table S–1). As illustrated in Table S–1, State contributions will decline each year until 2015, at which time the applicable 10 year phased-down factor for each year will be fixed at 75 percent.

As specified in proposed § 423.910(b)(3), failure on the part of a State to pay these State contribution amounts would result in interest accruing on those payments at the rate provided under section 1903(d)(5) of the Act, in accordance with section 1935(c)(1)(C) of the Act. In addition, as required by the statute, we would immediately offset unpaid amounts and accrued interest against Federal Medicaid matching payments due to the State under section 1903(a) of the Act. As specified in § 423.910(e), we would perform periodic data matches to identify full-benefit dual eligibles for purposes of computing State contributions. As we specified in § 423.910(d), States would be required to provide data on full- benefit dual eligible enrollees in order to conduct the data match required under section 1935(c)(1)(D) of the Act.

States will make contributions only on behalf of Medicare beneficiaries who would otherwise be eligible for outpatient prescription drug benefits under Medicaid. States will not make contributions on behalf of individuals such as those QMBs who are not otherwise eligible for Medicaid, SLMBs, and QIs for whom the State will pay only Part B premiums or Medicare cost sharing on their behalf.

In order to give meaning to the term full-benefit dual eligible individual for purposes of the baseline calculation, we needed to define it in a manner that would permit the baseline calculation to operate. Therefore, we proposed that Medicaid eligible individuals who receive comprehensive benefits including drug coverage under Medicaid and are also covered under Medicare Part A or Part B are to be full-benefit dual eligible individuals for purposes of calculating the baseline. The proposed definition of full-benefit dual eligible individuals excluded Medicare beneficiaries who receive Medicaid drug coverage under a section 1115 Pharmacy Plus demonstration.

As we specified in § 423.910(g), to assist States in their budget planning, we must notify States by October 15 each year of the projected monthly per capita drug payment calculation for the next calendar year.

The ten-year phased-down State contribution (PDSC) factors are identified below in Table S–1.

TABLE S–1

ANNUAL PHASED—DOWN PERCENTAGES OF STATE CONTRIBUTIONS TO MEDICARE PART D DRUG BENEFIT COSTS

Year	State Percentage
2006	90
2007	88 1/3
2008	86 2/3
2009	85
2010	83 1/3
2011	81 2/3
2012	80
2013	78 1/3
2014	76 2/3
2015 and thereafter	75

Comment: A few commenters expressed concern that the 2003 baseline per full-benefit dual eligible drug cost would fail to reflect cost containment measures by States. The commenters believed that the legislative reference to the use of ''other available data'' provides for a more expansive view of adjustments. Proposed changes included allowing States to submit documentation of the effects of cost containment measures to periodically re-base the cost, and the use of 2004 as a base year.

Response: The legislation specifies that we inflate the 2003 base year full-benefit dual eligible per capita drug costs for use in 2006 using the NHE projections for the years involved. This inflation factor should take into account changes in the rate of growth of per capita drug costs. Any effort to measure the differential effect of State cost containment against the specified inflation factor could be imprecise and would introduce new reporting requirements. We do not support the use of optional ad hoc State-reported data, which will be inconsistently defined, and would be applied unevenly to States. The use of a later base year, such as 2004, is precluded by the legislative language.

Comment: One commenter recommends that the regulations allow State-specific methods for the estimated actuarial value of capitated prescription drug benefits, allowing States to use their data for the dual eligible population.

Response: Since we believe the data available on managed care drug costs will vary by State, the final rule provides for use of a range of sources of managed care drug cost data.

Comment: One State commenter believes it may pay a disproportionate share in its phase-down contribution for less comprehensive coverage for its full-benefit dual eligible individuals.

Response: We believe that the Medicare drug benefit will pay, on average, more than 96 percent of full-benefit dual eligible individuals' drug costs. Additionally, about 1.5 million of these full-benefit dual eligible individuals are institutionalized, meaning they will not pay any premiums, deductibles or co-payments. While the nominal cost sharing of the Medicare prescription program is slightly higher than the cost-sharing under Medicaid, Medicare provides catastrophic drug coverage, offering additional protection to this vulnerable population. We further believe that Medicare Part D is likely to result in more stable and consistent prescription drug coverage for low-income Medicare beneficiaries since Medicaid is not a secure source of drug coverage, as eligibility is subject to meeting certain income and resource requirements. As a result of these requirements, Medicaid may only provide intermittent drug coverage to the full-benefit dual eligible individual.

Comment: One State commenter asked how member months are being counted, how people in MA plans will be counted for the phased-down payment, and whether individuals from their family planning waiver are included.

Response: For the phase-down baseline, we expect to count every MSIS reported enrollment for each month for individuals who are coded as full-benefit dual eligible individuals. MA plans have no effect on the baseline calculations, although we will distinguish between Medicaid individuals in comprehensive plans and those not in comprehensive plans. This distinction is necessary to establish the weighting between the fee-for-service and capitated populations in the baseline calculations. The only full-benefit dual eligible enrolled individuals who are excluded are those in Pharmacy Plus demonstrations and drug-only 1115 demonstrations. Those

in family planning demonstrations would not be excluded if they received benefits beyond drug coverage.

Comment: One commenter requested clarification on the process to inflate the baseline per-capita drug cost after 2006. The legislation specifies the use of the actual Part D costs for the 12 months prior to July of each year. For 2007 there will not be a 12-month history from 2006 available.

Response: We will provide further detail regarding the sources of data to be used and how the annual percentage increase will be determined via operational guidance to States.

Comment: A few commenters expressed concern about the use of the NHE factor to inflate the baseline to 2003, and suggested that we use either State-specific numbers, or the total public sector number.

Another commenter asked clarification as to which specific NHE projection will be used for the phase-down calculation.

Response: The legislation is clear in directing the use of the NHE estimate for the whole country as the basis for this inflation factor. That source provides very limited options for use. We believe the overall per capita drug cost numbers are the most consistent with the intent of the law. The specific NHE projection factor to be used will be discussed in operational guidance.

Comment: One commenter expressed concern that the 2003 base year data may not be representative of drug utilization experience. The commenter proposes using pooled data from 2001, 2002, and 2003 to obtain a utilization estimate. The commenter also expressed concern over the use of quarterly MSIS dual eligibility codes to establish monthly spending and enrollment base numbers.

Response: We believe that this proposal would introduce significant additional problems associated with the trending forward of that significantly older base data. This proposal also conflicts with the legislative language, which clearly specifies the use of the calendar year 2003 data. We will address the use of quarterly dual eligibility indicators in MSIS by applying an algorithm that incorporates both prior and current quarter values.

Comment: A few commenters proposed that States be allowed to submit drug rebate dollar amounts that reflect only the full-benefit dual eligible population. They propose that these numbers be used instead of the aggregate rebate and drug payment amounts reported on the CMS–64 report.

Response: While this proposal would allow the rebate adjustment to correspond more closely to the population affected by the PDSC, this is inconsistent with the legislative language, and would require that we impose new and complex reporting requirements on the States. We do not support the use of optional ad hoc State-reported data, which will be inconsistently defined, and would be applied unevenly to States.

Comment: A few commenters proposed that we allow States to submit, at their option, rebate collections after 2003 for rebate amounts identified in 2003. These additional rebate amounts would be used to reduce the base year drug costs in the baseline calculations.

Response: This comment presumes that the legislation intended that we use base year data for rebates on an incurred, rather than paid, basis. This is inconsistent with the definition of the CMS–64 referenced by the legislative language. Simply adding incremental collections of 2003 incurred rebates would inappropriately inflate the rebate totals, since the law does not provide for removal of 2003 rebate collections incurred in 2002. There is no standardized reported data that would allow creation of an incurred rebate amount, and no indication in the legislation that this was intended. We believe use of optional State-reported post–2003 rebate collections would introduce inconsistent treatment of States.

Comment: One commenter recommended that States that provide pharmacy-only benefits under an 1115 demonstration to a subset of its population be excluded from the definition of full- benefit dual eligible individual, since these programs generally provide the same benefits as offered by Pharmacy Plus Programs.

Response: We agree with this commenter and have clarified the definition of full-benefit dual eligible individual at § 423.902 to specifically exclude those individuals enrolled in 1115 demonstration programs that provide pharmacy-only benefits to a portion of its demonstration population.

Comment: One State commenter did not object to including its Medicare beneficiaries who are enrolled in its pharmacy assistance 1115 program in the baseline expenditures, but believes it is inappropriate to count them as part of the future Medicaid enrolled population that is multiplied by the trended per person cost as part of the formula.

Response: As indicated above, we will not be including these populations in the baseline expenditures. In order to remain consistent with the definition of the baseline and monthly billing counts, we would also exclude this population from the future Medicaid enrolled population.

Comment: One State commenter recommends CMS use the First Data Bank generic sequence number in lieu of the NDC when determining the excluded list of drugs used in establishing the State's phase-down contribution.

Response: We are using the NDC because it is the only available identifier on the MSIS drug claim record.

Comment: One commenter proposed that we allow States to submit auditable reports of reductions in base year drug payments due to judicial settlements with drug manufacturers and other accounting adjustments to base year cost.

Response: This comment presumes that the legislation intended that we use base year data on an incurred, rather than paid, basis. This is inconsistent with the definition of the MSIS and CMS–64 data sources referenced by the legislative language. Simply adding incremental collections of 2003 settlements would improperly reduce the total payments, since it does not provide for removal of 2003 settlements incurred during 2002. There is no standardized reported data that would allow creation of an incurred settlement amount, and no indication in the legislation that this was intended. The legislation directs that we derive the base year costs from the reported MSIS drug claims data, and there is no viable way to associate these settlement amounts with those individual drug claims; nor can these settlements be accurately associated with the target population on an aggregate basis. We believe use of optional State-reported post–2003 settlements would introduce inconsistent treatment of States.

Comment: One commenter proposed that full-benefit dual eligible individuals be enrolled in plans providing a formulary comparable to the existing Medicaid coverage, and several commenters proposed that that the PDSC payment exclude any payments for drugs outside the Part D formulary.

Response: There is no provision in the legislative language to ensure equivalency of drug formularies under Medicaid dual eligible and Part D coverage. The PDSC payments are based on actual Medicaid program payment levels, and are not linked to the Part D formularies.

Comment: One commenter proposed that 100 percent State funded drug benefits for drugs not in the Part D

formulary be excluded from the PDSC payment.

Response: The baseline is specified to be the actual Medicaid drug payment experience for each State based on MSIS data which does not include State-only programs. The legislation does not provide for adjustments based on subsequent State choices to offer drug coverage that wraps around the Part D coverage. There is no provision for Medicaid or other State programs to receive Federal matching or an exclusion from PDSC payment for drugs provided beyond those excluded drugs. The PDSC payments are based on the savings from historic State utilization levels, and do not guarantee equivalence in coverage formularies.

Comment: One commenter expressed concern about drugs to be excluded from the baseline.

Response: We have developed a list of drug codes for drugs to be excluded from the baseline based on the Part D exclusions in the legislation.

Comment: A few commenters asked that we clarify the start date and ongoing due dates for the PDSC payments.

Response: The final regulatory language includes this information. The ongoing due dates will parallel those for the Medicare Part B premium buy-in process.

Comment: One commenter requested that we move the due date for State notification of baseline amounts from October 15 to August 15 prior to the payment year. This would allow States more budgetary lead time.

Response: The legislation requires that the first year's baseline data be provided to States no later than October 15, 2005 for the 2006 payment year. In order to help support State budgeting needs, it is our intent to provide this information to States as soon as it can be developed. However, the timing to produce preliminary numbers will be contingent on timely State reporting of needed MSIS data.

In regard to years subsequent to 2006, the only changes to the base number will be the inflation factor and the Federal matching rate. States should be able to develop reasonably accurate estimates for later years based on the prior year's base.

Comment: One commenter expressed concern that if we require State payment by check or electronic funds transfer, payment could conflict with State-legislated caps. The commenter proposed that we allow a range of payment options comparable to the Medicare buy-in process.

Response: It is our intent, as evidenced by our clarification of the final regulatory language, to mirror the payment process for the buy-in process set forth in a **Federal Register** notice published on September 30, 1985 at FR 39784. This process includes funds transfers, with a provision that any late payments will be offset against the Medicaid grant with appropriate interest accrual. In this case, the Medicaid offset would be transferred to the Medicare Prescription Drug Account to complete the transaction. Since failure to pay is covered in this notice, we have removed text at § 423.910(b)(3) that was included in the proposed rule.

Comment: A few commenters requested that we include a process for State appeal of the PDSC payment amount.

Response: The legislation does not contain a specific provision for an appeal process. However, it requires CMS to disallow from the Federal financial participation in the State's Medicaid expenditures any amounts which the State should have paid under section 1935 of the act. Because this is a disallowance of Medicaid funds, any State disagreements with the phased-down billing would have to be handled through the existing disallowance process under § 430.42.

Comment: A few commenters expressed concerns about the need for more specific instructions for reporting monthly enrollment to CMS, and proposed the use of the MSIS.

Response: The final regulation includes more specific information on this reporting process. CMS has evaluated this option and has determined that the change of MSIS from quarterly to monthly reporting would represent an undue hardship to States. The enrollment reporting file would also require the addition of fields to address other program needs, such as subsidy determinations.

Comment: One commenter requested more detail on the process to be used to establish the actuarial value of the capitated prescription drug benefits for full-benefit dual eligible individuals in comprehensive managed care plans.

Response: We have provided clarification in the final regulation at § 423.902, based on feedback obtained from State workgroups addressing this issue.

T. Part D Provisions Affecting Physician Self-Referral, Cost-Based HMO, PACE, and Medigap Requirements

In the August 2004 proposed rule, subpart T discussed several other regulatory areas affected by the provisions implementing the Medicare prescription drug benefit. This section discussed the revised requirements for physician self-referral prohibition, cost-based HMOs, PACE organizations, and Medigap policies.

1. Definition of Outpatient Prescription Drugs for Purposes of Physician Self-Referral Prohibition (§ 411.351)

Section 1877 of the Act, also known as the physician self-referral law, prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which the physician (or an immediate family member of the physician) has a financial relationship (ownership, investment, or compensation), unless an exception applies. Section 1877 of the Act also prohibits the DHS entity from submitting claims to Medicare for DHS furnished as a result of a prohibited referral.

Outpatient prescription drugs are a DHS under section 1877 of the Act. As a result of the Medicare prescription drug benefit provisions, we proposed to amend the physician self-referral definition of ''outpatient prescription drugs'' at § 411.351 to include the additional outpatient drugs covered under the new Part D benefit. In other words, under the proposed definition, physician referrals for outpatient prescription drugs covered under Part D would be subject to the physician self-referral prohibition. We have finalized this proposal without substantive change because we believe that referrals for Part D drugs are subject to the same risk of over-utilization and anti-competitive behavior as referrals for Part B drugs when a financial relationship exists between the referring physician and the entity furnishing the drugs.

Comment: We received a number of comments, which supported our proposal. Some of the commenters cited analyses, which supported our proposed action.

Response: We appreciate the support given to our proposal. We believe that applying the physician self-referral provision to referrals for either Part B or Part D drugs will reduce the potential for over-utilization and other program abuse.

2. Cost-Based HMOs and CMPs Offering Part D Coverage (§ 417.440 and § 417.534)

Section 1860D–21(e) of the Act provides that Part D rules will generally apply to reasonable cost reimbursement HMOs and CMPs (Competitive Medical Plans) that contract under section 1876 of the Act and that offer qualified prescription drug coverage to Part D eligible individuals in the same manner as such rules apply to the offering of

qualified prescription drug coverage under MA-PD local plans. As a result, we proposed revising § 417.440(b) of this chapter to specify that a cost-based HMO or CMP may offer qualified prescription drug coverage. We also proposed adding new § 417.534(b)(4), specifying that to the extent that a cost HMO or CMP chooses to participate in the Part D program by offering qualified prescription drug coverage to its members, any costs associated with the offering of Part D benefits may not be claimed on its Medicare cost report. After reviewing comments and responding (below), we are adopting the proposed policy as final.

In the proposed rule, we incorrectly stated at 69 FR 46753 that cost-based HMOs and CMPs would offer qualified prescription drug coverage to Part D eligible enrollees under § 417.440(b)(1)(iii) as a basic benefit. We clarify in this final rule our belief that such a reading would not comply with the clear language of section 1876(c)(2)(A)(ii)(I) of the Act which provides that cost-based HMOs and CMPs may only offer non-Part A/B Medicare benefits as optional supplemental benefits. In this final rule, we therefore amend § 417.440(b)(2) to make the requirement clear that cost-based HMOs and CMPs may offer qualified prescription drug coverage to Part D eligible enrollees only as an optional supplemental benefit.

Section 1860D–21(e)(2) of the Act stipulates that section 1876 reasonable cost contractors offering qualified prescription drug coverage may only offer such coverage to individuals enrolled in its reasonable cost contract, or individuals who receive services covered under Medicare Parts A and B through its reasonable cost contract. After reviewing comments and responding (below), we are adopting the proposed policy as final. However, it is important to note that the HMO or CMP offering the cost plan is free to also apply to be a PDP sponsor and may, if approved, then offer a separate Part D plan to Part D eligible individuals enrolled in original Medicare who are not enrollees of its cost plan.

Section 1860D–21(e)(3) of the Act provides that the Part D bids of section 1876 reasonable cost contracts will not be included in the computation of the national average monthly bid amount and the low-income benchmark premium amount. We discuss the national average monthly bid amount in the subpart F preamble and the low-income benchmark premium amount in the subpart P preamble.

We proposed that the waiver authority provided in section 1860D–21(c) of the Act would be available to section 1876 reasonable cost HMOs and CMPs in the same manner as it is available to MA-PD local plans, namely that we will waive any requirement otherwise applicable under this part for section 1876 reasonable cost HMOs and CMPs to the extent such requirement conflicts with or is duplicative of a requirement under part 417, or such waiver is necessary to promote coordination of the Part D benefits with the benefits offered under part 417. We discuss section 1860D–21(c) of the Act and this waiver authority in subpart J of the preamble. We invited comment on whether there are any Part D requirements otherwise applicable to the offering of qualified prescription drug coverage under MA-PD local plans that would be uniquely problematic to implement for section 1876 reasonable cost HMOs and CMPs. After reviewing and responding to comments (below), we have not identified any additional Part D requirements that will be uniquely problematic for section 1876 reasonable cost HMOs and CMPs to implement. Nevertheless, in § 423.458(d) of the final rule, we provide for a process that will allow for waiver of Part D provisions for cost HMOs and CMPs that offer qualified prescription drug coverage under Part D to the extent that the provision duplicates, or is in conflict with provisions otherwise applicable to the section 1876 cost HMO/CMP under section 1876 of the Act, or when a waiver is necessary to promote coordination of the Part D benefits with the benefits offered under part 417.

Comment: Some commenters suggested that we make clear that once a cost plan offers Part D that it becomes an MA-PD plan and that some (or all) Part C provisions then supersede or replace section 1876 (and part 417 of title 42 CFR) provisions as controlling on such a cost plan. For instance, some commenters suggested that the State preemption authority in section 1856(b)(3) of the Act related to MA plans, and incorporated by reference in section 1860D–12(g) of the Act, should be interpreted to apply to the entire benefit package that a cost HMO/CMP offers and not just the prescription drug coverage portion of the package.

Response: We do not agree. We interpret section 1860D–21(e)(1) of the Act as providing that only those provisions of Part D and related provisions of Part C pertaining to the offering of qualified prescription drug coverage by a MA-PD local plan would apply to the offering of such coverage by a cost HMO or CMP. Consequently, the provisions of Parts C and D, including the preemption provisions under sections 1860D–12(g) and 1856(b)(3) of the Act, would not apply to benefits offered under a reasonable cost contract other than any qualified prescription drug coverage. In other words, the section 1876 cost-based HMO/CMP does not gain preemption protection related to the ''entire benefit package'' it offers. Accordingly, the preemption authority at section 1860D–12(g) of the Act does not, in and of itself, ''immunize'' the cost HMO/CMP from State laws with respect to the benefits the cost HMO/CMP offers under the authority in section 1876 of the Act.

Comment: One commenter said that section 1860D–21(e) of the Act says that a cost HMO/CMP that offers qualified prescription drug coverage to its members is deemed to be an MA-PD local plan. This commenter suggested that CMS should allow a cost plan that elects to offer qualified prescription drug coverage to its Part D eligible cost enrollees to apply related Part C provisions to those members.

Response: We do not necessarily agree. Section 1860D–21(e) of the Act extends to cost plans provisions of Part C applicable to MA-PD local plans to the extent they relate to the offering of qualified prescription drug coverage. Section 1860D–21(e) of the Act, however, does not deem a reasonable cost contract offering qualified prescription drug coverage a MA-PD local plan for all purposes. Consequently, those provisions applicable to MA-PD local plans that are unrelated to the offering of qualified prescription drug coverage would not apply to reasonable cost contracts. In other words, it is only in this limited way that a cost plan offering qualified Part D coverage is deemed to be an MA-PD.

Comment: One commenter suggested modifying § 417.436 to provide that that the requirement at § 417.436(a)(5) that a cost HMO or CMP disclose to its enrollees that they may receive services through any Medicare provider or supplier has no effect with respect to the offering of qualified prescription drug coverage under the reasonable cost contract.

Response: We believe that § 423.458 is clear in providing that rules related to Part D coverage, whether offered by a PDP or an MA-PD, are provided in the part 423 regulations. Therefore, it is not necessary to specifically say in the part 417 regulations that a specific part 423 regulation applies. Section 423.128(b) describes the specific information that PDPs and MA-PDs must disclose related to their Part D benefit offerings, which includes ''a disclosure of out-of-network

coverage consistent with § 423.124(a)''—see § 423.128(b)(6).

Comment: One commenter asked that we clarify that a legal entity that operates a Medicare cost plan may operate as a PDP sponsor as long as it meets all the relevant licensure and other requirements.

Response: We concur and have clarified this point in our preamble discussion in this subpart.

Comment: One commenter asked us to clarify that the definition of service area for cost HMOs/CMPs is found at § 417.1, while the definition for MA plans is found at § 422.2. The commenter asked us to clarify that the reference to service areas for MA-PD plans in § 423.120(a) had no applicability to cost plans.

Response: We agree with the commenter that the reference to service area of an MA-PD plan in § 423.120(a) does not apply to cost HMOs/CMPs that offer Part D coverage. The effect of section 1860D–21(e)(2) of the Act is not to ''deem'' that a cost plan offering qualified Part D coverage actually becomes an MA-PD local plan. Rather, it is that the rule applicable to the *provision of Part D coverage* by the cost plan to enrollees of the cost plan is similar to the *provision of Part D coverage* by MA-PD local plans. As we provide in subpart J of this rule at § 423.458(d), we will waive provisions in § 423.120(a) to the extent they duplicate or conflict with section 1876 provisions applicable to cost plans under section 1876 of the Act or part 417 of title 42 CFR, or to the extent waiver is necessary to improve coordination of Part D benefits offered under the plan with the other benefits offered by the cost plan. Although we do not specifically mention such a waiver at § 423.120(a) for a cost HMO/CMP offering qualified prescription drug coverage, such a waiver is available, to the extent it would meet the conditions for waiver in § 423.458(d).

Comment: One commenter asked if the disclosure requirements in § 423.128, to the extent they were more stringent than the disclosure requirements under section 1876 of the Act and § 417.436 of the title 42 CFR, would only apply to the Part D portion of a cost plan's benefit offerings.

Response: To the extent that a ''coordination'' waiver has not been granted under § 423.458(d), the disclosure requirements in § 423.128 would apply to the Part D portion of a cost plan's benefit offering.

Comment: One commenter suggested that section 1860D–21(e) of the Act provides to us clear authority to allow us to apply ''deeming'' authority in § 423.165 to cost HMOs/CMPs offering qualified Part D coverage to cost enrollees, which allows us to deem an entity as meeting certain requirements under this part if the entity is fully accredited (and periodically reaccredited) by a private national accreditation organization approved by us.

Response: We agree that section 1860D–21(e) of the Act extends the deeming authority under § 423.165 to section 1876 cost HMOs/CMPs, provided the provisions of § 423.165 are not otherwise waived under § 423.458(d) with respect to section 1876 cost HMOs/CMPs.

Comment: One commenter asked us to clarify that the waiver authority in § 423.458(c), which permits us to waive or modify any requirement under this part that hinders the design of, the offering of, or the enrollment in an employer- or labor-sponsored group prescription drug plan, would also apply to section 1876 cost HMOs/CMPs.

Response: We responded to a similar comment in the subpart J preamble. In short, we do not interpret the statute as permitting us to apply our waiver authority related to employer- or labor-sponsored group coverage as extending to the Medicare Part A and B benefits offered by a Medicare cost plan.

Comment: A few commenters asked if section 1876 cost plans that did not offer qualified prescription drug coverage would be permitted to offer non-qualified prescription drug coverage. One commenter also asked if such coverage would be creditable coverage under Part D fearing that such cost members would be penalized for electing Part D late.

Response: Section 1876 reasonable cost plans that do not offer their members qualified prescription drug coverage may offer non-qualified prescription drug coverage to their members, but only as an optional supplemental benefit and in accordance with § 417.440(b)(2). Such coverage will be considered creditable prescription drug coverage only if it meets the standards set forth in § 423.56(a) of the final rule.

Comment: One commenter asked if we would permit cost plans to waive Part A/B and to apply this waiver to the Part D premium that would otherwise be imposed on cost plan members.

Response: Such a waiver will not be permitted. A cost plan must claim its reasonable costs for services provided under the plan that are covered under Parts A and B in accordance with the applicable requirements of part 417 of this chapter. If the cost plan elects to provide its enrollees qualified prescription drug coverage under Part D, payment for such benefits will be governed by the payment rules under this part. In other words, the financing of services provided under the cost plan that are covered under Parts A and B is separate from the financing of any qualified prescription drug coverage provided under the plan. Please see § 417.534(c) where we clearly state that ''no costs related to the offering or provision of Part D benefits will be reimbursed under this Part [417].'' To the extent that we permitted waiver of A/B to apply to reduction in Part D premiums, dollars applicable to part 417 would flow to Part D, and therefore such a proposal cannot be allowed. If a cost plan wants to reduce cost-sharing values for A/B services as currently permitted, it may continue to do so. However, the revenue thus forgone related to benefits offered under part 417 cannot be passed over to reduce premiums required under part 423.

Comment: One commenter asked if the waiver of State premium taxes and the preemption authority granted under section 1860D–12(g) of the Act to PDP sponsors and prescription drug plans would also apply to cost plans offering qualified Part D. The commenter suggested that such a waiver and such authority should also be extended to the cost plan's A/B benefit offerings under part 417.

Response: We have previously provided guidance to cost plans related to State premium taxes. As we have previously indicated, we do not believe that States can impose a premium tax on the reasonable costs that we reimburse cost plans for covered Medicare Part A and B services. Such payments by us do not technically represent a premium so much as they represent reimbursement, under the Medicare program, for benefits to which Medicare enrollees are entitled. On the other hand, we have also said that premiums changed to cost plan members for the actuarial value of fee-for-service deductibles and coinsurance are properly construed as premiums and would be correctly subject to State taxes. On the other hand, for premiums related to the Part D offering of a cost plan, there is specific preemption and waiver of State taxes. See the subpart J preamble for an additional discussion on this issue.

3. PACE Organizations Offering Part D Coverage

a. Overview

Section 1860D–21(f)(1) of the Act provides that a PACE program may elect to provide qualified prescription drug

coverage to its enrollees who are Part D eligible individuals.

Currently, sections 1894 and 1934 of the Act require PACE organizations to provide enrollees with all medically necessary services including prescription drugs, without any limitation or condition as to amount, duration, or scope and without application of deductibles, co-payments, coinsurance, or other cost sharing that would otherwise apply under Medicare or Medicaid. Up until January 1, 2006, payment for drugs covered under Medicare Parts A and B is included in the monthly Medicare capitation rate paid to PACE organizations for Medicare beneficiaries, while payment for outpatient prescription drugs is included as either a portion of the monthly Medicaid capitation rate paid to PACE organizations for Medicaid recipients, or as a portion of the amount equal to the Medicaid premium paid by non-Medicaid recipients.

The MMA alters the payment structure for Part D drugs for PACE organizations by shifting the payer source for PACE enrollees who are full-benefit dual eligible individuals (as defined under section 1935(c)(6) of the Act) from Medicaid to Medicare, and in part from the beneficiary to Medicare in the case of non-full-benefit dual eligible individuals who elect to enroll in Part D.

Consequently, in order for PACE organizations to continue to meet the statutory requirement to provide prescription drug coverage to their enrollees, and to ensure that they receive adequate payment for the provision of Part D drugs, from January 1, 2006 forward, we explained in the proposed rule that PACE organizations would need to offer qualified prescription drug coverage to their enrollees who are Part D eligible individuals. We also indicated that prescription drug coverage for PACE enrollees who are ineligible for Part D (Medicaid-only enrollees) would continue to be funded by the State in which each PACE organization is located through its monthly capitation payment to the PACE organization.

Section 1860D–21(f)(1) of the Act provides that in the case of a PACE program that elects to provide qualified prescription drug coverage to its enrollees who are Part D eligible individuals, the requirements under this Part apply to the provision of the coverage in a manner that is similar to the manner in which the requirements apply to the provision of such coverage under MA-PD local plans. Furthermore, the PACE organization may be deemed to be MA-PD local plan.

We believe that the Congress did not intend to alter the way in which PACE services, including outpatient prescription drugs, are currently being provided to enrollees. Therefore, we proposed that PACE organizations not be deemed to be MA-PD local plans. Rather, we proposed that PACE organizations would be treated in a manner that is similar to an MA-PD local plan for purposes of payment under Part D for qualified prescription drug coverage provided under their PACE plans. We stated that we believed this approach was consistent with section 1894(d)(1) of the Act, which provides that payments will be made to PACE organizations in the same manner and from the same sources as payments are made to a MA organization.

PACE organizations have a longstanding history of providing prescription drug coverage under the authority of sections 1894 and 1934 of the Act and 42 CFR part 460. Therefore, many of the new Part D requirements are duplicative of, conflict with, or do not promote coordination with, the PACE benefit. For these reasons, many of the Part D requirements will be waived for PACE organizations. A background of the PACE model is provided below, followed by a discussion of Part D administrative and payment related requirements as they relate to PACE organizations.

b. *Background*

Sections 4801 through 4803 of the Balanced Budget Act of 1997 (Pub. L. 105–33) established PACE as a Medicare benefit category and a State plan option under Medicaid. PACE organizations provide services to frail, elderly individuals as an alternative to nursing home placement. The PACE benefit currently includes all Medicare benefits under Parts A and B, all services covered under the Medicaid State plan, and any other service(s) deemed necessary by the PACE interdisciplinary team.

The PACE benefit also currently includes all outpatient prescription drugs, as well as over-the-counter medications that are indicated by the participant's care plan. Thus, all PACE organizations currently provide at least the equivalent of qualified prescription drug coverage as described under subpart C.

PACE organizations are risk-bearing entities that receive a capitated monthly rate from Medicare for Medicare-covered services and from Medicaid for Medicaid-covered services. As required by sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act, the PACE organization pools payments received from all sources in order to provide all services needed by its enrollees, including services covered by neither Medicare nor Medicaid. Currently, most PACE enrollees are dually eligible for Medicare and Medicaid; however, participants may be eligible for Medicare only or Medicaid only. Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act require the PACE organization to provide all covered services to enrollees regardless of the source of payment. Sections 1894(b)(1)(A)(i) and 1934(b)(1)(A)(i) further clarify that PACE programs cannot charge deductibles, co-payments, coinsurance, or other cost-sharing responsibilities to PACE participants. Consequently, a PACE organization may not charge its participants any cost sharing.

The PACE Medicare and Medicaid regulations are located in 42 CFR part 460. As directed by sections 1894 and 1934 of the Act, these regulatory requirements are a blend of MA and Medicaid managed care requirements, as well as requirements from the PACE Protocol that was created by On Lok, Inc. under a demonstration waiver program with the Secretary. Thus, although certain PACE requirements are the same or similar to MA and Medicaid managed care requirements, many are unique to PACE.

We received 11 formal letters of comment from industry representatives, PACE organizations, States, and contractors. Most commenters identified multiple concerns, regarding the Part D administrative and payment related provisions in relation to PACE. Many commenters also expressed support for the waivers we proposed, as well as recommended that we waive additional Part D rules because they conflict with, duplicate, or do not promote coordination with, the PACE statute and regulations. We thank the commenters who submitted comments on waiver issues, and we have summarized all of the comments below. However, as explained below, we have chosen to finalize only our proposed waiver of section 423.265(b), which would have required PACE organizations planning to offer Part D prescription drug plans to submit bids and supplemental information no later than the first Monday in June of each year. We will issue further guidance that will list additional Part D provisions that we will waive for PACE organizations. In issuing such guidance, we will take into consideration all of the comments we received regarding waivers.

c. Application of Payment Related Part D Requirements to PACE Organizations

In using the term, payment related requirements, we are referring to

subparts F, G, and P of this regulation concerning submission of bids and monthly beneficiary premiums, plan approval, payments to PACE organizations for qualified prescription drug coverage, and premium and cost-sharing subsidies for low-income individuals.

In accordance with subpart F, we proposed that each organization would submit a Part D bid that would reflect its average monthly revenue requirements to provide qualified prescription drug coverage, including enhanced alternative prescription drug coverage, for a Part D eligible individual with a national average risk profile. This bidding process would have occurred in a similar manner as for traditional Part D plans. In accordance with § 423.265(c)(3) of this regulation, Part D bids were to be prepared according to CMS guidelines on actuarial valuation and actuarially certified.

We also proposed that plans would use qualified actuaries to prepare their bids in accordance with these principles. However, we were concerned that requiring small PACE organizations to independently contract with actuaries would be costly and burdensome. In order to minimize their cost, we suggested that PACE organizations collectively contract with an actuary to develop the methodology for establishing a bid, but stated that each bid would need to be actuarially certified.

Finally, we indicated that since PACE organizations are required to enroll Medicare-only individuals who meet PACE eligibility requirements, all PACE organization bids would be required to include the portion of the bid attributable to the cost of providing the enhanced alternative prescription drug coverage.

In the proposed rule, we proposed policies addressing each of the three primary categories of PACE enrollees: individuals enrolled in Medicaid, but not Medicare (Medicaid-only); individuals enrolled in Medicare and Medicaid (Dual eligible individuals); and individuals enrolled in Medicare, but not Medicaid (Medicare-only).

First, we indicated that prescription drug coverage for Medicaid-only enrollees would continue to be funded by Medicaid through a portion of the monthly capitation rate paid to the PACE organization because these enrollees are ineligible to receive Part D prescription drug coverage.

For dual eligible and Medicare-only PACE enrollees, we proposed that PACE organizations would offer enhanced alternative prescription drug packages with no enrollee cost sharing.

For both dual eligible individuals and Medicare-only enrollees, we proposed that we would pay PACE organizations the direct subsidy, calculated under § 423.329(a)(1). In addition, the PACE organization would receive low-income premium and subsidy payments or partial subsidy payments for those enrollees who qualify for the low-income subsidy. We noted that dual eligible beneficiaries would be deemed eligible for the full low-income subsidy under § 423.773(c), which included a premium subsidy not to exceed the basic premium for coverage under the Part D plan selected by the beneficiary, but no more than the greater of the low-income benchmark premium amount or the lowest beneficiary premium amount for a PDP offering basic prescription drug coverage in the PDP region where the beneficiary resides. To the extent a discrepancy occurred between the low-income premium amount and PDP or MA-PD plan's bid, § 423.286(d)(1) of the proposed rule required beneficiaries to pay this amount as a premium which would have been established by the PDP or MA-PD plan during the bidding process. The PACE regulations, however, conflict with this Part D provision since they preclude a PACE organization from charging premiums to dual-eligibles.

In addition, Medicare-only enrollees would have been required to account for the additional cost of providing a prescription drug package to enrollees without the application of cost sharing. This amount would have represented the ''enhanced'' portion of the Part D premium. Because PACE organizations are not precluded from charging premiums to Medicare-only enrollees, it would have been permissible for them to pass on the responsibility for any payment discrepancy and enhanced alternative coverage to their Medicare-only enrollees in order to comply with Part D requirements. The premium amounts actually paid by enrollees would have varied depending on whether the enrollee was eligible for both Medicare and Medicaid or only eligible for Medicare and according to whether the enrollee qualified for the low-income premium subsidy.

We were concerned about the impact on low-income dual eligible and Medicare-only PACE enrollees and requested public comment on other approaches to handling this premium differential.

We also indicated in the proposed rule that reinsurance and risk corridor costs as defined in § 423.308 would be applicable to PACE organizations and that PACE organizations would be required to track allowable costs for all Part D eligible PACE enrollees pertaining to reinsurance payments and under § 423.336(c) pertaining to risk corridor amounts. Specifically, low-income subsidy amounts received by the PACE organizations would count towards the annual out-of-pocket threshold applicable to reinsurance.

Comment: We received many bidding related comments. Some commenters requested that PACE organizations not be required to bid, others requested that PACE organizations be permitted to delay their bid submission until after the average benchmark premium and low income subsidy amounts are set, and others requested that we grant a waiver of the bidding requirements under subpart F of the proposed rule on behalf of PACE organizations. Commenters viewed the bidding process as administratively burdensome and costly to small scale PACE organizations that are currently able to effectively provide prescription drug coverage to enrollees under the authority of the PACE statutes and regulations.

Commenters did not view the bidding approach outlined in the proposed rule to be consistent with the unique attributes of PACE, including existing PACE statutory and regulatory guidance for the provision of prescription drugs which precludes cost sharing and small PACE organization enrollment as compared with traditional Part D plans.

Some commenters proposed a transition period during which PACE organizations would base their Part D bid on the amounts currently paid to them by Medicaid for drug coverage. These commenters recommend that we utilize the same data gathered under section 1935(c) of the Act as a basis for paying PACE organizations for the prescription drug costs of dually eligible individuals enrolled in PACE. Each State currently providing PACE as an option under its State plan would be required to reduce its capitation payment for dual eligible PACE enrollees by the amount of Medicaid expenditures for Part D covered drugs beginning January 2006. The difference between the old and new State payment amounts would be the basis for the PACE organizations' bids. Specifically, in States with more than one PACE organization, the bids of all PACE organizations located in the same State would be equal.

These commenters indicate that this proposed bidding approach would not only be consistent with the current cost of providing prescription drug coverage to the PACE population, but it would be less administratively burdensome to small organizations. In addition, a transition approach would also allow

us, States, and the industry additional time to evaluate the impact of Part D on PACE and develop a payment approach consistent with the PACE model. The commenters proposed that the transition period continue until an evaluation of the impact of the Part D program on PACE could be completed or appropriate legislative or regulatory changes could be made to reconcile the conflicting provisions of the PACE and Part D requirements.

Response: Because the MMA shifts responsibility for prescription drugs from Medicaid to Medicare for the full-benefit dual eligible beneficiaries, it will no longer be possible for PACE organizations to receive prescription drug payment on behalf of these beneficiaries from Medicaid. In addition, section 1860D–21(f) of the Act indicates that to the extent a PACE program elects to provide qualified prescription drug coverage to Part D eligible individuals, Part D requirements apply to the provisions of such coverage in a manner that is similar to that of MA-PD local plans. As stated previously, PACE organizations will be treated in a manner that is similar to that of MA-PD local plans, including the bidding provisions of subpart F. We do not view the proposed transition period as ''similar to'' the requirements under which MA-PD plans will operate. In addition, section 1860D–21(f)(3) of the Act implies that PACE organizations will submit bids by indicating that PACE organizations bids will not be included in national average benchmark amounts. We do not have the statutory authority to waive the Part D bidding requirement. Thus, PACE organizations will be required to submit bids in accordance with subpart F.

Comment: Many commenters expressed concern that requiring PACE plans to bid, and basing premium and subsidies on MA-PD bids rather than PACE bids will create an unlevel playing field for PACE.

Commenters were concerned that the small size of PACE organizations will hinder their ability to achieve volume related price breaks from drug manufacturers that may be available to the larger Part D plans. Thus, PACE organization Part D bids will be higher than those of traditional Part D plans. Because PACE organizations primarily serve dual eligible individuals with the exception of a few low-income Medicare-only enrollees, subsidy payments that accurately capture the cost of providing prescription drugs will be critical to the continued financial stability of PACE organizations. This importance is magnified by existing PACE statutory and regulatory provisions that preclude PACE organizations from imposing enrollee cost sharing upon any enrollee and from imposing premiums upon any Medicaid eligible enrollee. Thus, commenters believed that it was essential that the low-income premium and subsidy payments paid by us to PACE organizations on behalf of low-income enrollees be comparable to the cost of providing the benefit.

Response: We agree that PACE organizations differ from traditional Part D plans in terms of the number of enrollees. Thus, we do not view PACE organizations as closely comparable to traditional Part D plans for purposes of competition.

We believe that the small size of PACE organizations will hinder their ability to achieve volume related price breaks from drug manufacturers that may be available to the larger Part D plans. Thus, PACE organizations' Part D bids will be higher than those of traditional Part D plans. The MMA addresses this key difference, specifically as it relates to payment in section 1860D–21(f)(3) of the Act by indicating that the bids of PACE organizations are not to be included in determining the standardized bid amount. Ironically, however, bids included in the computation of the standardized bid amount are directly related to subsidy payments made to all plans, including PACE organizations. Because PACE organizations primarily serve dual eligible individuals, with the exception of a few low-income Medicare-only enrollees, subsidy payments that accurately capture the cost of providing prescription drugs will be critical to the continued financial stability of PACE organizations. This importance is magnified by existing PACE statutory and regulatory provisions that preclude PACE organizations from imposing enrollee cost sharing upon any enrollee and PACE regulatory provisions that preclude PACE organizations from imposing premiums upon any Medicaid eligible enrollee. Thus, it is essential that the direct subsidy, as well as the low-income premium and subsidy payments paid by us to PACE organizations on behalf of low-income, enrollees be comparable to the cost of providing the benefit.

The MMA did not amend sections 1894 and 1934 of the Act and it is clear that Part D applies to PACE. We have determined that the conflicting PACE and Part D requirements related to beneficiary cost sharing and the PACE preclusion of charging any Medicaid eligible enrollee a premium would result in a significant Part D payment discrepancy to PACE organizations absent our intervention. As a result, we are considering the application of section 1894(d)(2) of the Act and § 460.180(b)(5) of the PACE regulation authority which authorize the Secretary to adjust payment to PACE organizations based on ''other factors'' as appropriate. These adjustments will take into account the PACE preclusion of and the preclusion of charging any Medicaid eligible enrollee a premium. Additional CMS guidelines will be issued to PACE organizations following publication of this rule. These guidelines will outline the PACE/Part D payment methodology, including an appropriate payment adjustment applicable to PACE organizations. We believe that this guidance will minimize disruption to PACE organizations and their enrollees.

Comment: We received public comment in support of our proposed waiver on behalf of PACE organizations of the bid submission deadline of no later than the first Monday in June for each Part D plan intending to offer a Part D prescription drug plan in the subsequent calendar year under § 423.265(b).

Response: As indicated in the proposed rule, a new PACE organization may take from 2.5 to 3 years to develop the capacity to offer PACE services, including capital expenditures associated with construction or renovating space for a PACE Center. In addition, as required by sections 1894 and 1934 of the Act, many activities associated with PACE involve the States. For example, PACE applications are submitted to the State for review prior to our review and the PACE program agreement is a 3–party contract; CMS, the State in which the potential PACE program is located, and the PACE organization. Although we originally proposed that the bid submission deadline be broadly waived for all PACE organizations, we would like to clarify that we expect PACE organizations that are operational prior to the first Monday in June of each year to meet the bid submission deadline. However to the extent they are unable, we will waive the bid submission deadline for those organizations since PACE bids are not included in the computation of any average benchmark amount or low-income benchmark premium amount. In addition, we do not believe that it would be appropriate for a potential PACE organization that contracts with us after the June deadline to be unable to receive payment under Part D until the following year's June deadline is met and the bid has been approved. Therefore, the requirement of

§ 423.265(b) of this regulation will also be waived on behalf of potential PACE organizations which are not operational by the first Monday in June in order to promote coordination of benefits between Part D and PACE. As a result, new PACE organizations will be permitted to submit their Part D bids beyond the June deadline.

Further discussion of Part D waivers on behalf of PACE organizations is included below.

d. Application of Administrative Related Part D Requirements to PACE Organizations

In using the term, administrative related requirements, we are referring to requirements that pertain to subparts A, B, C, D, I, J, K, L, M, N, and O, of this regulation concerning general Part D provisions, eligibility and enrollment, benefits and beneficiary protections, cost control and quality improvement, compliance with State law and preemption by Federal law, coordination under Part D with other prescription drug coverage, application of procedures and contracts, the effect of a change of ownership or the leasing of facilities, grievances and appeals, coverage determinations, Medicare contract determinations, and sanctions.

In the proposed rule we identified several administrative related Part D provisions that we intended to waive on behalf of PACE organizations.

(1) Sections 423.48 and 423.128 of the proposed rule specified requirements for providing information about Part D and for the dissemination of plan information. These sections also indicated that plans would be required to provide information to CMS regarding benefits, formularies, premiums, , and enrollee satisfaction. This information would be published in Medicare's comparative plan brochures and provide key information for beneficiaries to use in making informed decisions about Part D prescription drug coverage. We indicated that the differences between MA-PD plans/PDPs and PACE would complicate comparison and confuse beneficiaries. In addition to specific eligibility requirements for enrollment in PACE, PACE organizations exist only in those States that elect to include PACE in their Medicaid State plan. We indicated that including PACE information in the comparative brochure would be misleading. As a result, we proposed that the requirements for providing information about Part D and for the dissemination of plan information be waived on behalf of PACE organizations in order to promote the coordination of benefits between Part D and PACE.

(2) Section 423.104(g) of the proposed rule would require MA-PD plans and PDPs to provide enrollees with access to negotiated drug prices. Since PACE enrollees receive the vast majority of their prescription drugs directly from the PACE organization with no applied, the negotiated price requirement is already accounted for under part 460. Therefore, we proposed a waiver of § 423.104(g) in order to promote better coordination of benefits between Part D and PACE.

(3) Section 423.120(a)(1) of the proposed rule would require that a plan's contracted pharmacy network be located within specified distances from enrollees. Because PACE enrollees receive their prescription drugs directly from their PACE organization as opposed to through a pharmacy, the distance between the enrollee and a network pharmacy is irrelevant. We believe that requiring a PACE organization to set up a pharmacy network would be burdensome, costly, and unnecessary and diverts funds from patient care. Thus, we proposed to waive this requirement in order to promote better coordination of benefits between PACE and Part D.

(4) Section 423.120(c) of the proposed rule would require plans to employ the use of a card or other type of standardized technology to assist enrollees in accessing negotiated prices for Part D drugs. Since PACE participants do not routinely acquire their prescription drugs directly from pharmacies, requiring PACE organizations to develop standardized technology would be burdensome, costly, and unnecessary and diverts funds away from patient care. Therefore, we proposed to waive proposed § 423.120(c) under the authority of section 1860D–21(c)(2) of the Act for PACE organizations to promote better coordination of benefits between Part D and PACE.

(5) Section 423.124 of the proposed rule specified access requirements for drugs obtained through out-of-network pharmacies. These provisions would ensure that enrollees residing in long term care facilities have access to drugs in an out-of-network long term care pharmacy and AI/AN enrollees have access to an out-of-network I/T/U pharmacy. Enrollees who obtain their Part D covered drugs from these out-of-network pharmacies would be financially responsible for deductibles or applicable under network pharmacies.

Under the current PACE regulations in § 460.90(a) and § 460.100, PACE organizations are responsible for all prescription drugs, including those provided to any participants residing in long term care facilities, AI/AN participants, and those associated with an emergency health event or an approved urgent care need. As noted previously, PACE participants are not responsible for deductibles, co-payments, coinsurance, or other associated with prescription drugs. In the PACE program, when participants are out of the service area and need prescription drugs, the PACE organization would arrange payment in full with the pharmacy.

As noted previously, PACE organizations are required to provide all PACE enrollees with prescription drug coverage. Therefore, we view the out of network pharmacy requirements as duplicative of PACE regulations. Thus, we proposed to waive § 423.124 of the proposed rule for the reasons noted above.

(6) Section 423.104(g)(2) of the proposed rule specifies that a plan may not offer enhanced alternative prescription drug coverage unless it also offers basic prescription drug coverage. In this instance, PACE organizations vary from MA-PD plans in that their enrollees are exempt from . It would be impractical to offer basic prescription drug coverage to PACE enrollees because stand-alone basic prescription drug coverage assumes beneficiary. Thus, we proposed to waive § 423.104(g)(2) of the proposed rule to promote coordination of benefits between Part D and PACE.

(7) Public disclosure requirements in proposed § 423.132 provide that a PDP or MA-PD plan must ensure that its pharmacies inform enrollees of any differential between the negotiated price for a covered Part D drug and the lowest priced generic equivalent. This requirement is inconsistent with the PACE model. PACE participants or their caregivers work with the PACE interdisciplinary team in making care planning decisions and have input into all aspects of their care, including prescription drug use. For this reason, we proposed a waiver of the public disclosure requirement in proposed § 423.132 under the authority of section 1860D–21(c)(2) of the Act for PACE organizations in order to promote better coordination of benefits between Part D and PACE.

(8) Requirements associated with privacy, confidentiality, and accuracy of enrollees' records under Part D are included in § 423.136 of the proposed rule. We view these requirements as duplicative of § 460.200(e) of the PACE regulation. We believe that the PACE regulations are providing the same protections as would be provided under

proposed § 423.136. For the reasons noted above, we proposed to waive § 423.136. We note that we also believe the requirements of § 423.136 are duplicative of § 460.210 of the PACE regulation.

(9) The medication therapy management program requirements in proposed § 423.150 would require MA-PDs and PDPs to employ pharmacists to counsel beneficiaries who have chronic conditions and use multiple drugs to ensure they are taking safe combinations of prescription drugs and using the drugs properly. PACE enrollees typically suffer from multiple health conditions that necessitate close monitoring by their interdisciplinary team. Currently, PACE organizations have pharmacists on staff or under contract, working with PACE primary care physicians as they develop the participants' care plans and monitor their drug regimens. In addition, the PACE interdisciplinary team, through its daily interactions with PACE participants and their caregivers, provides counseling to ensure that medication regimens are followed. We believe that the existing PACE regulations satisfy or exceed the medication therapy management program requirements in proposed § 423.150. For the reasons noted above, we proposed to waive § 423.150 for PACE organizations in order to promote the coordination of benefits between Part D and PACE.

(10) Proposed § 423.401 specifies licensing requirements for PDPs. A PDP must be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan. A similar requirement exists for MA-PDs. Organizations that are not licensed under State law would obtain certification from the State that the organization meets financial solvency and other standards required by the State for it to operate.

We view these requirements as duplicative of PACE requirements. First, sections 1894(e)(2)(iv) and 1943(e)(2)(iv) of the Act require PACE organizations to meet applicable State and local laws and requirements. In addition, sections 1894(f)(2)(B)(v) and 1934(f)(2)(B)(v) of the Act require PACE organizations to be at full financial risk. Therefore, we believe PACE organizations are meeting the intent of these MA requirements. For the reasons noted above, we proposed to waive § 423.401 for PACE because we believe this section is duplicative of PACE requirements.

(11) Subpart M proposed process requirements for grievances, coverage determinations, reconsiderations, and appeals under Part D. We believe the PACE grievance and appeals processes under § 460.120 and § 460.122 meet the intent of the MMA since they would accommodate complaints regarding prescription drug coverage. Therefore, we proposed to waive § 423.560 through § 423.638 for PACE organizations because we believe they are duplicative of PACE requirements.

(12) Subpart K includes requirements governing the application process, contracts with PDP sponsors, and reporting requirements. Sections 1894 and 1934 of the Act, as well as PACE regulations in subparts B and C specify application and contract (called a program agreement in accordance with sections 1894 and 1934 of the Act) requirements for PACE that duplicate requirements in subpart K. For this reason, we proposed to waive the sections in subpart K that address the application process and contract requirements.

We concluded by requesting comment on these proposed waivers including any additional waivers that may be needed to integrate the Medicare prescription drug benefit and the PACE benefit.

Commenters expressed support for all the administrative related waivers on behalf of PACE organizations that were identified in the proposed rule, requested clarification as to the breadth of specific waivers, and identified additional waivers that would be necessary to minimize disruptions to the PACE program in implementing Part D.

We proposed in § 423.458(d) of the proposed rule to codify section 1860D–21(c)(2) of the Act (as extended to PACE organizations under section 1860D–21(f)(1) of the Act), which establishes authority for us to waive Part D provisions for PACE organizations that: (1) duplicate PACE requirements; (2) conflict with PACE provisions; or, (3) as may be necessary to improve the coordination of benefits provided under Part D and the PACE program. Thus, we begin with a discussion of the administrative related Part D requirements.

Comment: One commenter requested confirmation as to whether PACE organizations will be required to provide Part D coverage to its enrollees who are Part D eligible individuals because section 1860D–21(f)(1) of the Act indicates that PACE organizations have a degree of discretion in whether or not to provide Part D coverage. Another commenter stated that to require a PACE eligible individual to obtain prescription drug coverage from a plan other than PACE (a PDP for example) would fragment care coordination associated with PACE.

Response: Section 1860D–21(f)(1) of the Act provides that PACE programs may elect to provide qualified prescription drug coverage to Part D eligible individuals enrolled in the program. However, section 1935(c)(6) of the Act prohibits Medicaid from paying for Part D drugs provided to full-benefit dual eligible individuals and requires that these drugs be paid for under Medicare Part D. Due to this statutorily mandated shift in payer from Medicaid to Medicare for full-benefit dual eligible individuals, we believe that PACE organizations will elect to provide Part D coverage to full-benefit Part D eligible individuals in order to receive adequate payment for providing Part D drugs.

In addition, section 1894(a)(1)(B)(i) of the Act requires that PACE enrollees receive Medicare benefits solely through the PACE program, and, therefore, prohibits them from simultaneously enrolling in both a PACE program and a separate Part D plan. As discussed elsewhere in this preamble under subpart B, Part D eligible individuals who enroll in a PACE plan offering qualified prescription drug coverage under Part D will be deemed to have elected to receive their Part D benefits through such PACE plan, and will be ineligible to enroll in another Part D plan, including a PDP. In addition, § 423.32(f) specifies that enrollees of PACE organizations offering qualified prescription drug coverage shall remain enrolled in that plan as of January 1, 2006 and receive benefits offered by that plan until one of the conditions of § 423.32(e) is met.

Effective January 1, 2006, States will continue to include the cost of prescription drugs in their monthly capitation payments to PACE organizations on behalf of those individuals ineligible for Part D coverage (Medicaid-only enrollees).

Comment: We received a comment indicating that there are cost benefits of the PACE model as an alternative to nursing home care. The commenter indicated that implementation of Part D should not place excessive burdens on PACE organizations and recommended that we develop a workgroup with the National PACE Association (NPA) and States in order to work through the administrative related issues with implementing Part D into PACE so as to minimize the administrative burden on PACE organizations.

Response: We appreciate the potential burden associated with implementing the Part D benefit into the existing PACE model. As a result, we proposed to

utilize waiver authority under § 423.458(d) of this rule: (1) in instances where Part D requirements are duplicative of PACE requirements; (2) in instances where Part D requirements conflict with PACE requirements; or, (3) in order to promote coordination between Part D and PACE. Under this authority, we are waiving section 423.265(b), which would have required PACE organizations planning to offer a Part D prescription drug plan to submit bids and supplemental information no later than the first Monday in June of each year. We will also use this authority to issue further guidance regarding additional Part D provisions that will be waived for PACE organizations. We believe that these waivers will minimize the administrative burden on PACE organizations that elect to provide Part D coverage.

Comment: We received many comments supporting our proposal to identify Part D provisions that we will waive on behalf of PACE organizations without requiring individual waiver applications. One commenter also requested that we outline a waiver application process that could be followed by organizations to the extent additional waivers are identified after publication of this final rule. As waivers are granted through this process, the commenter requested that we apply the waivers to other similarly situated organizations offering or seeking to offer qualified prescription drug coverage as a PACE organization that otherwise meets conditions of the waiver.

Other commenters requested that PACE waivers apply to other similar health plans such as social HMOs, Massachusetts Senior Care Options programs, or other plans that also serve significant numbers of full-benefit dual-eligible individuals.

Response: We believe that the application of § 423.458(d) waivers will minimize disruption of the positive aspects of the structure of PACE. However, to the extent a PACE organization identifies a specific need for additional Part D waivers, the organization may request such waivers from us under the authority of § 423.458(d) of this regulation. We will determine on a case-by-case basis whether to grant the waiver. If we grant it, the waiver will apply to all similarly situated PACE organizations, but will not apply to non-PACE organizations.

The waiver submission and review process for PACE organizations will be issued as additional CMS guidance. We will issue additional guidance to these programs following publication of this rule.

The following list summarizes comments we received on waiver issues. As stated previously, the only waiver we are finalizing at this time is a waiver of the June bid submission deadline in section 423.265(b). We will take into consideration comments regarding other waivers and issue further guidance on the Part D provisions that will be waived for PACE organizations.

(1) Several commenters indicated that due to the differences between traditional Part D plans and PACE, inclusion of PACE in a comparison brochure would confuse beneficiaries. These commenters supported our proposal to waive § 423.48 and § 423.128 concerning plan information. However, one commenter expressed concern that those eligible for special programs such as PACE, should be informed of all choices available under Part D. This information should include differences between obtaining services from a traditional Part D plan or PACE. The commenter believed that beneficiaries should also be informed of what would occur if they disenrolled from PACE to obtain benefits from a PDP. This commenter would like to work with us in developing appropriate materials and distribution mechanisms.

(2) One commenter asked for clarification that PACE organizations will not be required to share in the cost of enrollment related costs under § 423.6, reasoning that PACE organizations are neither subject to MA requirements related to dissemination of annual enrollment information, nor do PACE organizations contribute towards their costs.

(3) Commenters indicated that to the extent requirements under § 423.44 are duplicative of requirements under § 460.164 through § 460.172 of the PACE regulation or impede coordination of PACE and Part D benefits, these requirements should be waived, allowing for continued coordination of the prescription drug benefit with all other benefits provided by PACE organizations. One commenter recommended that existing requirements governing disenrollment from PACE organizations should apply in lieu of § 423.44.

(4) We received a comment in support of our proposed waiver of § 423.104(g)(2) of the proposed rule (now identified as § 423.104(f)(2) in the final rule) that indicates that a plan may not offer enhanced coverage for purposes of reducing co-payments and deductibles unless it also offers a plan with basic coverage. The commenter agreed with our rationale indicating that it would be impractical for a PACE organization to offer basic prescription drug coverage to PACE enrollees because stand-alone basic prescription drug coverage assumes beneficiary which is a PACE statutory preclusion.

(5) Commenters supported our proposal to waive the negotiated price requirements of § 423.104(h) of the proposed rule (now identified as § 423.104(g) in this final rule). One commenter pointed out that we had incorrectly referred to this section as § 423.104(g) on page 46756 of the proposed rule.

(6) Commenters concurred with our proposal to waive the pharmacy access requirements under § 423.120(a)(1). In addition, a commenter recommended a waiver of § 423.120(a)(4) of the proposed rule (now identified as § 423.120(a)(8) in the final rule) related to pharmacy network contracting. PACE organizations generally have close working relationships with a very limited number of pharmacies that can respond to the specialized requirements of PACE enrollees, for example, 24/7 access and specialized dispensing requirements. Requiring PACE organizations to contract with any willing pharmacy provider is not consistent with the PACE model and could compromise the PACE organizations' ability to negotiate favorable contract terms based on volume with one or two suppliers.

(7) One commenter indicated that PACE organizations typically provide an open formulary to the primary care physicians that allow immediate access to a wide variety of covered Part D prescription drugs in many different dosages and delivery forms. These open formularies do not restrict access or result in co-payment amounts charged to enrollees. Thus, the commenter does not believe the formularies used by PACE organizations should be subject to the requirements of § 423.120(b). This commenter also asked for clarification as to whether ''preferred drug lists'' utilized by PACE organizations would be subject to the requirements of § 423.120(b). These lists provide prescribing physicians with current data on the relative costs of various medications, such as name brand vs. generic alternatives. Physicians are not restricted from prescribing alternatives that do not appear on the preferred drug list, and the list does not result in co-payment amounts charged to enrollees. The commenter recommended that these preferred drug lists not be subject to the requirements of § 423.120(b).

(8) Several commenters concurred with our proposal to waive the standardized technology requirements of § 423.120(c). One commenter suggested that such technology be

limited to one card in order to avoid data sharing and coordination requirements.

(9) Several commenters concurred with our proposal to waive the out-of-network pharmacy requirements of § 423.124.

(10) Several commenters concurred with our proposal to waive the disclosure of price differences between the Part D drug and generic equivalent requirement of § 423.132.

(11) Several commenters concurred with our proposal to waive the privacy, confidentiality, and accuracy of records requirements of § 423.136.

(12) One commenter requested clarification regarding our proposal to waive the MTMP requirements of § 423.150 and whether we had intended to list the additional provisions of this section including cost and utilization management programs, quality assurance programs, programs to control fraud, abuse, and waste, CMS consumer satisfaction surveys, an electronic prescription program, and accreditation. The commenter believes that the existing PACE requirements satisfy or exceed each of these requirements.

(13) We received a comment requesting that consumer satisfaction surveys administered to PACE enrollees under § 423.156 take into account the differences between PACE enrollees and traditional Part D plan enrollees.

(14) We received a comment requesting that quality improvement organization activities performed under § 423.162 take into account the differences between PACE enrollees and traditional Part D plan enrollees.

(15) We received public comments concurring with our proposal to waive the licensure requirements of § 423.401 to reflect that PACE organizations' fiscal soundness is governed by requirements under sections 1894(e)(2)(iv) and 1934(e)(2)(iv) of the Act and § 460.80 of the PACE regulation.

(16) We received public comments of concurrence of our proposal to waive the application requirements of subpart K of this rule, agreeing that these requirements are addressed under subparts B and C of § 460. This commenter also requested that we utilize information already available in PACE organizations provider applications and program agreements to the greatest extent possible.

(17) One commenter requested clarification as to whether the requirements of the following sections would be waived on behalf of PACE organizations; § 423.502, § 423.503, § 423.504, § 423.505, § 423.506, § 423.507, § 423.508, § 423.509, § 423.510, and § 423.514. The commenter indicated that these requirements duplicate current PACE requirements.

(18) Commenters also indicated that the requirements of subpart K would be burdensome for plans, providers, and pharmacies in terms of tracking coverage issues. Adherence to these requirements would result in significant new expenditures for plans, advocates, clinics, pharmacies, long term care providers, and other providers in terms of care coordination and advocacy for beneficiaries to access the correct coverage. It will also be necessary to coordinate with other Part D plans concerning low-income enrollees at risk for institutionalization. The commenter suggests that we hire an outside facilitation contractor to review and match data with mechanisms similar to sharing of information on crossover claims. Yet, the commenter has concerns about the ability of States, plans, providers, and others to gear up quickly to handle the tracking and interface that working with these contractors would require.

(19) In addition, one commenter indicated that the minimum enrollment requirements of § 423.512 of the proposed rule should be waived on behalf of PACE organizations as such requirements do not currently apply to PACE organizations.

(20) Several commenters concurred with our proposal to waive the determinations and appeals processes of subpart M on behalf of PACE organizations. Commenters agreed that these requirements are being met by PACE organizations under § 460.120 and § 460.122 of the PACE regulation.

The MMA did not amend sections 1894 and 1934 of the Act and it is clear that Part D applies to PACE. As a result, we have determined that in order to merge the PACE and the Part D statutory requirements, waivers we identified in the proposed rule, as well as waivers beyond those identified in the proposed rule and via public comments will be necessary. Therefore, we are considering the application of § 423.458(d) waiver authority for all administrative related Part D requirements that duplicate or conflict with PACE requirements or do not promote coordination between Part D and PACE. Additional CMS guidelines will be issued to PACE organizations following publication of this rule to include the waiver submission process and a comprehensive listing of all Part D waivers applicable to PACE organizations. We believe that this guidance will minimize disruption to PACE organizations and their enrollees.

In accordance with § 423.458(d) of this regulation, PACE organizations will also be permitted to submit Part D waiver requests beyond those identified in CMS guidelines on an individualized basis.

We received several comments regarding the application of subpart S, which pertains to State eligibility determinations for subsidies and general payment provisions.

Comment: One commenter recommended that we develop a workgroup with the NPA and States to further discuss impacts related to the phased-down State contribution and PACE capitation rates. The phased-down State contribution is a percentage based on drug costs in the year 2003. Subpart T of the proposed rule indicates that States must continue to include drug costs in the Medicaid monthly capitation payment to PACE organizations on behalf of Medicaid-only PACE enrollees. Thus, 2 commenters believe that States will be required to develop two different PACE capitation rates; one for dual eligible beneficiaries and one for Medicaid only enrollees. Given the small percentage of Medicaid only PACE enrollees, the complexities in developing a separate Medicaid-only PACE capitation rate may be administratively cumbersome.

Response: The MMA shifts payment responsibility for prescription drugs from Medicaid to Medicare for full-benefit dual eligible beneficiaries. As a result, States will need to take into account the Part D premium payments when calculating the PACE capitation rate for full-benefit dual eligibles. The MMA does not change the prescription drug payment scheme for Medicaid-only eligible beneficiaries. Thus, we agree with the commenter that the States will need to establish separate capitation rates for Medicaid eligible PACE enrollees, including one for dual-eligible beneficiaries for whom the PACE organization elects to provide Part D coverage, and one for non-dual eligible (Medicaid-only) beneficiaries. In the case of full-benefit dual eligible PACE enrollees for whom the PACE organization elects to provide Part D coverage, the State in which the PACE organization is located will pay a phased-down contribution to Medicare that defrays a portion of the drug expenditures for these individuals assumed by Medicare Part D. State Medicaid agencies will be required to participate in this phased-down State contribution scheme under § 423.910 of this regulation. This amount will capture the full extent of a State Medicaid agency's responsibility for Part D prescription drug expenditures

on behalf of full benefit dual-eligible beneficiaries for whom the PACE organization elects to provide Part D coverage. In the case of Medicaid eligible PACE enrollees whose drug costs continue to be funded by Medicaid, States will continue to include a prescription drug cost amount in their monthly capitation payment to PACE organizations.

4. Medicare Supplemental Policies

a. Overview and Background

In the proposed rule, we included two provisions related to Medicare supplemental (Medigap) policies. As required under section 1882(v) of the Act, as added by section 104 of MMA, we set forth standards for the written disclosure notice that Medigap issuers must provide to their policyholders who have drug coverage. In addition, in order to reflect the addition of the Medicare drug benefit by MMA, we proposed to revise the definition of a Medigap policy.

• Medicare Supplemental Policies

A Medigap policy is a health insurance policy sold by private insurance companies to fill the ''gaps'' in original Medicare plan coverage. A Medigap policy typically provides coverage for some or all of the deductible and coinsurance amounts applicable to Medicare covered services and sometimes covers items and services that are not covered by Medicare. Under section 1882 of the Act, Medigap policies generally may not be sold unless they conform to one of the 10 standardized benefit packages that have been defined, and designated as plans A through J, by the NAIC. Three States (Massachusetts, Minnesota, and Wisconsin) are permitted by the statute to have different standardized Medigap plans and are sometimes referred to in this context as the waiver States.

Three of the 10 standardized Medigap plans (Plans H, I, and J) contain coverage for outpatient prescription drugs. In addition, there are Medigap policies issued before the standardization requirements went into effect (''prestandardized'' Medigap plans) that cover drugs, as well as Medigap policies in the waiver States, some of which have varying levels of coverage for outpatient prescription drugs.

• Legislative Authority and Background

In connection with the addition of a prescription drug benefit to Medicare, the MMA also prescribes changes to the law applicable to Medigap policies. Among other requirements, section 1882(v) of the Act, as added by section 104 of the MMA, requires Medigap issuers to provide a written disclosure notice to individuals who currently have a policy with prescription drug coverage. (Section 1882(v)(6)(A) of the Act specifies that this is to be called a ''Medigap Rx policy.'') The MMA also requires that the Secretary establish standards for this disclosure notice in consultation with the NAIC.

The purpose of this disclosure notice is to inform an individual who has a Medigap Rx policy about his or her Medigap choices once the new Medicare Prescription Drug Benefit Program goes into effect on January 1, 2006. Specifically, effective on that date, section 1882(v) of the Act will prohibit the sale of new Medigap Rx policies, and require the elimination of drug coverage from Medigap Rx policies held by beneficiaries who enroll under Part D. The statute permits the renewal of Medigap Rx policies if the policy was purchased prior to January 1, 2006, and the individual does not enroll in Part D.

In addition, beneficiaries who do not enroll in Part D during the Initial Enrollment Period, and choose to enroll later, will be charged higher Part D premiums unless they can establish that they had creditable prescription drug coverage prior to enrolling in Part D. Under section 1860D–13(b)(4)(F) of the Act, and § 423.56(a) of this rule, Medigap policies meet the definition of creditable prescription drug coverage if they also meet actuarial equivalence requirements.

Issuers of Medigap insurance policies are required to provide disclosure notices to policyholders with Medigap Rx policies that inform them of their options under the new legislation, as well as informing them whether or not their policies constitute ''creditable prescription drug coverage.'' As explained in the preamble to subpart B of this rule, to be considered creditable prescription drug coverage, the coverage must be determined (in a manner specified by the Secretary) to provide prescription drug coverage the actuarial value of which (as defined by the Secretary) equals or exceeds the actuarial value of defined standard prescription drug coverage under Medicare Part D. Subparts B and F of this rule provide additional detail on creditable coverage and actuarial equivalence.

b. Definition of Medicare Supplemental Policy

Because of the importance of these disclosure notices to beneficiaries, we believe it is necessary to clarify what comes within the scope of a Medigap Rx policy. We proposed to revise and clarify the definition of a Medicare supplement (Medigap) policy currently codified at § 403.205, to reflect the addition of the Medicare drug benefit by MMA.

We proposed to revise the definition of a Medigap policy, effective January 1, 2006, to include any insurance policies or riders that contain a prescription drug benefit, and that are primarily designed for, or are primarily marketed and sold to Medicare beneficiaries. We also proposed to clarify that any rider attached to a Medigap policy is an integral part of the policy. All the requirements that apply to the base policy, such as guaranteed renewability or disclosure requirements, would apply to the rider. Thus, for instance, if an issuer offers an optional prescription drug rider that can be added to any other policies, addition of the rider to a Medigap policy would make the entire policy a Medigap prescription drug policy (Medigap Rx policy) subject to the disclosure requirements for these policies in section 1882(v) of the Act.

Moreover, we proposed that any stand-alone drug policies that were not previously considered to meet the definition of a Medigap policy will meet that definition as of January 1, 2006 when the prescription drug benefit takes effect, if the policy is primarily designed for or primarily marketed and sold to Medicare beneficiaries. New sales of these policies would be prohibited after December 31, 2005.

c. Standards for the disclosure notice that Medicare Supplemental (Medigap) issuers are required to provide to individuals who currently hold policies with drug coverage

• General

We believe that the statute is quite clear about the choices that need to be made by beneficiaries who hold Medigap Rx policies. Therefore, we proposed to establish standards for the disclosure notice in the form of a required notice that sets forth those choices.

• Timing and Content of the Disclosure Notice

The statute requires Medigap issuers to send a written disclosure notice to each individual who is a policyholder or certificate holder of a Medigap Rx policy at the most recent available address of that individual. The issuers must send the disclosure notice during the 60-day period immediately proceeding the initial Medicare Part D enrollment period. The initial enrollment period (IEP) for Medicare Part D runs from November 15, 2005 through May 15, 2006. Accordingly, Medigap issuers must send the written disclosure notice between September 16, 2005 and November 15, 2005.

The written disclosure notice must inform the individual of his or her Medigap options if the individual does or does not enroll in Medicare Part D. These include the following:

- If the individual does enroll in Part D, he or she can keep the Medigap policy but the drug coverage must be eliminated.
- If the individual enrolls in a Medicare Part D PDP during the IEP, the individual also has the right to buy another Medigap plan from the same issuer that does not include drug coverage. The individual has a guaranteed right to buy Plan A, B, C, or F (including the high deductible Plan F) or one of the new Medigap benefit packages mandated by section 104(b) of the MMA (which have been designated Plans K and L), if these plans are offered by the issuer and available to new enrollees. The issuer may also offer other Medigap plans on a guaranteed issue basis.
- If the individual does not enroll in Part D, he or she has the option of keeping the Medigap policy with drug coverage.
- If the individual does not enroll in Part D during the IEP, the individual may continue enrollment in his or her current Medigap plan without change, but the individual will lose the right to buy another Medigap plan on a guaranteed issue basis. In addition, if the current Medigap plan does not provide creditable prescription drug coverage, there are limitations on the periods in a year in which the individual may enroll in Medicare Part D and any such enrollment may be subject to a late enrollment penalty (increased premium) if the current Medigap plan does not provide creditable prescription drug coverage.

We also proposed to require that the disclosure notice contain information on the potential impact of an individual's election on his or her Medigap premiums.

It is important to note that the disclosure requirement in section 104 of the MMA that applies to Medigap issuers is separate from the disclosure requirement contained in section 101 of the MMA (section 1860D–13 of the Act). The disclosure requirement in section 104 of the MMA applies exclusively to issuers of Medigap policies and contains very specific statutory criteria for the disclosure notice. The disclosure requirement in section 101 of the MMA applies to various forms of prescription drug coverage, including Medigap.

As discussed in subpart B of this preamble, section 101 of the MMA requires that these entities, including Medigap issuers, disclose to the Secretary, as well as to the Part D eligible individuals, whether the coverage they provide currently meets the actuarial equivalence requirement for creditable coverage. The entities must also notify the individuals if the coverage changes so that it no longer meets the actuarial equivalence requirement. Section 101 of the MMA directs the Secretary to establish procedures for the documentation of creditable prescription drug coverage by these entities.

- Medigap Policies as Creditable Coverage

Medigap issuers will be responsible for determining whether the drug coverage under their policies is creditable drug coverage in accordance with subpart B of this final rule. We cannot offer guidance for the likelihood that any particular pre-standardized policy, or policy in a waiver State, will meet this test. However, for standardized plans, the CMS actuaries determined that drug coverage in standardized Medigap Plans H and I cannot meet this standard. Since actuarial equivalence can be demonstrated using a group's experience, it is possible to have a specific group for which the drug coverage in standardized Medigap Plan J would be creditable prescription drug coverage. However, based on the distributions of drug utilization that the actuaries have seen so far, they believe that drug coverage in standardized Medigap Plan J will be unlikely to meet the definition of creditable prescription drug coverage based on this rule.

- Required Disclosure Notice

Section 1882(v) of the Act requires us to establish standards for the disclosure notice that issuers must provide to policyholders of Medigap Rx policies. In the proposed rule, we proposed a model disclosure notice with basic language that would be required to be included in all disclosure notices sent by Medigap issuers for policies that do not provide creditable coverage. We respond below to comments we received on the proposed model disclosure notice. However, because we have determined that the format and content of the notice could be improved based on information gathered through consumer testing, we now plan to publish the final model disclosure notice separately from this final regulation. We also plan to publish a model disclosure notice for policies that do provide creditable coverage.

Comment: We received numerous comments related to our proposed clarifications to the definition of a Medigap policy. Many commenters believe the proposed clarifications are too far-reaching and that all limited health benefit plans would be considered Medigap policies under the proposed clarifications to the definition. Many of these commenters added that they do not believe that we have the authority to make the proposed modifications to the definition of a Medigap policy.

One commenter supports our clarification that a rider to a Medigap policy becomes an integral part of the policy. The commenter stated that it is black-letter insurance law that a rider attached to an insurance policy becomes a part of the policy.

Response: We believe that the addition of the Part D drug benefit to Medicare makes it essential to clarify the definition of a Medigap policy. There has been some confusion about whether a rider attached to a Medigap policy is considered to be part of the policy, and therefore subject to Medigap requirements such as guaranteed renewability.

Similarly, there was ambiguity in the past about whether a policy that covered only prescription drugs, either as a separate, ''stand-alone'' policy or as a rider to another policy, met the definition of a Medicare supplement policy. The ambiguity was created by the fact that there was no Medicare drug benefit to supplement, and it has been resolved with the enactment of the Medicare drug benefit. With respect to both of these situations, we believe that it is extremely important to make clear which Medicare beneficiaries are entitled to receive a notice about their rights under the MMA.

First, it is necessary to clarify that a rider to a Medigap policy is not a separate insurance product, but rather is incorporated into, and becomes an integral part of, the policy. In order to carry out the intent of the MMA provisions, we believe that Medigap policies with drug riders must be treated the same as Medigap plans H, I, and J; prestandardized Medigap Rx plans; and Medigap plans with drug coverage in the waiver States. Accordingly, if a beneficiary has an outpatient prescription drug rider attached to his or her Medigap policy, that beneficiary should receive the disclosure notice that MMA requires Medigap issuers to send to their policyholders who have Medigap drug coverage. In addition, because new sales of Medigap policies with drug coverage are prohibited after December 31, 2005, the drug coverage offered through a rider to a Medigap policy should be eliminated from the policy (that is, the drug rider should be cancelled) as of the date of the

individual's enrollment in Medicare Part D.

We also believe it is necessary to clarify that stand-alone, limited benefit drug policies will be considered Medigap policies once the Part D drug benefit is implemented, but only if the coverage provided by the policy is primarily designed to supplement Medicare, or if the policy is primarily marketed and sold to, Medicare beneficiaries. Because these limited benefit drug polices will not be considered Medigap policies until the Part D prescription drug benefit is implemented on January 1, 2006, these plans are not subject to the requirement in section 104 of MMA that Medigap issuers send a disclosure notice to policyholders with drug coverage before that date. However, we encourage issuers of these policies to send the notice voluntarily, during the 60-day period immediately preceding the initial Part D enrollment that begins in November 2005.

We reject the argument that we lack the statutory authority to revise the regulation's definition of a Medigap policy. We are simply clarifying the scope of the definition. The statutory definition of a Medicare supplemental policy, set out in section 1882(g)(1) the Act states, in part, that a Medicare Supplemental policy ''provides reimbursement for expenses incurred for services and items for which payment may be made [by Medicare] but which are not reimbursable by reason of the applicability of deductibles, coinsurance amounts, or other limitations imposed pursuant to [title XVIII].'' Section 1882(g)(1) of the Act specifically excludes a MA plan, or any policy or plan sponsored by an employer or labor organization, from the definition. However, the language quoted above could be read to include *any* other policy that is not specifically excluded, if the policy pays anything toward the cost of an item or service that is generally covered under Medicare, but is not specifically reimbursable because of the application of deductibles, coinsurance, or other limitations. As of January 1, 2006, prescription drugs will be covered by Medicare, and we are simply clarifying that stand-alone policies will meet the definition.

As noted above, some commenters claim that the proposed clarifications are so far-reaching that all limited benefit plans will be considered Medigap policies. However, the definition also states that a Medicare Supplemental policy is a health insurance policy or other health benefit plan ''offered by a private entity to individuals who are entitled to have payment made under [title XVIII].'' The definition currently in the regulations essentially interprets this language to mean that a Medicare supplement policy is a policy that is offered to Medicare beneficiaries because they are Medicare beneficiaries. In other words, it does not encompass policies that are offered to a broader population, and happen to be purchased by a Medicare beneficiary.

Accordingly, since 1982, the regulatory language at § 403.205(a)(2) has specified that a Medigap policy means a policy or plan that is primarily designed, or is advertised, marketed, or otherwise purported to provide payment for expenses incurred for services and items that are not reimbursed under Medicare because of deductibles, coinsurance or other limitations under Medicare. Any policy that is not primarily designed to supplement Medicare reimbursements and that is not offered and sold primarily to Medicare beneficiaries would not be considered a Medigap policy. Therefore, we disagree that the proposed clarification of the definition in the regulation could be interpreted to apply to any limited benefit policy purchased by a Medicare eligible individual, regardless of how it is marketed and designed.

Many commenters believed that the language in proposed § 403.205(c) could be interpreted to mean that any individual or group health insurance policy or rider could be considered a Medigap policy. We have changed the regulatory language at § 403.205(c) to clarify that the individual or group health insurance policy or rider is a Medigap policy if the policy otherwise meets the definition in § 403.205.

Comment: One commenter asked that we clarify that the antiduplication disclosure statements applicable to limited benefit plans that are appended to the NAIC Model Regulation for Medicare supplemental insurance do not apply to stand-alone limited health benefit plans that are considered Medigap policies.

Response: The antiduplication statements that the commenter refers to do not apply to Medigap policies. We believe it is necessary to clarify that if a limited health benefit plan is considered a Medigap policy because of the way it is designed, marketed and sold, the sale of such a plan would be prohibited because it does not meet the requirements for standardization of Medigap policies.

Comment: We received numerous comments related to the proposed model disclosure notice that was published as part of the preamble to the Title I regulation. Commenters expressed concern about the model disclosure notice containing statements about the value of the Part D drug benefit being greater than the value of outpatient prescription drug coverage under a Medigap policy. Many commenters believe that the concept of ''value'' is subjective and goes beyond the concept of actuarial equivalence. Commenters stated that beneficiaries might consider their Medigap drug coverage to be of greater overall value than the Part D benefit for a number of reasons, including the fact that the Medigap drug coverage is guaranteed renewable and does not use drug formularies.

Commenters also stated that the proposed disclosure notice was too long and complicated and contained unnecessary information related to Part D benefit options. Commenters expressed concern about having any statements in the disclosure notice that may be viewed as requiring Medigap issuers to promote or advocate the competing alternative coverage under the Part D benefit. These commenters believe that information about the new Medicare drug benefit will be readily available from a variety of other sources and that including such information in the disclosure notice is confusing and is not required by MMA. They believe that statements about the value of Part D benefits and information concerning Part D enrollment are irrelevant for purposes of this disclosure notice.

Many commenters believe that we should adopt NAIC's version of the model disclosure notice as the disclosure notice that Medigap Rx issuers must send to policyholders. The NAIC version of the model disclosure notice was developed by a work group comprised of State insurance regulators, consumer representatives and Medigap issuers.

Response: We disagree that information concerning Part D enrollment options is irrelevant for purposes of this disclosure notice. The statute requires that the disclosure notice provide information to Medigap Rx policyholders explaining options in the event the individual does or does not enroll in Part D during the IEP. Therefore, we believe it is important to have some discussion about the Part D enrollment process in order to provide meaningful context for the Medigap options. For individuals who do not enroll in Part D during the IEP the statute requires the disclosure notice to explain, among other things, that the individual will be subject to a late enrollment penalty if his or her current

coverage does not provide creditable drug coverage and he or she later chooses to enroll in Part D. The test for creditable coverage is based on whether the economic value of the coverage is actuarially equivalent to the value of Part D coverage. Therefore, we believe it is appropriate to address how the actuarial value of Part D compares to the individual's current Medigap drug coverage.

As noted previously, we will publish the final standards for the disclosure notices separately from this final rule. We will give due consideration to the comments we received on the model disclosure notice set forth in the proposed rule. In addition, we have conducted a series of interviews with beneficiaries about the format and content of the model disclosure notice. Once we have completed our evaluation, the results of this consumer testing will also inform any changes we may make to the disclosure notice. We appreciate the efforts of the NAIC in developing a model disclosure notice and we intend to have further consultations with the NAIC.

Comment: Commenters expressed concern that the period for transition to Part D was too short and requested that we consider options to provide beneficiaries with additional time to adjust to the new changes. One commenter suggested that the Secretary use the ''exceptional circumstances'' authority to establish a special Part D enrollment period lasting at least through 2007 for beneficiaries who have Medigap drug coverage, thereby allowing for a longer period of transition to Part D. The commenter stated that Medicare beneficiaries may be reluctant to give up their Medigap drug coverage for a benefit that is new and untested and that an SEP would permit a longer period to enroll in Part D without a premium penalty. In the alternative, the commenter suggested that Medigap Plan J be deemed actuarially equivalent to Part D so that beneficiaries with Plan J who have the most drug coverage could enroll in Part D without penalty after the initial enrollment period.

Another commenter expressed concern about the possibility of a beneficiary being initially notified of creditable coverage when the coverage is no longer creditable or never was creditable. The commenter suggested that, in these cases, an SEP into Part D be established, along with a guaranteed issue right to a Medigap policy without drug coverage.

Response: The statute establishes the IEP for Part D as November 15, 2005 through May 15, 2006. Beneficiaries with Medigap drug coverage who enroll in Part D during the IEP have a guaranteed issue right to buy a Medigap policy without drug coverage. We are sympathetic to the complexity of the choices that beneficiaries must make during this time period, but we believe there is a strong public policy value in creating an incentive for immediate, widespread enrollment in this new, heavily subsidized benefit in order to ensure the affordability of the Part D benefit and the stability of the associated premium. It is our goal to provide beneficiaries with information that will help them make informed decisions about their health care options.

Since the statute clearly defines the IEP and provides a Medigap guaranteed issue right for beneficiaries who have Medigap drug coverage and who enroll in Part D during the IEP, we do not believe that it is an appropriate use of the Secretary's authority to create a blanket SEP for exceptional circumstances for these beneficiaries. We believe that the Secretary's authority to establish SEPs for exceptional circumstances should be reserved for situations that are not specifically contemplated in the statute and that this authority should be exercised on a case-by-case basis depending on the circumstances of a particular situation.

Even in a case where we would create an SEP for exceptional circumstances, there is no corresponding statutory authority to create a Medigap guaranteed issue right. The classes of beneficiaries who have Medigap guaranteed issue rights are clearly set out in section 1882(s)(3)(B) and section 1882(v)(3)(B) of the Act. We do not have statutory authority to establish additional classes of beneficiaries who would be entitled to buy a Medigap policy on a guarantee issue basis.

We do not believe that the statute permits us to deem all Medigap Plan J coverage as creditable coverage. Whether or not Plan J drug coverage will be considered creditable coverage must be based on whether the actuarial value of the coverage equals or exceeds the actuarial value of defined standard prescription drug coverage as demonstrated through the use of generally accepted actuarial principles and in accordance with the requirements of § 423.265(c)(3). Moreover, as noted above, it is unlikely that Plan J policies could meet this standard. Finally, for the concern about the possibility of a beneficiary being initially notified of creditable coverage when the coverage is no longer creditable or never was creditable, the regulations at § 423.38(c) permit the establishment of an SEP for Part D in cases where an individual was never informed that the coverage that he or she had was not creditable, or if current coverage is reduced so that it is no longer creditable coverage. If an individual establishes to CMS that he or she was not adequately informed that his or her prescription drug coverage was not creditable, the individual may apply to CMS to have such coverage treated as creditable coverage for purposes of applying the late enrollment penalty provisions at § 423.46.

Comment: One commenter urged us to establish Medigap guaranteed issue rights for individuals who lose partial benefits under a retiree plan and for individuals who lose Medicaid eligibility.

Response: The classes of beneficiaries who have Medigap guaranteed issue rights are clearly set out in section 1882(s)(3)(B) and section 1882(v)(3)(B) of the Act. We do not have statutory authority to establish additional classes of beneficiaries who would be entitled to buy a Medigap policy on a guaranteed issue basis. In limited cases, we have the authority under section 1851(e)(4)(D) of the Act to establish SEPs for MA enrollees that may trigger Medigap guaranteed issue rights for MA enrollees. This authority applies if we determine that there are exceptional circumstances that warrant an SEP, but it does not permit us to establish new classes of beneficiaries who would have Medigap guaranteed issue rights.

Comment: Comments were received suggesting that if a Medigap issuer becomes a Part D sponsor that the sponsor be allowed to limit enrollment in the Part D coverage to its Medigap policyholders.

Response: While the statute prohibits a Medigap issuer from providing drug coverage that supplements the Part D benefit, a Medigap issuer can choose to become a PDP or an MA-PD if the issuer wishes to offer the Part D benefit. However, a PDP sponsor or MA-PD plan must offer prescription drug coverage to all Part D eligible beneficiaries residing in the plan's service area, unless a specific statutory waiver authority applies. Examples include capacity or special needs waivers under Part C of Medicare, or an employer waiver under section 1860D–22(b) of the Act.

Comment: Comments were received requesting regulatory guidance on the MMA provision that provides for the application of the antiduplication penalties set out in section 1882(d)(3)(A)(ii) of the Act in cases where a Medigap policy with drug coverage is renewed for a Part D enrollee. The commenters expressed concern that a Medigap issuer may be

subject to penalties whether or not the issuer knows about the individual's decision to enroll in Medicare Part D. The commenter's request that the antiduplication provisions be enforced consistently using a standard whereby only ''knowing'' violations would be subject to penalty.

Response: Section 1882(v)(4)(A) of the Act, added by section 104 of the MMA, states that the penalties described in section 1882(d)(3)(A)(ii) of the Act shall apply for a violation of the prohibition on the sale, issuance, and renewal of a Medigap policy that provides drug coverage in the case of an individual who is enrolled in Medicare Part D. We are not incorporating the guidance suggested by the commenter into these regulations because these provisions are under the jurisdiction of the OIG of HHS. We recommend that Medigap issuers take reasonable steps to determine the policyholder's Part D status at the time the Medigap policy with drug coverage is due for renewal.

Comment: One commenter questioned whether HMO Medicare supplemental plans offered to its members are considered to be Medigap plans and, if so, whether these plans would be prohibited from offering prescription drug benefits to retirees.

Response: Medicare managed care plans that offer supplemental benefits are not Medicare supplemental (Medigap) policies. The statutory definition of Medicare supplemental (Medigap) policies contained in section 1882(g)(1) of the Act specifically excludes MA plans. While Medigap plans are prohibited from supplementing Part D drug coverage, MA plans will be permitted to offer coverage that supplements Part D drug coverage.

Comment: One commenter suggested that a process be defined for validating and approving a Medigap issuer's assessment whether the drug coverage under its policies is creditable in accordance with the final rule implementing the Part D drug benefit. This commenter also suggested that the determination of creditable coverage should consider the possibility that changes in Part D over time could cause a plan to become creditable coverage over time. The commenter recommends that proper advance notice of Part D changes be scheduled to allow time for creditable coverage determinations, disclosure to beneficiaries and decision-making time for beneficiaries. The commenter also suggested that aggregation of data (combining all ages, gender, locations, formularies) for a particular benefit design be allowed as reasonable in determining creditable coverage.

Response: The issues raised by the commenter are applicable to all forms of creditable coverage and are addressed at § 423.56.

III. Provisions of the Final Rule

For the convenience of the reader, in this section, we briefly summarize major provisions of the proposed rule on which we requested public comments, and our final decisions. It is important to note that this section is not intended as a comprehensive list of all changes to the final rule. For a detailed discussion of a specific issue, see the relevant portion of the preamble to this final rule.

Auto-enrollment

We requested comments on:

- Responsibility for auto-enrollment: Should CMS or the State perform the auto-enrollment function (or a contracted entity or entities on their behalf)?
- Timing of auto-enrollment.
- Auto-enrollment of MA-onlys: How to provide Part D to those full-benefit dual eligible individuals who are in an MA-only plan and who have failed to enroll in a PDP or MA-PD plan?
- How to provide Part D to a full-benefit dual eligible individual enrolled in an MA-only plan when the premium for the MA-PD plan(s) offered by the same MA organization exceeds the low-income premium subsidy amount?

Final Decision: Our response seeks to balance the twin goals of ensuring prescription drug coverage and respecting beneficiary choice. We will:

- Stipulate that CMS-not the States-will perform auto-enrollment;
- Perform the auto-enrollment in the fall of 2005 as soon as eligible Part D plans are known, and auto-enrollment will be effective January 1, 2006. After 2006, full-benefit dual eligible individuals will be auto-enrolled into plans as soon as their Medicare Part D eligibility is determined;
- Auto-enroll on a random basis among available PDPs with monthly beneficiary premiums at or below the low-income subsidy amount;
- Reserve the ability to conduct re-auto-enrollment if we find such action necessary to ensure adequate coverage for this population;
- Facilitate full-benefit dual eligible individuals who are MA enrollees into the MA-PD with the lowest Part D premium offered by their MA organization, and who are cost plan enrollees into their cost plans Part D benefit (if any) with the lowest Part D premium, even if the premium is not covered by the low-income premium subsidy amount.
- May facilitate enrollment for all others deemed or determined eligible for the low-income subsidy, that is, Qualified Medicare Beneficiaries (QMBs), Specified Low-Income Medicare Beneficiaries (SLMBs), Qualifying Individuals (QI–1s), and others who qualify for low income subsidies.

Optional Involuntary Disenrollment for Disruptive Behavior

We solicited comments on the applicability of MA rules to PDPs for involuntary disenrollment for disruptive behavior.

Final Decision: We developed policy to permit PDP sponsors to disenroll individuals for disruptive behavior consistent with statutory intent, while creating the necessary due process safeguards for individuals who are subject to our disenrollment rules and may, as a result, lose Part D coverage. In the final rule, we—

- Removed the expedited process;
- Required PDP sponsors to provide a reasonable accommodation as determined by CMS and in exceptional circumstances we deem necessary; and
- Reserved the right to deny a request from a fallback prescription drug plan to disenroll an individual for disruptive behavior.

Enrollment and Disenrollment Processes

We envisioned a paper enrollment form process and requested comments on other possible enrollment mechanisms that address data security and integrity, privacy and confidentiality, authentication, and other pertinent issues. We also asked if we should require PDPs to disenroll individuals if they no longer reside in the service area.

Final Decision: We will maintain the flexibility to allow PDPs to develop alternative mechanisms other than paper enrollment forms. We will look to our recent experience with the drug card for other mechanisms we may consider, such as enrollment over the telephone and through the Internet. We will require plans to disenroll individuals upon receipt of notification that they have moved outside of the plan service area.

Release of Beneficiary Information for Marketing

Should we provide individual beneficiary information to Part D sponsors for marketing purposes because Part D is an entirely new, voluntary benefit that would not otherwise be available to beneficiaries absent positive enrollment?

Final Decision: We will consider provision of such information pending

further research of the needs and capabilities of both organizations and CMS. If/when we do provide such information to PDPs and MA organizations, we will work with industry and advocates to develop appropriate guidance.

Creditable Coverage

We asked for comment on the format, placement, and timing of creditable coverage notices. We also asked whether there are more forms of coverage that we should consider creditable coverage?

Final Decision: We support linking the notice of creditable status to other required documents that sponsors must provided to plan participants as an acceptable vehicle provided it is conspicuous and includes standard information elements. We have revised § 423.56(c) and (d) to allow notices of creditable and non-creditable status to be provided in the same manner other required documents.

To ensure beneficiaries are making informed choices, we require that notice must be provided to all Part D eligible individuals prior to the commencement of the Annual Coordinated Election Period (AEP), which begins on November 15, 2005, and also prior to the AEP each year. We also believe there are three other key times when notice must be provided—(1) prior to the commencement of the individual's initial enrollment period for Medicare Part D; (2) prior to the effective date of enrollment in such coverage or any change in creditable status of that coverage; and (3) upon request by the beneficiary. We revised § 423.56(f) to require that notice be provided, at minimum, at these 4 times.

We revised § 423.56(b) to include section 1876 cost plans and coverage offered by State high risk pools as well as a provision permitting us to recognize other types of coverage as potentially creditable in guidance following publication of the final rule.

Marketing Multiple Products

Since companies frequently offer additional products that could provide additional tools to help beneficiaries manage expenses and financial security, we asked for comments on allowing such products to be provided in conjunction with PDP services and the appropriate limitations on such activities.

Final Decision: We will allow only additional health-related products to be marketed to Medicare beneficiaries in compliance with HIPAA. Additional non-health related marketing of products would need written authorization by the beneficiary.

Incurred Costs (TrOOP)

We asked a number of questions on how to treat certain costs for purposed of TrOOP accounting: How should we define group health plan (GHP), insurance or otherwise, and other third party arrangements for purposes of TrOOP? How should we treat HSAs (FSA, HRA, MSA) under TrOOP: Can we treat HSAs, FSAs, and MSAs as beneficiary money, and HRAs, as GHP? Should the price differential between the cost of an extended supply of a drug purchased at a retail pharmacy versus a mail-order pharmacy be counted as an incurred cost against the annual out-of-pocket threshold? What is the status of financial assistance and free goods and services from pharmaceutical manufacturers under the anti-kickback provisions? (Sections 1128A(a)(5), 1128A(i)(6) of the Act).

Final Decision: We included definitions in § 423.100 that are consistent with our goals of defining ''payments made by a beneficiary or another person on their behalf'' as broadly as possible, while maintaining the integrity of the exclusions of ''group health plan, insurance or otherwise, and other third party arrangements'' intended in the statute. These include:

- treating HSAs, FSAs, and MSAs as beneficiary money, but HRAs as a Group Health Plan for purposes of TrOOP accounting.
- allowing beneficiary payment differentials to count toward TrOOP in cases in which a beneficiary accesses a covered Part D drug consistent with the out-of-network policy in § 423.124(a) of this final rule, and when a beneficiary purchases an extended supply of covered Part D drugs at a retail rather than a mail-order pharmacy.
- allowing appropriate waivers or reductions of Part D cost-sharing by pharmacies to count toward TrOOP.
- allowing financial assistance from pharmaceutical manufacturers to count toward TrOOP.

Dispensing Fee

We invited comments on three definitions of ''dispensing fees''.

Final Decision: We will include only those activities related to the transfer of possession of the covered Part D drug from the pharmacy to the beneficiary, including charges associated with mixing drugs, delivery, and overhead (Option 1).

Covered Part Drug Definition

Part B/D Issues: We solicited comments concerning any drugs that may require specific guidance with regard to their coverage under Part D, and any gaps that may exist in the combined ''Part D & B'' coverage package.

Final Decision: We identify issues and discuss coverage of the following with respect to the definition of Part D drug:

- Vaccines.
- Compounded Drugs.
- Parenteral Nutrition.
- Insulin Supplies.
- Exclusion of A/B Drugs if individual could have enrolled in A or B.
- Tying Arrangements.

Long Term Care Facility Pharmacies

We requested comments regarding our definition of the term long-term care facility in § 422.100. We also solicited comments regarding how we should guarantee ''convenient access'' to the pharmacy benefit for Part D enrollees who reside in LTC facilities? We welcomed comments regarding how to balance convenient access to long-term care pharmacies with appropriate payment to long-term care pharmacies under the provisions of the MMA.

Final Decision: We have expanded the definition of the term ''long-term care facility'' in § 423.100 of our final rule to encompass not only skilled nursing facilities, as defined in section 1819(a) of the Act, but also any medical institution or nursing facility for which payment is made for institutionalized individuals under Medicaid, as defined in section 1902(q)(1)(B) of the Act.

In addition, we are adopting an approach requiring Part D plans to demonstrate ''convenient access'' to network long-term care pharmacies that will inject competition into the long-term care pharmacy market, but also allow the option of maintaining the relationships and levels of service that long-term care facilities now enjoy vis-à-vis their contracted long-term care pharmacies. We will require plans to demonstrate (in their applications) ''convenient in-network access'' to long-term care pharmacies and use of specialized any-willing-pharmacy (AWP) contracts for long-term care pharmacies to inject competition into the long-term care pharmacy market.

Network Access Standards—Home Infusion

In the proposed rule preamble, we stated that we were considering using the authority in section 1860D–4(b)(1)(C) of the Act (which establishes requirements regarding convenient access to network pharmacies) to require that plans contract with a sufficient number of home infusion pharmacies in their service areas to provide reasonable access for Part D enrollees, as stand-alone drug plans may not have an incentive to include home infusion pharmacies in their networks. We solicited comments on whether we should use the authority in section

1860D–4(b)(1)(C) of the Act to require that both MA-PD plans and PDPs contract with a sufficient number of home infusion pharmacies in their service area to provide reasonable access for Part D enrollees? How could such a requirement be structured?

Final Decision: We will require plans to provide adequate access to home infusion pharmacies but do not specify requirements in the final rule. Plans will be required to tell us how they will provide such access in their service area.

Network Access Standards—Tricare Standards (Retail)

We proposed to apply these access standards such that a PDP or regional MA-PD plan would have to meet or exceed the access standards across each region in which it operates, and a local MA-PD plan would have to meet or exceed the access in its local service area.

Final Decision: We will require plans to meet the TRICARE access standards at the State level.

Network Access Standards—Non-Retail

We requested comments on whether we should allow plans to count certain non-retail pharmacies, such as I/T/U pharmacies, toward the pharmacy access standards in some (or all) cases. We also solicited comments on permissible ways to ensure Part D enrollees' access to FQHC and rural pharmacies.

Final Decision: We will allow plans to count I/T/U pharmacies and other rural institutional pharmacies (for example, FQHCs, RHCs) toward the pharmacy access requirements in all cases, provided such pharmacies are under contract with the plan and do not substitute for available retail access in their network.

Network Access—I/T/U Pharmacies

We asked: How will I/T/U pharmacies and IHS beneficiaries achieve maximum participation in Part D benefits? What are the advantages and disadvantages for AI/AN enrollees who are eligible to enroll in Part D?

Final Decision: We will require Part D plan sponsors to include I/T/U pharmacies in their networks to the extent that those pharmacies are present in their service areas. We will require that plans offer any willing pharmacy (AWP) contracts to I/T/U pharmacies that include an addendum addressing certain minimum terms and conditions specified by us in separate guidance. We will require Part D plans to demonstrate that they have contracts with a sufficient number of I/T/U pharmacies to ensure ''convenient access'' to prescription drugs for AI/AN enrollees within the service area.

Any Willing Pharmacy

We asked: Should we require that PDP sponsors and MA organizations offering an MA-PD plan make available to all pharmacies a standard contract for participation in their plans' networks? Should ''any willing pharmacy'' provisions apply to non-retail—in particular mail order—pharmacies, as well as to retail?

Final Decision: We will require plans to offer standard terms and conditions to all pharmacies for purposes of ensuring that any pharmacy, and any type of pharmacy, willing to accept the standard contact terms and conditions can join the pharmacy network.

Out-of-Network (OON) Access

We requested comments on how emergency access standards should work. In the proposed rule, we required plans to ensure that their enrollees have adequate access to drugs dispensed at OON pharmacies when they cannot reasonably be expected to obtain covered Part D drugs at a network pharmacy. We requested comments on our proposed out-of-network access requirements.

In the preamble to our proposed regulations, we specified that the case of a Part D enrollee who is residing in a long-term care facility whose long-term care pharmacy does not contract with that enrollee's MA-PD plan or prescription drug plan is one in which we would expect plans to provide out-of-network access to drugs as provided under § 423.124 of our regulations.

Final Decision: We adopt the out-of-network access policy set forth in the proposed rule and clarify that § 423.124(c) of our final rules requires plans to establish reasonable rules to ensure that enrollees use out-of-network pharmacies in an appropriate manner. Plans must ensure adequate access to out-of-network pharmacies on a non-routine basis when enrollees cannot reasonably access network pharmacies.

We have defined the beneficiary cost sharing in relation to the total cost of the drug to the plan and the beneficiary. Therefore, in cases where the total payment is not limited by the plan allowable due to out-of-network status, the cost sharing should be defined as the total paid by the beneficiary, or in the case of a low-income individual, as the total cost sharing paid by both the beneficiary and CMS. However, we changed our proposed policy of allowing out-of-network access for long-term care pharmacies and now require Part D plans to provide network access.

Formularies

We requested comments on many aspects of formulary management, such as:

- Does requiring a formulary to be ''developed and reviewed'' by a P&T committee mean that a P&T committee's decisions regarding the plan's formulary must be binding on the plan?
- Should we strengthen the statutory requirement in section 1860D–4(b)(3)(A)(ii) of the Act by requiring that more than just one pharmacist and one physician on the P&T committee be independent and free of conflict?
- Should we require the direct involvement of a Pharmacy and Therapeutics Committee with cost containment measures, as well as with other areas of quality assurance and medication therapy management?
- What standards and criteria could we use to determine that a PDP sponsor or MA organization's formulary that is not based on the model classification system does not in fact discriminate against certain classes of Part D eligible beneficiaries?
- How can we balance plans' flexibility to maximize covered Part D drug discounts and lower enrollee premiums with the needs of certain special populations of Part D enrollees?
- What should be the minimum timeframes for periodic evaluation and analysis of protocols and procedures related to a plan's formulary by PDP plans and MA-PD plans (for example, quarterly, annually)?

Final Decision: We made changes to the regulatory formulary requirements to balance: (1) building specific requirements into regulatory language to ensure plans offer adequate coverage of the types of drugs most commonly needed by Part D enrollees; with (2) maintaining flexibility to fine-tune formulary review requirements via separate guidance consistent with our final formulary review standards and processes developed based on public comment. The regulatory text revisions:

- Clarify that P&T committee members must be independent and free of conflict with respect not just to plans, but also pharmaceutical manufacturers.
- Specify a role for P&T committees in the approval of policies that guide medical exceptions and other utilization management processes, as well as treatment protocols and procedures related to a plan's formulary.
- Require the provision of adequate coverage of the types of drugs most commonly needed by Part D enrollees, as recognized in national treatment guidelines—above and beyond the 2–drugs-per-category-and-class requirement.
- Provide us with the flexibility to specify additional requirements regarding plans' P&T committees and formularies via separate guidance.

• Specify that we will review plan formularies consistent with the non-discrimination provisions at § 423.272(b)(2). We intend to conduct a comprehensive review of the plan design consistent with explicit formulary review standards and criteria-driven processes.

Quality Standards

We asked: Are there industry standards for cost effective drug utilization management, and should we adopt any of these standards for PDPs and MA-PD plans? Among the issues we raised in the preamble is whether or not we should use the OBRA '90 Medicaid standards for these programs. OBRA '90 requires pharmacy programs to use proDUR and retroDUR and to offer counseling services.

Final Decision: We require plans to demonstrate that their network providers are required to comply with pharmacy practice standards established by the States, to establish concurrent and retrospective DUR policies and systems, and to establish internal medication error identification and reduction systems.

Medication Therapy Management Programs(MTMP)

We sought comments on what requirements or guidelines for MTMPs should be formulated in our regulations.

Final Decision: We received a significant volume of comments on MTMP. Almost all the comments agreed that MTMP can make a significant difference in improving therapeutic outcomes. Despite some best practice examples, however, no widely accepted MTMP standards of practice were identified. We will not specify further service and service level requirements at this time. We also will not specify multiple chronic diseases and multiple drug requirements.

Anti-Fraud Programs

We stated that we would be interested in comments on possible requirements in the area of fraud, waste and abuse over and above the incentives operating in at-risk plans.

Final Decision: In an effort to consolidate requirements on plans we moved the fraud and abuse provision to subpart K at § 423.504(b)(4)(vi)(H) as a component of a Part D sponsor's overall compliance plan. Plans will be required to add a program to combat fraud, waste and abuse in their prescription drug benefits to their compliance plans. In addition, we eliminated the mandatory self-reporting requirements that were proposed, but we expect all Part D sponsors to comply with the requirement for a comprehensive fraud and abuse plan.

E-Prescribing

We solicited comments on many aspects of developing and implementing e-prescribing standards.

Final Decision: While we included a fairly lengthy discussion of e-prescribing in the August 2004 proposed rule, we intend to issue a separate proposed rule devoted to the standards that will be used for e-prescribing and have reserved § 423.159(a) and § 423.159(b) of this final rule for such e-prescribing standards. Therefore, most of the proposals we made with respect to such standards are not being addressed in this final rule. One standard we are finalizing is the requirement that Part D plans support e-prescribing. We received no comments on this proposal and are adopting it at § 423.159(c).

Evaluating Bids

We asked for comments on whether we should we adopt the standards used by OPM in 48 CFR Chapter 16.

Final Decision: We have adopted most of the proposed rule provisions in the area of bid review, negotiation and approval, with the following clarifications: We-

• Clarify that the OPM-like authority (section 1860D–11(d)(2)(B) of the Act) is in addition to our general authority to negotiate (section 1860D–11(d)(2)(A) of the Act).

• Clarify that we will not be proposing additional regulations based on 48 CFR Chapter 16.

• Clarify that we intend to examine profit using this authority.

• Clarify that we do not intend to require detailed information on acquisition costs from each and every plan. We would request additional information only when necessary.

• Reiterate our interpretation that the bid review authority does not violate the non-interference directive.

Calculations

We solicited comment on the appropriateness of all of our proposed calculations.

Final Decision: We will adopt all of the proposed calculations with the exception of our interpretation of the ''negative premium.'' We will allow for a ''negative premium'' for plans with bids below the benchmark by an amount in excess of the base beneficiary premium.

Data Submission

We asked: What should be the content, format and frequency of data submissions?

Final Decision: Because of the complexity of the MMA payment provisions, collecting 100 percent events data is necessary. While the volume is large, the minimal number of data elements we expect to collect (<25) and the simplicity of our own data processing system should minimize the burden of this approach. Our goal will be to collect the minimum amount of data we need to perform our payment functions.

Payment Adjustments

We solicited comment on many operational aspects of payment of reinsurance and low-income subsidies, as well as for risk corridors and reconciliations.

Final Decision: Reinsurance will be paid on a monthly basis during the year based on estimated reinsurance costs; however, we may move to payment on an as-incurred basis in later years. Low income cost-sharing subsidies will be made on an interim basis. Final reconciliation on reinsurance and low income subsidies will occur after the close of the year.

We solicited comments on the nature of waivers that might be required for MA plans and employer-sponsored plans, among others.

Final Decision: Information on specific waivers we will or will not grant is not addressed in this regulation, but will be described in separate guidance.

Coordination with Other Plans

We requested comment on what basis Part D COB user fees should be imposed on Part D plans.

Final Decision: We intend to issue requirements for coordination with other prescription drug coverage by Part D plans as soon as possible in advance of the statutory deadline of July 1, 2005.

Part B/D Coordination of Benefits

We asked: Should Part D cover Part B drugs denied under Part B because the pharmacy does not have a Medicare supplier number? Are there any other circumstances under which a Part B drug denied coverage under Part B should be covered under Part D? Are automatic claims cross-over procedures feasible between Part B and Part D payers?

Final Decision: Based on the comments received regarding the various B/D coordination issues we described, we do not believe commenters identified any circumstances under which a drug denied coverage under Part B should automatically be covered under Part D, and we will not provide for automatic cross-over procedures.

Tracking TrOOP

We requested comment on the following issues:

Should CMS or the Part D plans be responsible for determining whether claims costs have been reimbursed by alternative coverage?

What are the operational capabilities of plans to manage COB at the point of sale, particularly with respect to alternative wrap around coverage?

Should reporting of third-party claims costs be mandatory or voluntary?

Should we require beneficiaries to give consent for release of data held by third parties as part of their enrollment application?

Are there any temporary or phased-in approaches to tracking TrOOP that may be necessary or advisable given the short timeframe between the final rule and program implementation?

How can Part D plans receive information from beneficiaries or others regarding payment made by entities that do not participate in a centralized coordination of benefits system?

Final Decision: In the proposed rule, we considered two options for operationalizing the data exchange related to the Part D coordination of benefits system and TROOP accounting:

- *Option 1*: The Part D plan s and MA-PD plans will be solely responsible for tracking TrOOP costs.
- *Option 2*: We will procure a TrOOP facilitation contractor to establish a single point of contact between payers, primary or secondary.

While this is not a regulatory issue, we will work toward some variation on Option 2, since we believe this is the most efficient and effective way to implement the TrOOP. Further information will be issued with our requirements for coordination with other plans by Part D plans as soon as possible in advance of the statutory deadline of July 1, 2005.

Appeals

We solicited comments on coverage determinations and notices and exceptions procedures.

We proposed a limited number of elements that must be included in a sponsor's formulary exceptions criteria. We also considered including a number of other exceptions criteria and adding criteria for the review process that is used to evaluate formularies and tier structures. We asked for comment on whether we should specify the decision criteria for beneficiary appeals, or whether Part D plans should be held accountable to follow their own decision criteria.

Final Decision: Consistent with the August 2004 proposed rule, we specify that a coverage determination is made by the Part D plan, not at the pharmacy, and we address notice and timing issues. We have shortened the coverage determination timeframes for making expedited and standard coverage determinations, redeterminations and reconsiderations. We limit tiering exceptions to obtaining a non-preferred drug at the price of a preferred drug, and specify that tiering exceptions need not be granted in cases where a Part D sponsor has a formulary tier in which it places very high cost and unique items, such as genomic and biotech products. We require that plans grant exceptions to tiering when the physician certifies that the preferred drug would not be as effective as the non-preferred on-formulary drug or would have an adverse effect on the individual and the plan agrees with such certification. Similarly, for off-formulary exceptions, if the physician certifies that the on-formulary drug would not be as effective as the prescribed drug or would have adverse effects and the plan agrees with such certification, a formulary exception must be granted. Grievance procedures also are revised to accordance with changes to the Medicare Advantage final rule.

Employer Sponsored Prescription Drug Programs and Appeals

We solicited comments on whether, and to what extent, the application of parallel procedures between employer sponsored prescription drug plans governed by ERISA and plans offered under part 423 of our proposed regulations might be a problem for plans, employers, or eligible individuals. We also solicited suggestions for addressing problems, if any, that result from the application of parallel procedures.

Final Decision: We have added § 423.562(d), which is intended to give ERISA plans the option, according to regulations of the Secretary of Labor, of electing the Part D process rather than the procedures under 29 CFR 2560.503–1 for claims involving supplemental benefits provided by contract with a Part D plan. The provision in § 423.562(d) would not take effect in the absence of regulations by the Secretary of Labor.

Low-Income Subsidy Determinations and Notification

We invited general comments on how we could ensure consistent eligibility determination, redetermination and appeal processes for low-income subsidies. We requested comments on how we should calculate the sliding scale premium subsidy for individuals with income from 135 percent up to 150 percent of the FPL. We offered an example to set a scale in a stepped fashion, for example, a set decrease in the subsidy amount for every 5 percent increase in income level.

Final Decision: We require that the Part D plan be responsible for direct reimbursement to beneficiaries for out-of-pocket costs incurred after the effective date of subsidy eligibility. We also require the Part D plan to have processes for reimbursing a charity or program for any premium and cost sharing amounts paid on behalf of an individual subsequent to the effective date of the subsidy. We adopted the proposed sliding scale premium methodology in this rule.

Fallback Plan Requirements

We invited comment on whether we should define ''offering a fallback plan'' as agreeing to potentially offer a plan in a region, or as actually providing a fallback plan in fallback service areas. We also solicited comment on whether we should use the Indefinite Delivery type of contract.

Final Decision: We adopted the interpretation that offering a fallback plan means actually providing a fallback plan in fallback service areas. We have also determined that fallback contracts will not be written under the FAR or 48 CFR provisions; therefore, it is no longer accurate to refer to the standby contracts as indefinite duration, indefinite quantity (IDIQ) contracts—which is a term used under the FAR.

Fallback Payment

We requested comment on fallback payment methodologies, particularly in regard to prospective or retrospective rebate allocation. We also requested comments on alternative reference points to the Average Wholesale Price (AWP) or alternative methodologies that could promote competitive pricing.

Final Decision: Information on the fallback payment process is not addressed in this final regulation, but will be described in separate guidance. The AWP remains the primary measuring stick for drug costs. We will therefore be incorporating it into our performance targets. However, we will be looking at other indicators or proxies for financial performance, such as rates of generic substitution, that will provide other perspectives on cost management.

Access Standards in the Territories

We asked whether the waivers proposed for the territories were appropriate, and were any others warranted to ensure access to individuals residing in the territories?

Final Decision: The only comments received with respect to the territories concerned the design of the regions, and these have been addressed in separate guidance. As a result, we have retained the broad waiver authority in § 423.859(c), and will continue to conduct research to determine how best to facilitate Part D coverage in the territories. Specific waivers will be addressed in separate guidance.

Subsidy Process

We solicited comments on many aspects of the proposed retiree drug subsidy process.

Final Decision: After reviewing the comments, we made many policy decisions in the final rule, including:

- Announcing that we would allow retiree drug plans the flexibility to receive subsidy payments on a monthly, quarterly or annual basis at their discretion;
- Providing insured plan sponsors the flexibility to use premiums as the cost basis for interim subsidy payments;
- Clarifying what information must be submitted with enrollment data;
- Providing sponsors the flexibility to use either the calendar year or their plan year (if different from the calendar year) for calculating the subsidy and for determining actuarial equivalence; and
- Allowing sponsors broad discretion in determining who meets the definition of a qualifying covered retiree for purposes of the subsidy.

Further details on the implementation of the subsidy program will be provided in separate guidance.

Actuarial Equivalence for Subsidy

We asked for comments on the likely responses of plan sponsors to the different approaches we proposed. In addition, we solicited comments not only on the desirability of the different options, but also on the legal bases for possible options.

Final Decision: The final regulation includes a two-part test for plan sponsors to determine whether ''actuarial equivalence,'' has been met.

Change in Definition of Outpatient Prescription Drugs

We solicited comments on the new definition for purposes of the physician self-referral prohibition.

Final Decision: We finalized this proposal without substantive change.

Waivers Needed for Cost Plans or CMPs

We invited comment on whether there are any Part D requirements otherwise applicable to MA-PD plans that would be uniquely problematic to implement for section 1876 reasonable cost HMOs and CMPs.

Final Decision: We have clarified that Part D will be offered somewhat differently by cost plans:

(1) Cost plans that choose to offer qualified Part D coverage under § 417.440(b)(2) may do so only by offering qualified Part D coverage as an optional supplemental benefit.

(2) Cost plans that offer qualified Part D coverage must offer basic prescription drug coverage. A cost plan that offers basic prescription drug coverage may offer additional qualified Part D coverage choices.

(3) A cost plan that does not offer qualified Part D coverage under § 417.440(b)(1)(iii) may offer non-qualified drug coverage that is not reimbursed under this part or title.

Creditable Coverage Notice for Medigap Policies

The proposed rule set forth a draft disclosure notice for Medigap issuers to use for policies that do not have creditable coverage. We solicited comments on how the draft disclosure notice could be adapted for the types of Medigap policies that do provide creditable coverage.

Final Decision: We have determined that the format and content of the notice could be improved based on information gathered through consumer testing, so we now plan to publish the final model disclosure notice separately from this final regulation. We also plan to publish a model disclosure notice for policies that do provide creditable coverage.

PACE Waivers

We invited comments on the MMA requirements we proposed to be waived for PACE organizations and asked for comment on additional waivers that may be needed to integrate the Medicare prescription drug benefit and the PACE benefit.

Final Decision: We have finalized our proposed waiver of section 423.265(b) and will allow PACE plans to submit Part D bids after the first Monday in June each year. However, we clarified that we expect PACE plans that are operational as of the first Monday in June each year to meet the bid submission deadline. Information on additional waivers will not be addressed in this regulation, but will be described in separate guidance.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether OMB should approve an information collection, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Below is a summary of the information collection requirements in this regulation.

Subpart A—General Provisions

Subpart A does not contain any requirements subject to the PRA.

Subpart B—Eligibility and Enrollment.

- § 423.32 Enrollment process.

(a) A Part D eligible who wishes to enroll in a Part D may enroll during the enrollment periods specified in § 423.38, by filing the appropriate enrollment form with the Part D plan or through other mechanisms CMS determines are appropriate.

The burden associated with this requirement is the time and effort necessary for an individual to submit the required enrollment application to a Part D plan sponsor. We estimate that it will take 30 minutes to complete and submit the required application to the Part D plan. During the first Part D initial enrollment period, it is estimated that 24 million individuals will complete and submit these applications. This estimate is based on preliminary estimates of the number of individuals who will enroll in Part D plans in 2006. In 2007, and beyond, the number of enrollments will be substantially less, since an individual will generally be limited to changing Part D plans during the annual coordinated election period. Therefore, it is estimated 6 million individuals may change their Part D plans annually and that 2 million new beneficiaries will be making first time enrollments into Part D plans.

(b) *Enrollment form or CMS-approved mechanism.* The enrollment must be completed by the individual and include an acknowledgement by the beneficiary for disclosure and exchange of necessary information between the U.S. Department of Health and Human Services (or its designees) and the Part D plan sponsor. Persons who assist beneficiaries in completing the enrollment, including authorized representatives, must indicate they have provided assistance and their relationship to the beneficiary.

The burden associated with this requirement is reflected above under section 423.32(a).

A Part D plan sponsor may require Part D eligible individuals enrolling or enrolled in its Part D plan to provide information regarding reimbursement for Part D costs through other insurance, group health plan or other third-party payment arrangement, in a form and manner approved by CMS.

The burden associated with the requirement for individuals to provide information regarding reimbursement

for Part D costs through other insurance, group health plan or other third-party payment arrangement enrolled or enrolling in a Part D plan is total annual burden of 43,333 hours. We estimate that 2.6 million beneficiaries will need 1 minute to disclose reimbursement for Part D costs to the appropriate entity on an annual basis, for a total annual burden of 43,333 hours.

(d) *Notice requirement.* The Part D plan sponsor must provide the individual with prompt notice of acceptance or denial of the individual's enrollment request, in a format and manner specified by CMS.

The burden associated with this requirement is the time and effort necessary for a Part D plan sponsor to disclose to an individual notice of acceptance or denial of the individual's enrollment request. We estimate that during the first Part D initial enrollment period a total of 24 million notices will be disclosed, affecting approximately 64 Part D plans (based upon an estimate of 2 Part D plans per 34 regions). Given that each Part D plan will be creating disclosure notices for mass mailings, we are proposing the following burden estimates. We estimate that it will take each Part D plan approximately 8 hours to produce each notice—either an acceptance or a denial notice must be provided. We further estimate that on average, it will take each Part D plan sponsor 1 minute to assemble and disseminate each notice. We further estimate that on average, it will take each sponsor 5,860 hours to disclose 375,000 notices during this first year. In 2007, and beyond, we estimate that 93,750 notices will be disclosed annually at 1,465 hours per sponsor. This assumption is based on the premise that once the notices have been standardized, a Part D plan sponsor will mass-produce and mail the required notices.

• § 423.36 Disenrollment process.

(b) The Part D plan sponsor must submit a disenrollment notice to CMS within timeframes CMS specifies; provide the enrollee with a notice of disenrollment as CMS determines and approves; and file and retain disenrollment requests for the period specified in CMS instructions.

The burden associated with this requirement is the time and effort necessary for a Part D plan sponsor to disclose to an individual notice of disenrollment. We estimate that on an annual basis it will require a total of 576,100 notices, affecting each Part D plan sponsors to some degree, as described below. Given that each Part D plan sponsor will be creating disclosure notices for mass mailings, we are proposing the following burden estimates. We estimate that it will take each Part D plan sponsor approximately 8 hours to produce the standardized notice. We further estimate that on average, it will take each Part D plan 1 minute to disclose each notice.

• § 423.38 Enrollment periods.

(c) Under the special enrollment period provisions, an individual is eligible to enroll in a Part D plan or disenroll from a Part D plan and enroll in another Part D plan, if the individual demonstrates to CMS, in accordance with guidelines CMS issues, that the Part D plan sponsor offering the Part D plan substantially violated a material provision of its contract under this part that meets the requirements set forth in this section. The burden associated with this requirement is the time and effort necessary for an individual to submit the required materials to CMS demonstrating that a Part D plan substantially violated a material provision of its contract. Based on our experience with the current Medicare Advantage program, we would expect that few, if any, individuals will avail themselves of this option. Generally, in those instances where CMS has found that an M+C organization has substantially violated a material provision of its contract, CMS has taken the necessary action on behalf of these individuals. Thus, we do not estimate any burden on individuals under this provision.

• § 423.44 Involuntary disenrollment by the Part D plan.

(c) If the disenrollment is for any of the reasons specified in paragraphs (b)(1), and (b)(2) of this section (that is, other than death Part D eligibility), the Part D plan sponsor must give the individual timely notice of the disenrollment with an explanation of why the Part D plan is planning to disenroll the individual. Notices for reasons specified in paragraphs (b)(1) through (b)(2) of this section must be provided to the individual before submission of the disenrollment notice to CMS; and include an explanation of the individual's right to a hearing under the Part D plan's grievance procedures.

(d) A Part D plan sponsor may disenroll an individual from the Part D plan for failure to pay any monthly premium if the Part D plan sponsor can demonstrate to CMS that it made reasonable efforts to collect the unpaid premium amount.

The burden associated with this requirement is the time and effort necessary for a Part D plan sponsor to submit the required materials to CMS demonstrating that the Part D plan sponsor made reasonable efforts to collect the unpaid premium amount and the time and effort necessary for a Part D plan sponsor to disclose to an individual the notice of disenrollment. We estimate that it will take a Part D plan 5 minutes to submit the required transaction to CMS for each occurrence and that each of the Part D plan sponsors will be required to submit the necessary documentation to CMS 960 times on an annual basis. We estimate that on an annual basis 96,000 individuals will be disenrolled for failure to pay premiums, and it will take each Part D plan 1 minute to disclose each notice and that each Part D plan will be required to disclose 960 notices on an annual basis for a annual burden of 16 hours.

A Part D plan may disenroll an individual whose behavior is disruptive, only after it meets the requirements described in this section and after CMS has reviewed and approved the request.

To disenroll an individual from its Part D plan, based on an individual's behavior, the Part D plan sponsor must document the enrollee's behavior, its own efforts to resolve any problems and any extenuating circumstances. The Part D plan must submit this information and any documentation received by the beneficiary to CMS. The Part D plan sponsor may request from CMS the ability to decline future enrollment by the individual.

The burden associated with this requirement is the time and effort necessary for a Part D plan to document and retain the documentation that meets the requirements set forth in this section. We estimate that it will take a Part D plan 3 hours to capture and retain the required documentation for each occurrence and that each Part D plan will have 1 occurrence on an annual basis.

In addition, the Part D plan must inform the individual of the right to use the Part D plan 's grievance procedures.

The burden associated with this requirement is captured under section § 423.128.

When a Part D plan contract terminates as stipulated under 423.507 and 423.510 the Part D plan sponsor must send a notice to the enrollee before the effective date of the plan termination or area reduction. The notice must give provide an effective date of the plan termination and a description of alternatives for obtaining benefits under Part D.

The burden associated with these requirements is discussed below under sections 423.507 and 423.510.

• § 423.48 Information about Part D.

Each Part D plan and MA-PD plan must provide, on an annual basis, and

in a format and using standard terminology that CMS may specify in guidance, the information necessary to enable CMS to provide to current and potential Part D eligible individuals the information they need to make informed decisions among the available choices for Part D coverage.

The burden associated with this requirement is the time and effort necessary for a Part D plan to submit the required materials to CMS. We estimate that on an annual basis it will take 68 Part D plan sponsors 2 hours to submit the required documentation to CMS.

• § 423.50 Approval of marketing materials and enrollment forms.

(a) At least 45 days (or 10 days if using marketing materials that use, without modification, proposed model language as specified by CMS) before the date of distribution, the Part D plan sponsor must submit the its marketing materials and forms to CMS for review.

The burden associated with this requirement is the time and effort necessary for a Part D plan to submit the required materials to CMS. We estimate that on an annual basis it will take 68 Part D plan sponsors 2 hours to submit the required documentation to CMS.

• § 423.56 Procedures to determine and document creditable status of prescription drug coverage.

(c) Each entity that offers prescription drug coverage under any of the types described in § 423.56(b) must disclose, to all Part D eligible individuals whether such coverage meets the actuarial requirements specified in guidelines provided by CMS. These notices must be provided to Part D eligible individuals, at minimum, at the following times: (1) prior to an individual's initial enrollment period for Part D, as described under § 423.38(a); (2) prior to the effective date of enrollment in the coverage, and upon any change in creditable status; (3) prior to the commencement of the Annual Coordinated Election Period (ACEP) that begins on November 15 of each year, as defined in 423.38(b); or (4) upon request by the individual. In an effort to reduce the burden associated with providing these notices, we have revised our final regulations to allow most entities (with the exception of Medigap insurers) to provide notices of creditable and non-creditable status with other information materials that these entities distribute to beneficiaries (rather than separately) and, as discussed in the preamble, we anticipate providing model language for both types of notices.

The burden associated with this requirement is the time and effort necessary for each of these entities to disclose to an individual notice of coverage. We estimate that it will require slightly over 400,000 entities to provide notices in existing plan materials (including 400,000 employer and union-sponsored group health plans with Medicare-eligible workers, and fewer than 50 other entities including State Pharmaceutical Assistance Programs, a handful of State Pharmacy Plus programs), and over 100 Medigap insurers to provide 1,900,000 separate initial notices in 2005. In addition to these initial notices, we estimate that in each subsequent year these same entities will be required to distribute notices in plan materials (including initial notices to new beneficiaries, annual notices prior to the ACEP, and notices of changes in creditable coverage status), as well as 447,789 additional separate notices to individuals upon request. [Note: A discussion of the costs and burden associated with the disclosure notices for public and private employers and unions sponsoring retiree coverage can be found in the impact analysis section on administrative costs associated with disclosure notice requirements and the PRA section on requirements for qualified retiree prescription drug plans, respectively.]

Given that each entity (with the exception of Medigap insurers) will be creating most of these disclosure notices for inclusion in existing plan materials, we make the following burden estimates. For initial notices of creditable coverage, subsequent notices prior to the commencement of the ACEP, and notices of changes in creditable coverage, we estimate that it will take each entity approximately 8 hours to produce the standardized notice. We further estimate that on average, it will take each entity (with the exception of Medigap insurers) a negligible amount of time to disclose each notice, since they will be incorporating notices into existing plan materials that are provided to beneficiaries (which are already being disseminated to their participants). In the case of Medigap insurers, we estimate that they will spend 1 hour per 60 notices for mass-mailing separate notices to beneficiaries. We further estimate that each entity will spend approximately 5 minutes per notice for providing separate additional copies of the notices to individual beneficiaries upon request. It is estimated that the burden per entity will be as follows:

• On average, the 4 State Pharmacy Plus programs will provide initial notices in existing beneficiary plan materials in 2005 for an annual burden of 8 hours (these notices are required even though, as discussed elsewhere in this preamble, these States may decide to lower their costs while maintaining equivalent benefits by replacing or reforming these programs).

• On average each of the 400,000 group health plans will provide initial notices in existing beneficiary plan materials in 2005 for an annual burden of 2 hours. Additionally, in subsequent years, on average, we estimate that these 400,000 group health plans will provide 100,000 additional separate notices to individuals upon request for an annual burden of 1.25 minutes. We also estimate that in subsequent years, on average, 4,000 of these group health plans will experience changes in creditable coverage status and provide notice of their new creditable coverage status in their plan materials, for an annual burden of 2 hours. We estimate that the annual burden associated with providing notices prior to the ACEP in subsequent years will be negligible, since they will be able to include these notices in their existing plan materials with minimal modifications.

• On average each of the 20 State Pharmaceutical Assistance Programs will provide initial notices in existing beneficiary plan materials in 2005 for an annual burden of 8 hours per State. We estimate that the annual burden associated with providing notices prior to the ACEP in subsequent years will be negligible, since they will be able to include these notices in their existing plan materials with minimal modifications.

• On average each of an estimated 120 Medigap issuers will provide 15,833 separate initial notices in 2005 for an annual burden of 264 hours. Additionally, in subsequent years, on average, we estimate that these 120 Medigap issuers will provide 40 additional separate notices to individuals upon request for an annual burden of 3.3 hours. We estimate that the annual burden associated with providing notices prior to the ACEP in subsequent years will be negligible, since the regulatory impact analysis assumes that the vast majority of beneficiaries with Medigap drug coverage will enroll in Part D.

(e) Each entity must disclose their creditable coverage status to CMS in a form and manner described by CMS. Each entity must disclose their initial creditable coverage status to CMS in 2005, as well as any subsequent change in creditable coverage status.

The burden associated with this requirement is the time and effort necessary for each entity to submit the required creditable coverage status materials to CMS. We estimate that it

will take each entity 1 hour to submit the required documentation to CMS.

Subpart C—Benefits and Beneficiary Protections.

• § 423.104 Requirements related to qualified prescription drug coverage.

(g) A Part D plan sponsor is required to disclose to CMS data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers, as well as data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers that are passed through to beneficiaries, via pharmacies and other dispensers, in the form of lower subsidies paid by CMS on behalf of low-income individuals or the form of lower monthly beneficiary premiums or lower covered Part D drug prices at the point of sale.

The burden associated with this requirement is the time and effort necessary for a Part D plan sponsor to disclose to CMS the aggregate negotiated price data on concessions. We estimate that on an annual basis it will take 100 Part D plan sponsors and 350 MA organizations 10 hours to submit the required documentation to CMS for total annual burden of 4,500 hours.

• § 423.120 Access to covered Part D drugs.

(b) A Part D plan sponsor's formulary must be reviewed by a pharmacy and therapeutic committee that must maintain written documentation of its decisions regarding formulary development and revision.

The burden associated with this requirement is the time and effort necessary for a Part D sponsor's pharmacy and therapeutic committee to document and retain the documentation that meets the requirements set forth in this section.

We estimate that it will take 100 Part D plan sponsors and 350 MA organizations 1 hour each to capture and retain the required documentation on an annual basis for total annual burden of 450 hours.

Prior to removing a covered Part D drug from its plan's formulary, or making any change in the preferred or tiered cost-sharing status of a covered Part D drug, a Part D plan sponsor must provide at least 60 days notice to CMS, State Pharmaceutical Assistance Programs, entities providing other prescription drug coverage (as described in § 423.464(f)(1)), authorized prescribers, network pharmacies, and pharmacists.

The burden associated with this requirement is the time and effort necessary for a Part D sponsor to provide notice of at least 60 days to CMS, State Pharmaceutical Assistance Programs, entities providing other prescription drug coverage, authorized prescribers, network pharmacies, and pharmacists of the removal of a covered Part D drug from its formulary.

Given that each entity will be creating disclosure notices for mass mailings, we are proposing the following burden estimates. We estimate that on an annual basis it will take each entity approximately 1 hour to produce the standardized notice. We further estimate that on average, it will take 100 Part D plan sponsors and 350 MA organizations 40 hours to disclose the required notice for a total annual burden of 18,450 hours.

(c) A Part D sponsor must issue and reissue, as necessary, a card or other type of technology to its enrollees to use to access negotiated prices for covered Part D drugs.

The burden associated with this requirement is the time and effort necessary for an entity to provide each enrollee a card. The burden associated with this requirement is reflected in section 423.128.

• § 423.128 Dissemination of Part D plan information.

(a) A part D sponsor must disclose information about its Part D plan(s) as required by this section to each enrollee of a Part D plan offered by the Part D sponsor under this part and to Part D eligible individuals.

The burden associated with this requirement is the time and effort necessary for a Part D sponsor to disclose information and materials about its Part D plan(s). We estimate that it will require 100 Part D plan sponsors and 350 MA organizations 80 hours on an annual basis to prepare the plan materials. We further estimate that on an annual basis, on average, it will require each entity 120 hours on an annual basis to disclose the required materials to enrollees and eligible individuals for a total annual burden of 90,000 hours.

(e) A Part D sponsor must furnish directly to enrollees an explanation of benefits when prescription drug benefits are provided under qualified prescription drug coverage that meets the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for 100 Part D plan sponsors and 350 MA organizations to provide an explanation of benefits when prescription drug benefits are provided to enrollees. We estimate that it will require each entity 160 hours on an annual basis disseminate the required materials for total annual burden of 56,000 hours.

• § 423.132 Public disclosure of pharmaceutical prices for equivalent drugs.

(a) Except as provided under paragraph (c) of this section, a Part D sponsor must require a pharmacy that dispenses a covered Part D drug to inform an enrollee of any differential between the price of that drug and the price of the lowest priced generic version of that covered Part D drug that is therapeutically equivalent and bioequivalent and available at that pharmacy, unless the particular covered Part D drug being purchased is the lowest-priced therapeutically equivalent and bioequivalent version of that drug available at that pharmacy.

Subject to paragraph (d) of this section, the information under paragraph (a) of this section must be provided after the drug is dispensed at the point of sale or, in the case of dispensing by mail order, at the time of delivery of the drug.

The burden associated with this requirement is the time and effort necessary for the Part D sponsor to notify the pharmacy of the disclosure requirement referenced in this section and the burden on a pharmacy to provide the necessary disclosure to the enrollee. While these requirements are subject to the PRA, the burden associated with the requirements is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2) and (b)(3). These paragraphs of the PRA regulation state that a usual and customary business activity incurred by persons in the normal course of business, or a requirement sponsored by the Federal government that is also sponsored by a unit of a State or local government does not impose additional burden.

• § 423.136 Privacy, confidentiality, and accuracy of enrollee records

(c) and (d) For any medical records or other health and enrollment information it maintains with respect to enrollees, a Part D plan sponsor must maintain the records and information in an accurate and timely manner and provide timely access by enrollees to the records and information that pertain to them.

While these requirements properly maintain and disclose enrollee records are subject to the PRA, the burden associated with the requirements is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2) and (b)(3).

These paragraphs of the PRA regulation state that a usual and customary business activity incurred by persons in the normal course of business, or a requirement sponsored by the Federal government that is also sponsored by a unit of a State or local

government does not impose additional burden.

Subpart D—Cost Control and Quality Improvement Requirements for Part D Plans

• § 423.153 Drug utilization management, quality assurance, and medication therapy management prgrams (MTMPs).

(b) A Part D sponsor must provide CMS with information concerning the procedures and performance of its drug utilization management program, according to guidelines specified by CMS.

The burden associated with this requirement is the time and effort necessary for the Part D sponsor to provide CMS with information concerning its drug utilization management program, according to guidelines specified by CMS.

We estimate that is will require 100 Part D sponsors, 30 minutes each to provide the required material to CMS for consideration for a total annual burden of 50 hours.

(c) A Part D sponsor must provide CMS with information concerning its quality assurance measures and systems, according to guidelines specified by CMS.

The burden associated with this requirement is the time and effort necessary for the Part D plan sponsor to provide CMS with information concerning its quality assurance measures and systems, according to guidelines specified by CMS.

We estimate that is will require 100 Part D plan sponsors 30 minutes each to provide the required material to CMS for consideration for a total annual burden of 50 hours.

(d) A Part D sponsor must provide drug claims data to CCIPs for those beneficiaries that are enrolled in CCIPs in a manner specified by CMS and a Part D sponsor must provide CMS with information regarding the procedures and performance of its MTM program, according to guidelines specified by CMS.

The burden associated with this requirement is the time and effort necessary for each Part D sponsor to provide drug claims data to CCIPs for those beneficiaries that are enrolled in CCIPs and to provide CMS information regarding the procedures and performance of its MTM program, according to guidelines specified by CMS.

We estimate that is will require 100 Part D sponsors 60 minutes each to provide the required material to CCIPs and 100 Part D plan sponsors and 30 minutes each to provide the required material to CMS for consideration for a total annual burden of 150 hours.

An applicant to become a Part D plan sponsor must describe in its application how it will take into account the resources used and time required to implement the MTM program it chooses to adopt in establishing fees for pharmacists or others providing MTM services for covered Part D drugs under a prescription drug plan and disclose to CMS upon request the amount of the management and dispensing fees and the portion paid for MTM services to pharmacists and others upon request. Reports of these amounts are protected under the provisions of section 1927(b)(3)(D) of the Act.

The burden associated with this requirement is captured under § 423.265.

• § 423.168 Accreditation organizations.

(c) An accreditation organization approved by CMS must provide to CMS in written form and on a monthly basis all of the information required by this part.

Since CMS expects to contract with less then 10 organizations on an annual basis, this requirement is not subject to the PRA.

• § 423.171 Procedures for approval of accreditation as a basis for deeming compliance.

(a) A private, national accreditation organization applying for approval must furnish to CMS all of the information and materials set forth in this part.

Since CMS expects to less then 10 applicants on an annual basis, this requirement is not subject to the PRA.

Subpart F—Submission of Bids and Monthly Beneficiary Premiums; Plan Approval

• § 423.265 Submission of bids and related information.

(a) An applicant may submit a bid that meets the requirements set forth in this section and related sections of this regulation, to become a Part D sponsor.

The burden associated with this requirement is the time and effort necessary for an entity to submit the required materials to CMS. We estimate we will receive 100 Part D sponsor applications on an annual basis and that it will requires each entity 80 hours to submit the required documentation to CMS for total annual burden of 8,000 hours.

Subpart G—Payments to Part D plan sponsors and MA-PD Plans For All Medicare Beneficiaries For Qualified Prescription Drug Coverage

• § 423.329 Determination of payment.

(b) Part D plan sponsors must submit data regarding drug claims to CMS that can be linked at the individual level to Part A and Part B data in a form and manner similar to the process provided under § 422.310 and other information as CMS determines necessary.

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors submit the required claims data to CMS. We estimate that on an annual basis it will take 100 Part D plan sponsors 52 hours to submit the required documentation to CMS for total annual burden of 5,200 hours.

(ii) MA organizations that offer MA-PD plans to submit data regarding drug claims that can be linked at the individual level to other data that the organizations are required to submit to CMS in a form and manner similar to the process provided under § 422.310 and other information as CMS determines necessary.

The burden associated with this requirement is the time and effort necessary for MA organizations submit the required claims data to CMS. We estimate that on an annual basis it will take 350 MA organizations 15 hours to submit the required documentation to CMS for total annual burden of 5,250 hours.

• § 423.336 Risk-sharing arrangements.

(a) A Part D plan sponsor may submit a bid that requests a decrease in the applicable first or second threshold risk percentages or an increase in the percents applied under paragraph (b) of this section.

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors submit the required bid materials to CMS. We estimate that on an annual basis it will take 10 Part D plan sponsors 20 hours to submit the required documentation to CMS for total annual burden of 200 hours.

(c) Within 6 months of the end of a coverage year, the Part D plan plan must provide the information that CMS requires.

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors submit the required cost data to CMS. We estimate that on an annual basis it will take 100 Part D only sponsors and 350 MA organizations 10 hours to submit the required documentation to CMS for total annual burden of 45,000 hours.

• § 423.343 Retroactive adjustments and reconciliations.

(c) Within 6 months of the end of a coverage year, the Part D plan plan must provide the information that CMS requires.

The burden associated with this requirement is the time and effort necessary for Part D only sponsors to submit the required data to CMS. We estimate that on an annual basis it will take 100 Part D Only sponsors and 350 MA organizations 10 hours to submit the required documentation to CMS for total annual burden of 4,500 hours.

(d) Within 6 months of the end of a coverage year, the Part D plan plan must provide the information that CMS requires.

The burden associated with this requirement is the time and effort necessary for Part only sponsors to submit the required cost data to CMS. We estimate that on an annual basis it will take 100 Part D only sponsors and 350 MA organizations 10 hours to submit the required documentation to CMS for total annual burden of 4,500 hours.

Subpart I—Organization Compliance With State Law and Preemption by Federal Law

• § 423.410 Waiver of certain requirements to expand choice.

(e) Under this section a Part D plan sponsor applicant may submit a waiver application to CMS to waive certain State licensure and fiscal solvency requirements in order to contract with CMS.

The burden associated with this requirement is the time and effort necessary for a Part D plan sponsor applicant to submit a waiver application that meets the requirements of this section. We estimate that on an annual basis it will take 15 applicants 10 hours to submit the required waiver documentation to CMS for total annual burden of 150 hours.

Subpart J—Coordination of Part D Plans with Other Prescription Drug Coverage

• § 423.458 Application of Part D rules to Certain Part D Plans on and after January 1, 2006.

(b) Organizations offering or seeking to offer a MA-PD plan may request from CMS in writing waiver or modification of those requirements under this part that are duplicative of, or that are in conflict with provisions otherwise applicable to the plan under Part C.

The burden associated with this requirement is the time and effort necessary for an organization to submit the required waiver information to CMS for consideration. We estimate on average that we will receive 10 waiver applicants, 20 hours to provide the required material to CMS for consideration for a total annual burden of 200 hours.

(c) Any entity seeking to offer, sponsor, or administer an employer-sponsored group prescription drug plan may request, in writing, a waiver or modification of additional requirements under this Part that hinder its design of, the offering of, or the enrollment in, such employer-sponsored group prescription drug plan.

The burden associated with this requirement is the time and effort necessary for an organization to submit the required waiver information to CMS for consideration.

We estimate on average that we will receive 500 waiver applicants, 20 hours to provide the required material to CMS for consideration for a total annual burden of 10,000 hours. However, it should be noted that the number of respondents is an average for over the initial five year period and over time we expect an increase in the number of applicants.

(d) A cost plan (as defined in 42 CFR 417.401) or PACE organization (as defined in 42 CFR 460.6) that offers qualified prescription drug coverage under Part D may request, in writing, a waiver or modification of those requirements under this part otherwise applicable to cost plans or PACE organizations that are duplicative of, or that are in conflict with, provisions otherwise applicable to cost plans under section 1876 of the Act or PACE organizations or under sections 1894 and 1934 of the Act, or as may be necessary in order to improve coordination of this Part with the benefits offered by cost plans or PACE organizations.

The burden associated with this requirement is the time and effort necessary for a cost plan or PACE organization to submit the required waiver information to CMS for consideration. We estimate we will receive 10 waiver applicants, 20 hours to provide the required material to CMS for consideration for a total annual burden of 200 hours.

• § 423.464 Coordination of benefits with other providers of prescription drug coverage

(f) A Part D plan must exclude expenditures for covered Part D drugs made by insurance or otherwise, a group health plan, or other third party payment arrangements, including expenditures by plans offering other prescription drug coverage for purposes of determining whether a Part D plan enrollee has satisfied the out-of-pocket threshold provided under § 423.104(d)(5)(iii). To ensure that this requirement is met, A Part D enrollee must disclose all these expenditures to a Part D plan in accordance with requirements under § 423.32(b)(ii).

The burden associated with this requirement is the time and effort necessary for a Part D enrollee to disclose all these expenditures to a Part D plan in accordance with requirements under § 423.32(b)(ii). The burden associated with this requirement is captures and discussed above under § 423.32(b).

Subpart K—Application Procedures and Contracts With Part D Plan Sponsors

• § 423.502 Application requirements.

(b) In order to become a Part D sponsor, an entity, or an individual authorized to act for the entity (the applicant), must complete, comply with, and submit a certified application in the form and manner required by CMS that meets the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for Part D sponsors and MA organizations to submit the required application materials to CMS. We estimate that on an annual basis it will take 100 Part D sponsors and 350 MA organizations 10 hours to submit the required documentation to CMS for total annual burden of 4,500 hours.

• § 423.505 Contract provisions

(d) The Part D sponsor agrees must maintain for 10 years books, records, documents, and other evidence of accounting procedures and practices that are sufficient to meet the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for Part D sponsors and MA organizations to maintain the required documentation outlined in this section. We estimate that on an annual basis it will take 100 Part D sponsors and 350 MA organizations 52 hours to maintain the required documentation on an annual basis, for total annual burden of 23,400 hours.

(f) The Part D sponsor must submit to CMS certified financial information that must include the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for Part D sponsors and MA organizations to submit the required certified data to CMS. We estimate that on an annual basis it will take 100 Part D plan sponsors and 350 MA organizations 8 hours to submit the required documentation to CMS for total annual burden of 3,600 hours.

• § 423.507 Nonrenewal of Contract.

(a) If a Part D sponsor does not intend to renew its contract, it must notify CMS in writing by the first Monday of June in the year in which the contract ends and notify, in an manner that meets the requirements of this section, each Medicare enrollee, at least 90 days

before the date on which the nonrenewal is effective.

The burden associated with this requirement is the time and effort necessary for a Part D sponsor to submit a notice of nonrenewal to CMS. Since this requirement affects less than 9 entities per year, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

• § 423.508 Modification or termination of contract by mutual consent.

(b) If the contract is terminated by mutual consent, the Part D sponsor must provide notice to its Medicare enrollees and the general public as provided in paragraph (c) of this section.

Based on our experience with the M+C program CMS does not anticipate that more then 9 of these terminations will occur on an annual basis.

• § 423.509 Termination of Contract by CMS.

(b) If CMS notifies the Part D sponsor in writing 90 days before the intended date of their termination the Part D plan sponsor must notify its Medicare enrollees of the termination by mail at least 30 days before the effective date of the termination.

The Part D sponsor must also notify the general public of the termination at least 30 days before the effective date of the termination by publishing a notice in one or more newspapers of general circulation in each community or county located in the Part D sponsor's service area.

Based on our experience with the M+C program CMS does not anticipate that more then 9 of these terminations will occur on an annual basis.

• § 423.510 Termination of contract by the Part D sponsor.

(b) If a Part D sponsor terminates its contract because CMS fails to substantially carry out the terms of the contract the Part D sponsor must give advance notice to CMS, its Medicare enrollees, and the general public in a manner that meets the requirements set forth in the section.

Based on our experience with the M+C program CMS does not anticipate that more then 9 of these terminations will occur on an annual basis.

• § 423.514 Reporting requirements.

(b) Each Part D sponsor must report to CMS or other Federal agencies, on an annual basis the information necessary to meet the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for 100 Part D sponsors to submit the required document that meets all of the requirements referenced in this section to CMS or other Federal agencies. We estimate that on an annual basis it will take 100 Part D plan sponsors 40 hours to submit the required documentation, for total annual burden of 4,000 hours.

(d) For an employees' health benefits plan that includes a Part D sponsor in its offerings, the Part D plan sponsor must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (for the particular Part D plan sponsor) under the Employee Retirement Income Security Act of 1974 (ERISA). The Part D sponsor must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term ''administrator'' is defined in ERISA.

The burden associated with this requirement is the time and effort necessary for 100 Part D plan sponsors to submit the required document that meets all of the requirements referenced in this section. We estimate that on an annual basis it will take 100 Part D plan sponsors 40 hours to submit the required documentation, for total annual burden of 4,000 hours.

(e) Each Part D plan sponsor must notify CMS of any loans or other special financial arrangements it makes with contractors, subcontractors and related entities.

The burden associated with this requirement is the time and effort necessary for 100 Part D plan sponsors to notify CMS of any loans or other special financial arrangements it makes with contractors, subcontractors and related entities. We estimate that on an annual basis it will take 100 Part D plan sponsors 1 hour to notify the required entities, for total annual burden of 100 hours.

(f) Each Part D plan sponsor must make the information reported to CMS under this section available to its enrollees upon reasonable request.

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors to disclose the required materials that meet all of the requirements referenced in this section to the public upon request. We estimate that on an annual basis it will take 100 Part D plan sponsors 20 hours to submit the required documentation, for total annual burden of 2,000 hours.

Subpart L—Effect of Change of Ownership or Leasing of Facilities During Term of Contract

• § 423.551 General provisions

(c) states that a Part D plan sponsor that has a Medicare contract in effect under § 423.502 of this part and is considering or negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change. The Part D plan sponsor must also provide updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

The burden associated with this requirement is the time and effort of the Part D plan sponsor considering or negotiating a change in ownership, to notify CMS and provide the information specified in this section. While this requirement is subject to the PRA, we believe that it would affect less than 10 entities on an annual basis; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.4.

• § 423.552 Novation agreement requirements

(a) Discusses the conditions for CMS approval of a novation agreement. This paragraph requires the Part D plan sponsor to notify CMS at least 60 days before the date of the proposed change of ownership and requires them to provide CMS with updated financial information and a discussion of the financial solvency impact of the change of ownership on the surviving organization.

The burden associated with this requirement is discussed above in § 423.551 of the PRA section.

This paragraph also requires the Part D plan sponsor to submit to CMS, at least 30 days before the proposed change of ownership date, 3 signed copies of the novation agreement containing the provisions specified in this section, and 1 copy of other relevant documents required by CMS.

The burden associated with this requirement is time and effort of the Part D plan sponsor to provide CMS with the required documentation. While this requirement is subject to the PRA, we believe that it would affect less than 10 entities on an annual basis; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

Subpart M—Grievances, Coverage Determinations, and Appeals

• § 423.562 General Provisions

(a) A Part D plan sponsor must ensure that all enrollees receive written information about the grievance, coverage determination, and appeals procedures that are available to them through the Part D plan sponsor and that meet the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for each of the 100 Part D plan sponsors to disclose the necessary information to an enrollee. We estimate that it will require each of the 100 Part D plan sponsors 8 hours on an annual

basis to disclose the information for a total annual burden of 800 hours.

• § 423.564 Grievance procedures.

(e) The Part D plan sponsor must notify the enrollee of its decision as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 days after the date the plan sponsor receives the oral or written grievance.

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors to notify enrollee of its decision as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 days after the date the plan sponsor receives the oral or written grievance. We estimate that on an annual basis it will take 100 Part D plan sponsors 52 hours to meet the notification requirements of this section an annual basis, for total annual burden of 5200 hours.

(g) The Part D plan sponsor must maintain records on all grievances received both orally and in writing, including, at a minimum, the date of receipt, final disposition of the grievance, and the date that the Part D plan sponsor notified the enrollee of the disposition.

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors to maintain the required documentation outlined in this section. We estimate that on an annual basis it will take 100 Part D plan sponsors 52 hours to maintain the required documentation on an annual basis, for total annual burden of 5,200 hours.

• § 423.568 Standard timeframe and notice requirements for coverage determinations.

(a) When a party makes a request for a drug benefit, the Part D plan sponsor must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request, or, for an exceptions request, the physician's supporting statement.

The burden associated with this requirement is the time and effort necessary for each of the 100 Part D plan sponsors to disclose the necessary information to an enrollee whenever a coverage determination is unfavorable. We estimate the universe of such determinations to be 140,000 (approximately 80 percent of which will be ''exceptions requests'' under § 423.578). We estimate that it will take 30 minutes to prepare a notice of unfavorable decision. The total estimated annual burden is 56,000 hours.

(b) When a party makes a request for payment, the Part D plan sponsor must notify the enrollee of its determination no later than 72 hours after receipt of the request.

The burden associated with this requirement is the time and effort necessary for the 100 Part D plan sponsors to disclose the necessary information to an enrollee. We estimate that approximately 10 percent of coverage determinations will involve payment disputes. Thus, the annual associated burden will be 7000 hours.

(c) The burden associated with requirement is discussed above in § 423.568(a).

• § 423.570 Expediting certain coverage determinations.

(c) The Part D plan sponsor must document all oral requests in writing and maintain written and oral request documentation in the case file.

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors to maintain the required documentation outlined in this section. We estimate that on an annual basis 10 percent of all coverage determinations will be expedited requests. Of the 12,600 requests, we estimate that approximately 90 percent will be oral requests. Thus, it will take 100 Part D plan sponsors 57 hours to maintain the required documentation on an annual basis, for total annual burden of 5700 hours.

(d) If a Part D plan sponsor denies a request for expedited determination, it must give the enrollee prompt oral notice of the denial and subsequently deliver, within 3 calendar days, a written letter that explains the notice requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for each of the 100 Part D plan sponsors to disclose the necessary information to an enrollee. We estimate that 1 percent of the expedited requests will be transferred to the standard process. We estimate that it will take each of the 100 Part D plan sponsors 15 minutes to process each of the 126 cases. Thus, it will take Part D plan sponsors 32 hours an annual basis to disclose the information.

• § 423.572 Timeframes and notice requirements for expedited coverage determinations.

(a) Except as provided in paragraph (b) of this section, a Part D plan sponsor that approves a request for expedited determination must make its determination and notify the enrollee (and the prescribing physician involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request, or, for an exceptions request, the physician's supporting statement.

The burden associated with this requirement is the time and effort necessary for each of the 100 Part D plan sponsors to disclose the necessary information to an enrollee and prescribing physician involved in 11,340. We estimate that it will require each of the 100 Part D plan sponsors 30 minutes to disclose adverse coverage determinations. We estimate that approximately 15 percent of the cases (1700) will involve adverse coverage determinations, for a total annual burden of 850 hours. We estimate that it will take 5 minutes for the Part D plan sponsors to disclose favorable decisions for the remaining 9640 cases for a total annual burden of 803 hours.

(b) The burden associated with this requirement is discussed above in § 423.572(a).

• § 423.578 Exceptions process.

(a) An enrollee, the enrollee's representative, or the enrollee's prescribing physician (on behalf of the enrollee) may file a request for an exception that meets the requirements of this section.

The burden associated with this requirement is the time and effort necessary for an individual to submit a request for exception. We estimate it will require an individual 30 minutes to provide the request and that the 100 Part D plans sponsors will receive 112,000 requests on an annual basis. Therefore, we estimate a total annual burden of 56,000 hours.

(b) An enrollee, the enrollee's representative, or the prescribing physician (on behalf of the enrollee) may file an exception request that meets the requirements of this section.

The burden associated with this requirement is the time and effort necessary for an individual to submit a request for exception. We estimate it will require an individual 30 minutes to provide the request and that that the 100 Part D plan sponsors will receive 112,000 requests on an annual basis. Therefore, we estimate a total annual burden of 56,000 hours.

A Part D plan sponsor may require a written supporting statement from the enrollee's prescribing physician that the requested prescription drug is medically necessary to treat the enrollee's disease or medical condition. The Part D plan sponsor may require the prescribing physician to provide additional supporting medical documentation as part of the written follow-up.

The burden associated with this requirement is the time and effort necessary for a prescribing physician to submit the required documentation to the Part D plan sponsor. We estimate it will require a prescribing physician 15 minutes to provide the supporting documentation and that that the 100 Part D plan sponsors will make 5,600 requests on an annual basis. Therefore, we estimate a total annual burden of 1400 hours.

• § 423.582 Request for a standard redetermination.

(a) An enrollee must ask for a redetermination by making a written request with a Part D plan sponsor that made the coverage determination. The Part D plan sponsor may adopt a policy for accepting oral requests.

The burden associated with this requirement is the time and effort necessary for an individual to submit a request for redetermination. We estimate that approximately 15 percent of the 140,000 coverage determinations will be adverse. Of those 21,000 cases, we estimate that approximately 50 percent will be appealed. We further estimate it will require an individual 30 minutes to provide the request and that the 100 Part D plan sponsors will receive 9,450 standard requests on an annual basis. Therefore, we estimate a total annual burden of 4,725 hours.

(c) If the 60-day period in which to file a request for a redetermination has expired, an enrollee may file a request for redetermination and extension of time frame with the Part D plan sponsor.

The burden associated with this requirement is the time and effort necessary for an individual to submit a request for extension of redetermination. We estimate it will require an individual 15 minutes to provide the request and that each of the 100 Part D plan sponsors will receive 100 requests on an annual basis. Therefore, we estimate a total annual burden of 2500 hours.

(d) The person who files a request for redetermination may withdraw it by filing a written request for withdrawal at the location listed in paragraph (a) of this section.

The burden associated with this requirement is the time and effort necessary for an individual to submit a withdrawal request. We estimate it will require an individual 15 minutes to provide the request and that each of the 100 Part D plan sponsors will receive 5 requests on an annual basis. Therefore, we estimate a total annual burden of 125 hours.

• § 423.584 Expediting certain redeterminations.

(c) The Part D plan sponsor must document all oral requests in writing, and maintain the documentation in the case file.

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors to maintain the required documentation outlined in this section. We estimate that on an annual basis, 10 percent of the 10,500 redeterminations will be expedited requests. Of the 1,050 expedited requests, we estimate that approximately 90 percent will be oral requests. Thus, it will take the 100 Part D plan sponsors approximately 5 hours to maintain the required documentation on an annual basis, for total annual burden of 500 hours.

(d) If a Part D plan sponsor denies a request for expedited redetermination, it must give the enrollee prompt oral notice, and subsequently deliver, within 3 calendar days, a written letter that explains the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for each of the 100 Part D plan sponsors to disclose the necessary information to an enrollee. We estimate that 10 percent of the expedited requests will be transferred to the standard process. We further estimate that it take each of the 100 Part D plan sponsors 15 minutes to process each of the 105 cases to disclose the information for a total annual burden of 26 hours.

• § 423.590 Timeframes and responsibility for making redeterminations.

(a) When a party makes a request for a drug benefit, the Part D plan sponsor must notify the enrollee in writing of its redetermination as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for a standard redetermination.

The burden associated with this requirement is the time and effort necessary for each of the 100 Part D plan sponsors to disclose the necessary information to an enrollee. We estimate that it will require each of the 100 Part D plan sponsors 30 minutes to disclose the information for a total annual burden of 4,725 hours.

(b) When a party makes a request for payment, the Part D plan sponsor must issue its redetermination no later than 7 calendar days from the date it receives the request for a standard redetermination. We estimate that 10 percent of the 9,450 standard redetermination requests will involve payment disputes.

The burden associated with this requirement is the time and effort necessary for each of the 100 Part D plan sponsors to disclose the necessary information to an enrollee. We estimate that it will require each of the 100 Part D plan sponsors 30 minutes on an annual basis to disclose the information for a total annual burden of 473 hours.

(d) A Part D plan sponsor that approves a request for expedited redetermination must complete its redetermination and give the enrollee (and the prescribing physician involved, as appropriate), notice of its decision as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request for an expedited redetermination.

The burden associated with this requirement is the time and effort necessary for each of the 100 Part D plan sponsors to disclose the necessary information to 895 enrollees (and the prescribing physicians involved, as appropriate). We estimate that it will require each of the 100 Part D plan sponsors 30 minutes on an annual basis to disclose the information for a total annual burden of 448 hours.

Subpart N—Medicare Contract Determinations and Appeals

This Subpart deals with Contract Determinations and Appeals; therefore, the information collection requirements referenced in this Subpart are exempt from the PRA in accordance with 5 CFR 1320.4(a)(2) during the conduct of an administrative action, investigation, or audit.

Subpart O—Intermediate Sanctions

• § 423.756 Procedures for imposing sanctions.

(a) Before imposing the intermediate sanctions specified in this section, CMS will allow the Part D plan sponsor to provide evidence that it has not committed an act or failed to comply with the requirements as described. In addition, CMS may allow additional time for the Part D plan sponsor to provide the evidence if the Part D plan sponsor sends a written request providing a credible explanation of why additional time is necessary.

These information collection requirements are exempt from the PRA in accordance with 5 CFR 1320.4(a)(2) during the conduct of an administrative action, investigation, or audit.

Subpart P—Premiums and Cost-Sharing Subsidies for Low-Income Individuals

• § 423.774 Eligibility determinations, redeterminations, and applications.

Paragraph (d) of this section discusses the application requirements for individuals applying for low-income subsidy. This paragraph states that individuals applying for low-income

subsidy, or a personal representative applying on the individual's behalf, must complete all required elements of the application, provide any statements from financial institutions, as requested, to support information in the application, and certify, as to the accuracy of the information provided on the application form.

The burden associated with this requirement is the time and effort for the individual or personal representative applying on the individual's behalf, to complete the low-income subsidy application, provide financial statements as requested and to certify that the information provided is accurate. These collection requirements are subject to the PRA; however, the burden associated with these requirements is currently approved under OMBı 0938–0467 with a current expiration date of October 31, 2005. We will revise this currently approved PRA package to incorporate the burden being imposed on new enrollees. We estimate that this requirement will impose a burden on 4.5 million new enrollees for a total additional burden of 750,000 hours annually (4.5M X 10 minutes).

• § 423.800 Administration of subsidy program.

Paragraph (b) of this section requires the Part D plan sponsor offering the Part D plan plan, or the MA organization offering the MA-PD plan, to reduce the individual's premiums and cost-sharing as applicable and provide information to CMS on the amount of such reductions, in a manner determined by CMS. This paragraph also requires the Part D plan sponsor offering the Part D plan to maintain documentation to track the application of the low-income cost-sharing subsidies to be applied to the out-of-pocket threshold.

The burden associated with these requirements is the time and effort for the Part D plan sponsor offering the Part D plan to provide information to CMS and to maintain documentation. We estimate that it will take each of the 450 Part D plan or MA-PD sponsors offering the Part D plans or MA-PD approximately 52 hours on an annual basis to provide the information to CMS. We also estimate that it will take approximately 26 hours for each of the 450 entities to maintain the information for tracking purposes. Therefore, we estimate that it will take approximately 35,100 total hours annually to comply with these requirements.

Subpart Q—Guaranteeing Access to a Choice of Coverage

• § 423.859 Assuring access to a choice of coverage.

(c) states that CMS may waive or modify the requirements of this part if an entity seeking to become a prescription drug plan in an area such, as a territory, other than the 50 States or the District of Columbia requirement Part D in order to provide qualified prescription drug.

The burden associated with this requirement is the time and effort for the Part D plan to make a request of waiver or modification to CMS. We estimate that approximately 2 Part D plan s will request a waiver or modification on an annual basis. Since this requirement affects less than 10, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

• § 423.863 Submission and approval of bids.

(a) discusses the process CMS uses for the solicitation and approval of bids. CMS solicits bids from eligible fallback entities for the offering in all fallback service areas in one or more Part D plan regions of a fallback prescription drug plan. CMS specifies the form and manner in which fallback bids are submitted in separate guidance to bidders.

The burden associated with this requirement is the time and effort for the fallback entities to prepare and submit a bid that meets the requirements of the section and related sections.

We estimate as an upper limit that approximately 20 fallback entities will submit a bid every three years. We also estimate that it will take each fallback entity approximately 80 hours to complete and submit the bid to CMS. Therefore, we estimate it will take a total of (20 * 80) /3 = 533.33 hours on an annual basis to comply with this requirement.

(b) Negotiation and Acceptance of Bids discusses the procedures CMS uses to enter into contracts. CMS solicits bids from eligible fallback entities and uses competitive procedures to enter into contracts.

The burden associated with this requirement is the time and effort for the fallback entities to enter into a contract with CMS that meets the requirements of this section and related sections.

We estimate, again as an upper limit, that approximately 5 fallback entities will enter into a contract with CMS on an annual basis. Since this requirement affects less than 10, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

• § 423.871 Contract terms and conditions.

(f) states that each contract for a fallback prescription drug plan requires an eligible fallback entity offering a fallback prescription drug plan to provide CMS with the information CMS determines is necessary to carry out the requirements of this section.

The burden associated with this requirement is the time required of the fallback prescription drug plan to provide CMS with the information CMS determines necessary. We estimate that approximately 5 fallback prescription drug plans will enter into a contract with CMS. Since this requirement affects less than 10, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

Subpart R—Payments to Sponsors of Retiree Prescription Drug Plans

• § 423.884 Requirements for qualified retiree prescription drug plans.

(a),(b), (c),and (d) In order to qualify for the retiree drug subsidy, the employer or union sponsor shall file an annual application with CMS that meets the requirements of this section and related sections, for each qualified retiree prescription drug plan maintained, including an attestation as to actuarial value.

The burden associated with this requirement is the time and effort necessary for an entity to submit the application to CMS. The requirements of this part state that an application must provide sponsor and plan identification information, together with an actuarially-certified attestation that the actuarial value of the retiree prescription drug coverage in each plan (benefit option) is at least equal to the actuarial value of standard Medicare Part D prescription drug coverage in accordance with actuarial guidelines established by CMS in accordance with generally accepted actuarial principles. If there is a change during the year that materially affects the actuarial value of their drug coverage, sponsors will need to submit an updated attestation. Sponsors will also be required to collect identifying information on their qualifying covered retirees and submit this information with their application, along with a signed sponsor agreement. If we determine that a sponsor of a retiree prescription drug program meets all of the requirements of this section, we will send to the sponsor a written notification regarding the sponsor's eligibility to receive a subsidy payment along with a list of qualified retirees that has been verified with the Medicare Beneficiary Database (MBD).

For each entity we estimate an average of 2 hours administrative work to assemble the application, 31 hours for systems changes to extract identifying information on qualifying covered retirees, about 7 hours for preparation of the actuarial attestations, and about 30 minutes to sign the required sponsor

agreement, for a total of approximately 40.5 hours, for each prescription drug plan (benefit option). The 7–hour estimate for preparation of actuarial attestations represents an average and varies substantially across firm size (see the economic impact section of this proposed regulation for the analysis pertaining to the range of time needed for sponsors of various sizes and numbers of plans).

For the number of entities applying for the subsidy, we have used 50,000, our estimate of the total number of public, private, and union sponsors projected to offer retiree prescription drug coverage in 2005. We have estimated on the basis of this figure in order to calculate the highest potential burden.

The total burden for preparation and filing of the 2005 applications for 50,000 sponsors is 2,025,000 hours. We also estimate that 5 percent of the initial applications may have to be re-filed due to mid-year changes to drug coverage that materially affect actuarial value. We estimate 101,250 hours for this activity.

(e) Each entity must disclose the creditable coverage status for each prescription drug plan to CMS in a form and manner described by CMS. We estimate this activity to take about 1 hour each for a total of approximately 50,000 hours. Additionally, in future years, each entity must notify CMS of any changes in creditable coverage status for an average annual burden of 1 hour.

In addition, each entity must notify each Part D eligible individual of the plan's creditable coverage status in a form and manner prescribed by CMS. The burden associated with the sponsor notices is required by § 423.56 of the proposed regulation, as discussed earlier in this analysis.

For the sponsors of retiree drug coverage, we estimate that it will take 50,000 entities approximately 8 hours each to produce a standardized notice for a total of 400,000 burden hours.

Since each entity can include initial disclosure notices in existing beneficiary plan materials, which are already being disseminated to their participants, we estimate that this will involve a negligible amount of time. Additionally, in subsequent years, on average, we estimate that each entity will provide 13 additional separate notices to individuals upon request for an annual burden of about 1 hour. We also estimate that in subsequent years some of these sponsors of retiree coverage will provide notices of a change in creditable coverage for an average annual burden of 8 hours. We estimate that the annual burden associated with providing notices prior to the ACEP in subsequent years will be negligible, since they will be able to include these notices in their existing plan materials with minimal modifications.

If an individual establishes to CMS that he or she was not adequately informed that he or she no longer had creditable prescription drug coverage or the coverage is involuntarily reduced, the individual may apply to CMS to have the coverage treated as creditable coverage so as to not be subject to the late enrollment fee described in § 423.46. The burden associated with this requirement is the time and effort necessary for an individual to apply to CMS to have such coverage treated as creditable coverage. While we have no way of determining how many individuals will apply to CMS, for the purpose of providing an upper bound estimate for public comment we estimate that on an annual basis it will take 100,000 individuals 15 minutes to apply to CMS, for a total of 25,000 hours.

(f) The employer or union sponsor of the plan must maintain the records outlined in this section for 6 years after the expiration of the plan year in which the costs were incurred.

The burden associated with this requirement is the time and effort necessary for an entity to maintain the required documentation for six years. We estimate that on an annual basis it will take 50,000 entities 20 hours in total to retain the required documentation prescribed in this section and in § 423.888(d), for a total of 1,000,000 burden hours. We believe that for a small firm the total number of hours required for record retention will be less than 20 hours, but for purposes of the PRA we assume 20 hours for firms of all sizes.

- § 423.888 Payment methods, including provision of necessary information.

(b) and (c) To receive payment under this section, each qualified entity must submit information in a form and manner and at such times provided in this paragraph and under other guidance specified by CMS, by the sponsor or any party designated the sponsor.

If a sponsor elects to receive monthly or quarterly retiree subsidy payments or an interim annual retiree subsidy payment, the plan sponsor must submit aggregated gross cost data, an estimate of the difference between these gross costs and allowable costs (based on expected rebates and other price concessions), and any other data CMS may require upon submission of data for payment at each of the time intervals elected by the sponsor, with a final reconciliation within 15 months after the end of the plan year. For final reconciliation purposes, sponsors must submit total gross cost data segregated per qualifying covered retiree; actual rebates, discounts or other price concessions received with respect to such costs; and any other data CMS may require, within 15 months after the end of the plan year. In addition, plan sponsors are required to provide on a monthly basis an update to their enrollment file, (for example, accretes and deletes).

The burden associated with this requirement is the time and effort necessary for an entity to submit the required data and information that meets the requirements of this section. We estimate that on an annual basis it will take 50,000 entities 17 hours to provide the required documentation, for a total of 850,000 burden hours. The 17–hour estimate reflects an average across firms of various sizes and reflects our expectation that the time involved in the data submission process will be lessened by the development of automated systems to calculate this information. (See the regulatory impact analysis for more detailed discussion of these estimates.)

(d) Participating entities must maintain the records outlined in this section for 6 years after the expiration of the plan year in which the costs were incurred and fully meets the requirements of this section.

The burden associated with this requirement is the time and effort necessary for an entity to maintain the required documentation for six years. We estimate that on an annual basis it will take 50,000 entities 20 hours to retain the required documentation prescribed in this section and in § 423.884(e), for a total of 1,000,000 burden hours.

- § 423.890 Appeals

The information collection requirements set forth in this section are exempt from the PRA as stipulated in 5 CFR 1320.4.

- § 423.892 Change in Ownership.

(c) A sponsor who is contemplating or negotiating a change of ownership must notify CMS at least 60 days before the anticipated effective date of the change. We estimate that approximately 5 percent of sponsors will fall into this category in a given year.

The burden associated with this requirement is the time and effort necessary for a sponsoring entity to submit the required notification to CMS. On an annual basis it will take 2,500 entities (5 percent of 50,000) about 30

minutes to submit the required notification to CMS, for a total of approximately 1,250 burden hours.

Subpart S—Special Rules for States-Eligibility Determinations for Low-Income Subsidies and General Payment Provisions.

• § 423.904 Eligibility determinations.

Paragraph (b) of this section states the State agency must inform CMS of cases where eligibility is established or redetermined.

The burden associated with the requirement on State agencies to inform CMS of cases where eligibility is established or redetermined is estimated to total approximately 11,220 annual hours. We estimate that there will be approximately 600,000 of these cases on an annual basis. We also estimate that it will take approximately 10 hours per month for the State agency to inform CMS of these cases.

Paragraph (d) of this section requires States to make available—low-income subsidy application forms, information on the nature of, and eligibility requirements for the subsidies under this section, and offer assistance with the completion of the application forms. States must require an individual or personal representative applying for the low-income subsidy to complete all required elements, provide documents as necessary, and certify as to the accuracy of the information provided. In addition, States must provide CMS with other information as specified by CMS that may be needed to carry out the requirements of the Part D prescription drug benefit.

The burden associated with the requirement on States to make available the information specified in this section is subject to the PRA; however, we believe the burden for this requirement to be a reasonable and customary business practice; therefore, imposes no additional burden on the States.

The burden associated with the requirement on States to require the applicant of the low-income subsidy to complete all required elements, to provide documents, and to certify as to the accuracy of the information is subject to the PRA; however, the burden associated with this requirement is discussed in § 423.774 above.

The burden associated with the requirement on States to provide CMS with other information as specified by CMS is estimated to total approximately 1,020 annual hours. Since it is difficult to determine at this time the volume of information CMS will request, we are estimating that it will take on average 20 hours per State on an annual basis to provide CMS with the specified information.

• § 423.907 Treatment of Territories

Paragraph (a) of this section discusses the requirements on territories to submit plans for approval by the Secretary to receive increased grants. This paragraph states that a territory may submit a plan to the Secretary under which medical assistance is to be provided to low-income individuals for the provision of covered Part D drugs. Paragraph (b) of this section describes what a plan must include.

The burden associated with this requirement is the time and effort of territories to prepare and submit a plan for approval. While this requirement is subject to the PRA, we estimate that this requirement would affect only 5 territories; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

• § 423.910 Requirements.

(c) This subpart sets forth the requirements for State contributions for Part D drug benefits based on dual eligible drug expenditures. It requires States to submit MSIS data to provide accurate and complete coding to identify the numbers and types of Medicaid and Medicare dual eligibles in their MSIS data submittals.

The burden associated with the requirement on States to provide accurate and complete coding in their MSIS data submittals is subject to the PRA; however, this requirement is already approved under OMB ı0938–0502 with a current expiration date of January 31, 2006.

(d) The subpart also requires States to submit an electronic file, in a manner specified by the Secretary, identifying each full benefit dual eligible enrolled in the State for each month with Part D drug coverage who is also determined to be full benefit eligible by the State for full Medicaid benefits.

The burden associated with the requirement on States to submit an electronic file identifying each full benefit dual eligible enrolled in the State for each month with Part D drug coverage is estimated to total approximately 120 hours per State on an annual basis. We estimate that it will take approximately 10 hours for each State to submit an electronic file on a monthly basis. Therefore, we estimate a total burden of 6,120 hours on an annual basis. Startup development effort is estimated at 100 hours per State for a total of 5,100 hours.

Subpart T—Financial Relationships Between Physicians and Entities Furnishing Designated Health Services.

Subpart T does not contain any requirements subject to the PRA.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare and Medicaid Services

Office of Strategic Operations and Regulatory Affairs,

Attn: John Burke (CMS–4068–F)

Room C5–13–28, 7500 Security Boulevard,

Baltimore, MD 21244–1850;

and Office of Information and Regulatory Affairs,

Office of Management and Budget,

Room 10235, New Executive Office Building,

Washington, DC 20503,

Attn: Christopher Martin, CMS Desk Officer (CMS–4068–F),

christopher__martin@omb.eop.gov. Fax (202) 395–6974

V. Regulatory Impact Statement

A. Overall Impact

We have examined the impacts of this rulemaking under Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism, and the Congressional Review Act (5 USC 804(2)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impact and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year). Our estimate is that this rulemaking is ''economically significant'' as measured by the $100 million standard, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a regulatory impact analysis.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amends Title XVIII of the Social Security Act (the Act) to create a voluntary prescription drug benefit within the Medicare program beginning in 2006. The Medicare prescription drug benefit will make prescription drugs more affordable for beneficiaries by offering subsidized Medicare prescription drug coverage to all beneficiaries, with even more generous assistance available to low-income

beneficiaries. We believe that this is an important step in modernizing the Medicare program to better meet beneficiaries' needs. We anticipate that by giving beneficiaries access to affordable insurance coverage that helps them to pay for their outpatient prescription drugs—which have become a critical component in the delivery of comprehensive, quality health care services—the Medicare prescription drug benefit will help beneficiaries to lead healthier, more productive lives, while also helping to improve the effectiveness of the Medicare program.

The MMA also includes provisions to help employers and unions continue to provide drug coverage to their Medicare eligible retirees that is at least as generous as the new Medicare coverage. The MMA authorizes Medicare to make retiree drug subsidy payments to employers and unions that provide qualified retiree prescription drug coverage to beneficiaries who do not enroll in a Part D plan. This retiree drug subsidy provides special tax-favored payments to the sponsors of qualified retiree health plans. The retiree drug subsidy program has highly flexible rules that permit employers and unions to retain their current plan designs that are at least equivalent to the standard Part D benefit while using the drug subsidy to reduce the cost of providing generous coverage.

With the trend toward declining retiree health insurance coverage that has occurred over the past decade, the Medicare retiree drug subsidy is intended to ''help employers [to] retain and enhance their prescription drug coverage so that the current erosion in coverage would plateau or even improve'' (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Conference Report, p. 53).

Medicare Part D also offers employers and unions a variety of other options for continuing to assist their Medicare retirees, and our final regulation reflects comments on how Medicare can best implement all of these approaches to achieve the maximum support for retiree coverage. In addition to having the opportunity to obtain the Medicare retiree drug subsidy, employers and unions can choose to provide additional drug coverage to their Medicare-eligible retirees through or in coordination with Part D by encouraging their Medicare-eligible retirees to enroll in Part D (with Medicare subsidizing the costs of their standard Part D benefits), and providing enhanced or supplemental coverage over and above the standard Part D benefit. This can be achieved by either providing separate supplemental drug coverage that wraps around a Part D plan (similar to policies that wrap around Medicare benefits under Part A and Part B), arranging for a Part D plan (that is, a Part D plan (PDP) or Medicare Advantage Prescription Drug Plan (MA-PD)) to provide enhanced benefits to their retirees, or choosing through waivers to become a Part D plan that offers enhanced benefits to their retirees. In all of these cases, financial support from the new Medicare benefit and retiree drug subsidy can augment contributions by employers and unions to provide a more generous and less costly drug benefit for retirees than is possible through employer/union support alone.

We described this range of employer/union options in our proposed rule and in a subsequent white paper and public meetings, and we received extensive public comments on the key issue of how this combination of employer/union options can be used to achieve maximum support for retiree drug coverage. Based on the public comments and further analysis, we believe that the mechanism for implementing options for strengthening employer and union coverage with Medicare Part D, including the Medicare retiree drug subsidy and the other opportunities it affords employers and unions for providing continued prescription drug assistance to their Medicare retirees, will result in combined aggregate payments by employers/unions and Medicare for drug coverage on behalf of retirees that are significantly greater than they otherwise would have been without the enactment of the MMA. Furthermore, the Medicare prescription drug benefit and retiree drug subsidy represent a particularly important strengthening of health care coverage for future Medicare-eligible retirees, given the erosion in the availability and generosity of employment-based retiree coverage for future Medicare beneficiaries that has already been taking place, as is discussed in further detail subsequently in this impact analysis.

We have updated our impact analysis from what was presented in our August 3, 2004 proposed rule. Our update reflects responses to public comments, changes due to final policy and implementation decisions, improvements to the analysis based on additional information and new research studies (see, for example, our discussion of the financial value of the Part D benefit to beneficiaries), and updated data and actuarial and economic assumptions. A discussion of our updated assumptions and the effects of these various changes is presented subsequently in the impact analysis.

We estimate that in calendar year (CY) 2006 about 39 million Medicare beneficiaries will receive creditable drug coverage either through a Medicare Part D plan (including beneficiaries who receive additional drug coverage or premium assistance from other sources such as a former employer or union), or through an employer/union sponsored retiree plan that is eligible for the Medicare retiree drug subsidy. By CY 2010, with growth in the overall Medicare population, we estimate that about 42 million Medicare beneficiaries will receive such coverage.

The Medicare drug benefit, including the retiree drug subsidy, will lead to an increase in Federal spending on Medicare benefits and a decrease in Federal spending on Medicaid benefits (as dual eligibles' drug coverage is shifted from Medicaid to Medicare). The net effect of these changes on Federal outlays is estimated to be about $49 billion in CY 2006 and about $68 billion in CY 2010, with the total effect estimated to be roughly $293 billion over the period from CY 2006–2010. The vast majority of this Federal spending is on Medicare subsidies that defray the cost of the Medicare drug benefit for beneficiaries, that provide substantial additional cost-sharing and premium assistance to low-income beneficiaries, and that make it more affordable for employers and unions to continue to provide and support high quality retiree drug coverage. We also anticipate that some of the Federal spending will generate savings for States, as responsibility for drug coverage for full-benefit dual eligibles is shifted from Medicaid to Medicare and as State spending on State prescription drug assistance programs is likely to be at least partly displaced by the Medicare drug benefit. We also estimate that more eligible low-income beneficiaries will enroll in Medicaid and other low-income benefits, in addition to the comprehensive Medicare drug benefit, as a result of the additional value of the drug benefit and unprecedented beneficiary outreach activities. Taking together the various State savings and costs related to Medicare Part D, we estimate that the Medicare drug benefit will lead to net State budgetary savings of about $1.0 billion in CY 2006 and $2.2 billion in CY 2010, with total net savings of about $7.9 billion over the period from CY 2006–2010.

As discussed in more detail in section L of the impact analysis, from both an economic and budgetary accounting perspective, Federal spending on the Medicare drug benefit largely represents transfers of Federal budget revenue from taxpayers to Medicare beneficiaries and

retiree plans sponsored by private and public sector employers and unions. Also, from an economic perspective, there is effectively a transfer of Federal budget revenues from taxpayers to State governments, as Medicare pays for some of the costs of drug coverage for full-benefit dual eligibles that had been previously paid for by States and as the Medicare drug benefit displaces some State spending on prescription drug assistance programs. In addition, a portion of the Federal spending on Medicare Part D is for administrative costs incurred by PDPs and MA-PDs to administer the benefit effectively.

B. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. We anticipate that this rule would not impose costs above the $110 million UMRA threshold on State, local, or tribal governments. We have determined that this rule would not impose costs on the private sector exceeding $110 million. We note that the provisions of the Act related to electronic prescribing are dealt with in a separate rule.

1. Private Sector

The provision of this rule related to disclosure notices of creditable coverage represents a mandate on the private sector. As discussed elsewhere in this document, certain private sector entities—Medigap plans and private sector employer or union sponsored health plans that provide drug coverage to Medicare beneficiaries who are retired or who are active workers—are required to provide at certain times disclosure notices on whether the coverage provided equals or exceeds the actuarial value of defined standard Part D coverage. Later in the impact analysis we provide a discussion of the costs expected to be borne in providing such notices. The largest cost for providing these notices is expected to occur in the months preceding the implementation of the drug benefit in January 2006 when the largest volume of notices need to be provided. Following receipt of these notices, beneficiaries will be making choices regarding where they receive their drug coverage.

For private sector employers and unions that provide retiree drug coverage, the implementation of Medicare Part D, including the Medicare retiree drug subsidy program, is expected to produce net savings that far exceed the costs of the disclosure notices. This is true both for employers and unions that choose to obtain the retiree drug subsidy, and for employers and unions that decide to restructure their prescription drug coverage to provide continued assistance by supplementing the Medicare prescription drug benefit and/or paying Medicare Part D premiums.

For those private entities that will not achieve savings—Medigap insurers and employer/union group health plans that offer coverage only to beneficiaries who are active workers, not retirees—as discussed in greater detail later in this analysis, the cost of providing disclosure notices is estimated to be approximately $62 million in 2005 (which translates into an average of roughly $151 per employer/union that offers drug coverage to Medicare beneficiaries who are active workers and about $11,050 per Medigap insurer). Thus, the costs associated with the notice requirements are not expected to reach the $110 million UMRA threshold.

We also note that Section 104 of the MMA, which prohibits the sale of new Medigap policies with drug coverage or the renewal of existing Medigap policies that contain drug coverage for Medicare drug benefit enrollees, is not an unfunded mandate as defined by UMRA. This statutory Medigap prohibition does not result in the ''expenditure'' of funds by the private sector, one part of the statutory test for an unfunded mandate. For a discussion of the effect on Medigap insurers of the MMA prohibition, see section J of the impact analysis.

2. States, Local and Tribal Governments

While States will incur direct costs as a result of this rule, as discussed in greater detail in section H on State impacts, States will achieve net savings under this rulemaking, as now Medicare will be paying for prescription drug costs previously funded under Medicaid, State Pharmacy Assistance Programs (SPAPs), and State sponsored retiree health insurance, or will be providing subsidies for State sponsored qualified retiree prescription drug coverage. There are several sources of the direct costs States will incur. As described below, several of these, taken alone and without consideration of offsetting gains, would reach or exceed the threshold level in UMRA.

In order to defray a portion of the Medicare drug expenditures for full-benefit dual eligibles, States will be responsible for making monthly payments to the Federal government beginning in January 2006. These payments are estimated to be $9.0 billion in CY 2006, reaching $13.0 billion by CY 2010. These payments represent the largest direct cost to States.

States will also incur administrative costs associated with Medicare Part D. The statute gives States, as well as the Social Security Administration, responsibility for eligibility determinations for the Medicare Part D low-income subsidy. States are also responsible for screening and enrolling low-income subsidy applicants in the Medicare Savings Program. While we anticipate that the Social Security Administration will play a substantial role in Part D low-income subsidy eligibility determinations, we anticipate that States will incur some administrative costs related to these activities, including costs associated with refining their data on dual eligibles; developing eligibility determinations systems; training staff; performing eligibility determinations, re-determinations, and appeals; and screening and enrolling for the Medicare Savings program. To the extent allowable under Title XIX, Federal matching payments will be available to assist in paying for these administrative costs. We estimate that the State share of Medicaid administrative costs associated with Medicare Part D will be $39 million in FY 2004, $73 million in FY 2005, and average about $90 million per year over the period 2006 to 2010. We are undertaking collaborations with the Social Security Administration (SSA), the State Health Insurance Assistance Programs (SHIPs), and other groups to assist in outreach and enrollment, and to help minimize administrative burdens for States as much as possible. Furthermore, as discussed in more detail in the State section of the impact analysis, we anticipate that SSA will play a substantial role in the eligibility determinations process for the low-income subsidy, lessening the administrative burden on States.

In addition, States will also have revenue losses associated with the MMA prohibition on States imposing taxes on premiums related to Part D coverage. As a result of the shift of beneficiaries from prescription drug coverage subject to State premium taxes to Part D coverage, we estimate that the loss in premium tax revenue to States will be about $62 million in CY 2006, and $145 million by CY 2010, totaling about $504 million over this period. States will also incur direct costs attributable to required disclosure notices for creditable coverage. Similar to the requirement for private sector

group health plans, State governments that offer retiree health insurance benefits with drug coverage will need to provide disclosure notices to Medicare beneficiaries enrolled in those plans. States will also need to provide disclosure notices to Medicare beneficiaries who receive drug coverage through State Pharmacy Plus programs, and State Pharmacy Assistance Programs. As noted elsewhere in this document, the costs of providing such notices are small and are more than offset by the savings achieved from receiving the Medicare retiree drug subsidy (because States may also qualify for this subsidy) or through the enrollment of beneficiaries in the Part D benefit. As discussed elsewhere in the preamble we will be deeming beneficiaries who are full-benefit duals as eligible for the full low-income subsidy. As part of the notices to these beneficiaries regarding their eligibility for the low-income subsidy we will also inform them of the change to receiving their drug coverage through Medicare and that Medicaid will no longer provide creditable coverage to Medicare beneficiaries. Our notices to beneficiaries will relieve State Medicaid programs of the burden of providing disclosure notices to full-benefit dual eligibles.

As discussed in the State section of the impact analysis, the direct and indirect costs and revenue losses to States are offset by savings States will achieve as a result of the implementation of the Medicare prescription drug benefit and retiree drug subsidy. As noted in that section, the net savings to States increase over time, as the share of drug coverage costs for full-benefit dual eligibles for which States are required to compensate Medicare declines. States do, however, begin incurring administrative costs prior to implementation of Medicare Part D. We estimate that States will incur net administrative costs in FY 2005 of $73 million. These costs do not exceed the UMRA threshold. Furthermore, we estimate that State costs in 2005 will be more than offset by State savings related to Medicare Part D beginning in 2006.

Local governments that offer retiree health insurance benefits that include coverage for prescription drugs also will need to provide disclosure notices to Medicare beneficiaries enrolled in their group health plans related to that coverage. As noted previously, the costs of providing such notices are small, and are more than offset by the savings achieved either from receiving the Medicare retiree drug subsidy (because local governments may also qualify for this subsidy) or through the enrollment of beneficiaries in the Part D benefit.

We have determined that this rule does not mandate any requirements for Tribal governments.

Comment: We received comments from a number of States that asserted that Medicare Part D represents an unfunded mandate on States. Several States asserted that it is an unfunded mandate because the Federal government provides matching payment for State administrative expenses related to Medicare Part D, rather than providing 100 percent reimbursement. A few States asserted that they should not be responsible for auto-enrollment of dual eligibles and asserted that it would represent an unfunded mandate. One State asserted that eligibility determination costs in the initial start-up period would exceed the UMRA threshold.

Response: The statute gives States certain administrative responsibilities related to Medicare Part D enrollment. To the extent allowable under Title XIX, the Federal government will provide Federal matching payments for those activities, which cover at least 50 percent of State costs related to those activities. Within the context of the Unfunded Mandates Reform Act, we are obligated to determine whether this regulation imposes costs on States (as well as local and tribal governments and the private sector) in excess of $110 million in any one year.

As discussed previously, in 2005 prior to implementation of Medicare Part D, we anticipate that States will incur administrative expenses related to Medicare Part D, including refining their data on dual eligibles; developing eligibility determinations systems; training staff; performing eligibility determinations, re-determinations, and appeals; and screening and enrolling for the Medicare Savings program. We estimate that those costs are approximately $73 million in FY 2005, and consequently, do not exceed the UMRA threshold. Furthermore, savings that States achieve in future years once Medicare Part D is implemented will substantially outweigh the administrative costs they incur in 2005. Finally, with respect to the auto-enrollment responsibilities that a few States were concerned would be an unfunded mandate, the final rule indicates that these responsibilities will be handled by CMS.

C. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications. Specifically, an agency must act in strict accordance with the governing law, consult with State officials, and address their concerns.

As discussed previously, the MMA and this rule have implications for States. In addition to the provisions addressed in the UMRA discussion, the statute includes specific provisions prohibiting State regulation of PDP plans, except for licensure and solvency, and permitting the Secretary to waive even State licensure and solvency requirements. The majority of these waivers, however, are temporary and may not exceed 36 months, except in the case of a State that does not have a licensing process for PDP sponsors. As specified in the MMA, we have consulted with the National Association of Insurance Commissioners (NAIC) on establishing the financial solvency and capital adequacy standards that will be used in the waiver process. In addition, because of the national nature of the Medicare Part D benefit, the statute prohibits States from limiting the amount that a PDP sponsor can recover from liable third parties under Medicare Secondary Payer provisions. Also, as discussed in the preamble, the statute preempts State any willing pharmacist laws with respect to a plan's Part D business. Finally, the statute permits Federal grievance procedures to preempt State grievance requirements for PDPs and MA-PDs. As discussed in subpart M of the preamble, we have established Federal grievance procedures that preempt State requirements because we believe that one set of grievance standards protects beneficiaries, promotes consistency among plans, and reduces confusion and burden for enrollees and plans. However, enrollees would still have access to various State remedies in cases in which an issue is unrelated to the plan's status as a PDP or MA-PD. We note that State law has been preempted in an identical way for the Medicare Advantage program, through MMA changes expanding a preemption law that had previously applied to that program. The impact analysis for the final Medicare Advantage rule (CMS 4069–F) contains a discussion of the preemption issue as it applies to these Federal programs.

As discussed earlier in this preamble, especially in subpart I, we received a number of comments on preemption issues. Our responses to these comments are included in subpart I and other relevant preamble sections. Although most of these comments

opposed the broad scope of the MMA's preemption clauses, the Congress intended to provide that scope and it is necessary to the operation of the prescription drug program. Should any issues of interpretation arise in any particular State, we would work with that State to resolve these issues.

In addition, we have also consulted extensively with States regarding the numerous provisions related to the Medicare prescription drug benefit that have implications for States. Among these, our Center for Medicaid and State Operations has regular meetings with State Medicaid Directors and has used these opportunities to provide our State partners with information about the MMA. For example, in March 2004, we held conference calls with State representatives to provide them with an overview of the MMA and information on what to expect during implementation, to discuss the provisions in the statute dealing with State payments to the Federal government under Section 103 of the MMA, and to allow States to raise issues about the implementation process. In April and May 2004, we held conference calls with State representatives to discuss the calculation of State phased-down contribution, definition of ''full-benefit dual eligibles'', excluded drugs, enhanced FMAP on family planning drugs, and related State payment issues. We have also organized a group of interested States to work collaboratively on proposals for addressing the managed care adjustment component of the phase-down calculation. We have set up special email addresses for phase-down issues so that States may send questions and communicate specific concerns to the appropriate experts.

We are currently working with State Medicaid Directors, State Pharmaceutical Assistance Program staff, and State Health Insurance Assistance Program (SHIP) counseling staff to raise awareness of the Medicare prescription drug discount card program, and we are building on those efforts for the implementation of the Medicare Part D prescription drug benefit. In August of 2004, we convened the State Issues Workgroup, which includes State Medicaid Directors (including members of the Executive Council of the National Association of State Medicaid Directors), SSA, and CMS. The purpose of this group is to identify all significant issues and concerns related to Medicare Part D (and other MMA changes) that affect States and to identify potential solutions, including providing recommendations for data exchanges and systems processes and developing a protocol for working with SSA on training and outreach associated with the low-income subsidy. Numerous meetings and conference calls of the full workgroup and its five subgroups have already taken place. The efforts of this workgroup are continuing and have been extremely valuable in identifying State issues and concerns and potential solutions. We have also been working with the State Pharmaceutical Assistance Transition Commission, which was established by the statute, to provide support and technical assistance as it develops recommendations for addressing the unique transitional issues facing SPAPs. In addition, we have consulted with the NAIC on Medigap issues.

The Medicare retiree drug subsidy is an optional program that public or private sector employers or unions may choose to participate in if they offer qualified retiree prescription drug coverage. Like other plan sponsors, State and local governments that offer qualified retiree prescription drug coverage and wish to receive Medicare retiree drug subsidy payments will need to comply with the reporting requirements of this rule, such as attestation of actuarial equivalence and certain data reporting necessary for calculating the retiree drug subsidy payments. However, these are not requirements because no public or private employer or union need apply for Medicare retiree drug subsidy payments. Thus, we have determined that the retiree drug subsidy provisions of this rule would not impose direct costs on State and local governments. In addition, we have been conducting outreach to prospective applicants for Medicare retiree drug subsidy payments, including public sector employers, for example through open door forums and an educational web cast, in an effort to better understand the needs of this segment of the employer community, share information about the Medicare retiree drug subsidy program and its implementation. We have also had discussions with representatives of individual State retiree benefit systems, as well as the National Conference on Public Employee Retirement Systems, to hear their concerns about the retiree subsidy program.

D. Limitations of the Analysis

The following analyses present projected effects of this rule on Medicare beneficiaries, the Federal budget, States, private sector organizations that provide drug coverage to Medicare beneficiaries, and small entities. Unless otherwise noted, all estimates in this impact analysis are net budgetary spending based on calendar year data.

We have updated our impact estimates from what was presented in our August 3, 2004 proposed rule. Since publication of the proposed rule, we have continued to refine our assumptions and estimates of Medicare Part D impacts to take into account policy decisions made in the final rule and to incorporate more up-to-date data, additional research, information from industry experts, and public comments on the expected impact of Medicare Part D. The estimates presented in this rule are a result of those efforts and represent our best estimate of the likely effects of Medicare Part D. Discussion of the public comments and the updates made to our estimates is included in the relevant sections of the impact analysis.

While we believe the estimates in this final rule represent our best estimate of the likely impact of Medicare Part D, we emphasize that there is considerable uncertainty in these estimates and the discussion throughout the impact analysis reflects this. Because 2006 will be the first year of the Medicare prescription drug benefit and retiree drug subsidy program, we do not have program experience from prior years. In estimating the impact of a completely new program, there are limited data and considerably greater uncertainty than would be the case with modifications to existing programs. Furthermore, we note that analyses in the 2004 Medicare Trustees Report (currently available) and in future annual Trustees Reports, including the 2005 Medicare Trustees Report (forthcoming in spring 2005), can provide a sense of the range of uncertainty inherent in these types of estimates. (The Trustees Report is available on the CMS website at *http://www.cms.hhs.gov/publications/trusteesreport/*).

E. Enrollment Estimates

1. Summary

Table IV–1A shows for CY 2006–2010 our estimates of the number of beneficiaries projected to receive creditable drug coverage through a Medicare Part D plan (that is, by enrolling in a PDP or MA-PD), or through an employer/union sponsored retiree plan that is eligible for the Medicare retiree drug subsidy. We estimate that in CY 2006 about 39 million Medicare beneficiaries will receive drug coverage either through a Medicare Part D plan or through an employer/union sponsored retiree plan that is eligible for the Medicare retiree drug subsidy. By CY 2010, due to growth in the overall Medicare

population, we estimate that about 42 million Medicare beneficiaries will be receiving such coverage.

Tables IV–1B and 1C provide further details on these estimates. Table IV–1B shows for CY 2006–2010 our estimates of the number of beneficiaries projected to receive drug coverage through a Medicare Part D PDP or MA-PD, and the number of individuals receiving the low-income subsidy. In 2006, we estimate that about 29 million beneficiaries will receive their drug coverage through a Part D plan. We estimate that this number will grow to about 35 million in 2010.

As mentioned previously, Medicare Part D offers additional assistance with Medicare drug benefit cost-sharing and premiums to low-income beneficiaries who meet certain income and assets requirements. We estimate that about 10.9 million beneficiaries will enroll in the Medicare Part D low-income subsidy program in CY 2006. Among low-income subsidy participants, we estimate that in 2006 about 6.3 million would be full-benefit dual eligibles, about 3.0 million would be other beneficiaries with income less than 135 percent of FPL and meeting the lower assets test (including newly enrolled beneficiaries in the Medicare Savings Program), and 1.6 million would be other beneficiaries with income less than 150 percent of FPL and meeting the higher assets test. By 2010, we estimate that 11.8 million beneficiaries will be receiving the low-income subsidy.

Table IV–1C presents estimates related to employment based retiree drug coverage. The table includes an estimate of the number of Medicare beneficiaries who would have employment-based retiree drug coverage absent the law change, including those with access-only coverage where the beneficiary pays the entire premium. For the population with retiree coverage, the table presents estimates of their anticipated sources of drug coverage following implementation of Medicare Part D. Our estimates of drug coverage for these beneficiaries reflect the various options that are available to employers and unions through the Medicare prescription drug benefit and the Medicare retiree drug subsidy for continuing to provide prescription drug assistance to their retirees.

In 2006, we estimate that 11.4 million beneficiaries would have had retiree drug coverage absent the law change.[5] We estimate that 9.8 million of these Medicare beneficiaries will receive creditable drug coverage through an employer/union sponsored retiree plan that is eligible for the Medicare retiree drug subsidy, and that 0.4 million will receive drug coverage through a PDP or MA-PD plan, with their previous employers/unions offering enhanced benefits or providing wraparound or coordinated coverage. We also estimate that 1.3 million beneficiaries will enroll in the standard Part D drug benefit through a PDP or MA-PD, including those who receive additional employer/union premium assistance or other financial assistance and those who will benefit from the more generously subsidized coverage of Medicare Part D (for example, those who would otherwise have had unsubsidized ''access-only'' employer plans that are becoming increasingly common). We note that recent employer surveys suggest significant interest in providing comprehensive drug benefits through additional supplemental or wraparound coverage. Depending upon the amount of time it may take employers/unions to adopt such approaches, it is possible that the provision of wraparound coverage might be more prevalent in the earlier years of Medicare Part D.

In 2010, we estimate that 11.8 million beneficiaries would have had retiree drug coverage absent the law change. By 2010, we estimate that 7.2 million beneficiaries will be receiving creditable drug coverage through an employer/union sponsored plan that is eligible for the Medicare retiree drug subsidy, and 2.4 million will have drug coverage through a PDP or MA-PD plan while also receiving enhanced benefits or wraparound coverage through their former employers or unions, including Part D plans that employers or unions are sponsoring under waivers. We note, however, that there is a great deal of uncertainty in estimating employers' and unions' responses to the various options available under Medicare Part D and the retiree subsidy. As discussed in greater detail subsequently, these estimates do reflect our expectation that, over time, some employers and unions will choose to take advantage of the other opportunities for continuing to provide high quality retiree drug coverage that are available to them under Medicare Part D—by transitioning from providing drug coverage that qualifies for the retiree subsidy to providing their own enhanced Part D plan (through waivers), purchasing enhanced Part D coverage, or providing supplemental drug coverage that wraps around Medicare Part D.

Given the trends in decreasing generosity of employment-based retiree coverage and the increasing provision of ''access-only'' coverage, we also estimate that by 2010 approximately 2.3 million beneficiaries will receive drug coverage through standard Medicare Part D plans, including those receiving additional premium assistance or other financial assistance from their former employers or unions, and those who may benefit from the more generously subsidized coverage of Medicare Part D. For example, recent employer surveys have shown that more new retirees are paying a larger share of the cost of their retirement benefits, with new retirees in about 20 percent of large private-sector firms (1,000 or more employees) having ''access-only'' benefits in which they receive no employer premium subsidy. Assuming this trend continues, increasingly more of the retirees with employer/union coverage would be paying for much or all of the cost of their retiree drug coverage in the absence of the law change. With the availability of Medicare Part D drug coverage these beneficiaries will gain access to a generous subsidized benefit.

These enrollment estimates above have been updated from those that were presented in the August 3, 2004 proposed rule. A discussion of how these estimates have been updated to incorporate policy decisions made in the final rule and to take into account additional information and data is included in the following section on projection assumptions.

[5] This figure includes Federal retirees.

TABLE IV–1A. TOTAL BENEFICIARIES ESTIMATED TO RECEIVE CREDITABLE DRUG COVERAGE, EITHER THROUGH MEDICARE PART D PLANS (PDPS OR MA-PDS), OR THROUGH EMPLOYER/UNION SPONSORED RETIREE PLANS THAT ARE ELIGIBLE FOR THE MEDICARE RETIREE DRUG SUBSIDY, CY 2006–2010

	2006	2007	2008	2009	2010
Total Beneficiaries Receiving Creditable Drug Coverage Through a Medicare Part D Plan or Through an Employer/Union Sponsored Retiree Plan That Is Eligible For the Medicare Retiree Drug Subsidy	39.1	39.8	40.5	41.4	42.2

TABLE IV–1B. BENEFICIARIES ESTIMATED TO RECEIVE PRESCRIPTION DRUG COVERAGE THROUGH MEDICARE PART D PLANS (PDPS OR MA-PDS), CY 2006–2010

	2006	2007	2008	2009	2010
Total Beneficiaries Enrolling in Medicare Part D Plans (including those receiving additional assistance from employers/unions, see Table IV–1C)	29.3	30.6	32.0	33.5	35.1
Subtotal Medicare Part D Enrollees Receiving Low-Income Subsidy	10.9	11.1	11.3	11.6	11.8
—Full-Benefit Dual Eligibles	6.3	6.4	6.6	6.7	6.8
—Other beneficiaries with income less than 135% FPL and meeting the lower assets test*,**	3.0	3.1	3.2	3.2	3.3
—Other beneficiaries with income less than 150% FPL and meeting the higher assets test*	1.6	1.6	1.6	1.7	1.7
Subtotal Medicare Part D Enrollees Not Receiving Low-Income Subsidy	18.4	19.5	20.7	21.9	23.2

* In CY 2006, an individual beneficiary must have assets not in excess of $6,000 ($9,000 per couple) for the lower assets test and $10,000 per individual ($20,000 per couple) for the higher assets test. In years after 2006, these dollar amounts will be indexed to the Consumer Price Index.

** This group includes beneficiaries deemed eligible for the full low-income subsidy based on their status as QMB, SLMB, or QI individuals, or as recipients of SSI benefits, including those beneficiaries who we estimate will newly enroll in the Medicare Savings Program. In 2006, this is estimated to be approximately 2 million individuals.

Note: Numbers may not sum to total due to rounding.

TABLE IV–1C. ESTIMATES RELATED TO EMPLOYER/UNION SPONSORED RETIREE DRUG COVERAGE, CY 2006–2010[1]

Estimated beneficiary counts (in millions)	2006	2007	2008	2009	2010
Total beneficiaries with employment-based retiree drug coverage absent the law change*	11.4	11.5	11.6	11.7	11.8
Beneficiaries receiving creditable drug coverage through an employer/union sponsored retiree plan that is eligible for the Medicare retiree drug subsidy	9.8	9.1	8.5	7.8	7.2
Beneficiaries enrolling in Medicare Part D through PDP or MA-PD plans and receiving enhanced benefits or wraparound coverage through their former employer or union	0.4	0.9	1.4	1.9	2.4
Beneficiaries enrolling in the standard Medicare Part D benefit through PDP or MA-PD plans (including, for example, those receiving additional premium or other financial assistance from their former employer or union, and those previously enrolled in ''access only'' retiree plans)	1.3	1.5	1.8	2.0	2.3

Note: Numbers may not sum to total due to rounding.

* Includes Federal retirees.

2. Projection assumptions

We project that there will be nearly 43 million beneficiaries entitled to or enrolled in Medicare Part A or enrolled in Medicare Part B in 2006 who will be eligible for Medicare Part D. We estimate that about 91 percent of these beneficiaries, about 39 million, will receive creditable drug coverage either through a Medicare Part D plan (that is, a PDP or MA-PD) or through an employer or union-sponsored retiree plan that is eligible for the Medicare retiree drug subsidy.

First, we assume that Medicare beneficiaries who are active workers (or spouses and dependents of active workers) and who have employment-based insurance as their primary payer with Medicare as a secondary payer (MSP), will not participate in Medicare Part D at this time. Since these beneficiaries receive coverage that is related to active worker employment, and they are not retirees (or spouses/dependents of retirees), their plan sponsors would not be able to claim the Medicare retiree drug subsidy on their behalf. In addition, we believe that it is unlikely that these beneficiaries will enroll in the Medicare drug benefit at this time. These beneficiaries are likely to have creditable drug coverage and that coverage would be the primary payer (if their employer is subject to MSP requirements by virtue of having 20 or more employees, or 100 or more employees in the case of disabled

workers) regardless of enrollment in the Medicare drug benefit. In the future, when these beneficiaries retire, they will have an opportunity to enroll in Medicare Part D without being subject to a late enrollment penalty as long as they had creditable drug coverage through their previous primary group health plan.

Second, we assume that all full-benefit dual eligibles and other beneficiaries who are deemed to be full subsidy eligibles (that is, QMBs, SLMBs, QIs, and beneficiaries with Supplemental Security Income (SSI)) will enroll in the Medicare drug benefit. As discussed in the preamble for subpart B, there will be automatic processes put in place to ensure that full-benefit dual eligibles will be automatically enrolled in a Medicare Part D plan. In addition, we will establish a facilitated enrollment process for non-full-benefit dual eligible individuals who are deemed or determined eligible for the low-income subsidy.

Third, among all other Part D eligible beneficiaries, except those beneficiaries estimated to have retiree drug coverage absent the law change who are discussed later, we assume 95 percent uptake among these beneficiaries, with the exception of beneficiaries who have very low drug spending (that is, beneficiaries with spending in the lowest quintile) for whom we assume about 71 percent uptake. We anticipate somewhat lower uptake among beneficiaries with very low drug spending because some may decide to forgo enrollment in Part D, since there is the possibility that they may pay more in premiums than they realize in savings in a particular year. However, we assume that the majority of beneficiaries with very low drug spending will choose to enroll in Medicare Part D to gain protection against higher drug costs, including catastrophic costs, that they could experience in the future. In addition, given the presence of the late enrollment penalty, we expect that many beneficiaries with low drug spending will enroll in Medicare Part D at the outset of the program, recognizing that they will very likely achieve savings in subsequent years as they age and have increasing drug costs.

Our uptake assumptions for this group of beneficiaries are slightly lower than those used in the proposed rule. In the proposed rule, we assumed that 99 percent of these beneficiaries would enroll in Medicare Part D. While we have lowered our uptake assumptions slightly based on additional research and technical discussions, as well as input from public comments, we continue to believe that there will be very high uptake of Medicare Part D for a number of reasons. This expectation is based in part on the experience of high participation rates in Medicare Part B, but on other factors as well. The standard Medicare Part D benefit shares several similar features with Medicare Part B that encourage enrollment. Both are subsidized benefits, where the beneficiary premium is set at roughly 25 percent of the cost of the insurance, with the government providing a subsidy to cover the remaining 75 percent. In addition, under both Part B and Part D, beneficiaries face a late enrollment penalty or surcharge (in the form of higher premiums) unless they enroll within the initial enrollment period, have met creditable coverage requirements in the case of Medicare Part D, or have met certain other requirements that occur in a limited number of circumstances. We think that beneficiaries' concern about current prescription drug costs and the likelihood that an elderly or disabled individual will have even greater need for prescription drugs as they age, in combination with the late enrollment penalty, will promote high initial enrollment in the Medicare drug benefit.

Other features of the Medicare drug benefit are also likely to encourage high enrollment. In addition to the Federal subsidy of the beneficiary premium (which is a part of the standard benefit), a subset of beneficiaries, specifically those who meet certain income and assets requirements, are eligible for additional low-income subsidies. We along with the Social Security Administration will be conducting aggressive outreach efforts to individuals eligible for the low-income subsidy. In addition, we expect that States will also be doing outreach particularly related to the lower income population. For example, many States have been working with us to facilitate enrollment of beneficiaries participating in State Pharmaceutical Assistance Programs into the Medicare drug discount card program (including auto-enrollment arrangements for some States). In addition, as discussed elsewhere in the preamble, the MMA also provides for transitional grants to States with Pharmaceutical Assistance Programs in each of fiscal years 2005 and 2006 to among other things help facilitate enrollment in Part D. Also as discussed elsewhere in the preamble, to facilitate the enrollment process for low-income beneficiaries our final regulation includes auto-enrollment for the full-benefit dual eligibles and we will also implement steps to facilitate enrollment for other individuals who are determined or deemed eligible for the low-income subsidy. In addition, any beneficiary currently enrolled in an MA plan that offers any prescription drug coverage (as of December 31, 2005) would be deemed to be enrolled in an MA-PD plan offered by that same organization as of January 1, 2006.

Also, in the months preceding the implementation of the Part D benefit, beneficiaries who have drug coverage (other than full-benefit duals, who will be deemed) should receive disclosure notice information from the entities from which they receive that coverage regarding enrollment in the Medicare prescription drug benefit and the applicability of the late enrollment penalty. These notices from other sources are in addition to the extensive outreach efforts that CMS and SSA will conduct.

Fourth, for those beneficiaries who we anticipate would have employer or union sponsored retiree drug coverage (including unsubsidized coverage) absent the law change, we made assumptions about their anticipated sources of drug coverage following implementation of Medicare Part D. We begin by making assumptions about the percent of beneficiaries (excluding those with MSP) that would have employer or union sponsored retiree drug coverage absent the law change. In 2006, we assume that 28 percent of beneficiaries—11.4 million—would have retiree drug coverage from a former employer or union absent the law change. By 2010, we assume that about 27 percent of beneficiaries—11.8 million—would have employer or union sponsored drug coverage absent the law change. Since the availability and generosity of retiree drug coverage has been declining over the last decade, we assume that absent the law change there would be a continuation of this baseline trend. However, the number of beneficiaries that we estimate would receive employer or union sponsored retiree drug coverage absent the law change actually increases due to growth in the Medicare population.

We next make assumptions about sources of future drug coverage for these beneficiaries after the implementation of the Medicare prescription drug benefit and the retiree drug subsidy. In making these assumptions, we took into account that Medicare Part D offers employers and unions a variety of options for continuing to provide high quality retiree drug coverage at a lower cost for both retirees and employers and unions. Employers and unions that offer retiree drug coverage that is at least actuarially

equivalent to Medicare Part D can apply for the tax-free 28 percent Medicare retiree drug subsidy (which is equal to 28 percent of allowable prescription drug costs attributable to the portion of gross prescription drug costs between $250 and $5,000 in 2006). The Medicare retiree drug subsidy lowers the cost of providing drug benefits for employers and unions that sponsor qualified retiree plans, making it more affordable for employers and unions to provide this comprehensive subsidized coverage than it would otherwise be.

In addition to the retiree drug subsidy, Medicare Part D also offers employers and unions other opportunities to continue to provide comprehensive prescription drug coverage at a lower cost. Employers and unions can choose to provide supplemental drug coverage to their Medicare-eligible retirees through or in coordination with Part D by encouraging their retirees to enroll in Part D (with Medicare subsidizing the costs of their standard Part D benefits), and paying for supplemental coverage over and above the standard Part D benefit. This can be achieved by either: 1) arranging for a PDP or MA-PD Part D plan to provide enhanced benefits to their retirees; 2) arranging for a PDP or an MA-PD under a waiver to offer a customized plan that is exclusive to the employer's retirees; 3) choosing through a waiver to become a Part D plan for their retirees that offers enhanced benefits (this is equivalent to offering a self-insured benefit); or 4) providing separate supplemental drug coverage that wraps around a Part D plan. The various options available for providing supplemental drug coverage make it possible for employers/unions to provide coverage that mimics their current benefits package, while achieving cost savings due to the Federal government subsidizing a significant portion of the cost of standard Part D coverage (a subsidy which, not taking into account the value of the reinsurance,[6] is estimated to average about $900 per beneficiary). In other words, employers/unions can offer comprehensive drug coverage by wrapping around standard Medicare Part D coverage for, on average, at least $900 less than it would cost the employer/union to do so absent the new law. This supplementation by employers/unions also results in lower Medicare costs. The supplemental employer coverage results in lower out-pocket-costs for beneficiaries, and thus fewer individuals reaching the catastrophic out-of-pocket threshold, and those that do, having lower catastrophic costs for which the government would provide reinsurance payments to Part D plans.

As discussed in more detail later in this impact analysis, employers' and unions' evaluations of the relative advantages and disadvantages of choosing among the options that are available under the MMA for assisting their retirees with prescription drug coverage (for example, taking the Medicare retiree drug subsidy versus offering enhanced prescription drug benefits through a Part D plan) will be influenced by a number of factors. For example, these include current benefit design, employer/union and retiree contributions and other financial considerations, tax status, labor relations, and contractual agreements. Regardless of whether employers and unions seek to obtain the Medicare retiree drug subsidy or provide drug coverage to their retirees by encouraging them to participate directly in the Medicare prescription drug benefit while providing enhanced benefits or wraparound coverage, Medicare Part D is estimated to significantly lower their cost of providing retiree drug coverage. Thus, the Medicare prescription drug benefit and retiree drug subsidy make the provision of employer/union sponsored retiree benefits much more affordable. The amount of financial support available under each option will vary depending in part on the characteristics of each sponsor and their retiree population. As discussed in more detail subsequently in section F.4 of the impact analysis, we estimate that retiree drug subsidy payments will average about $668 per retiree in 2006. While the tax-free nature of the retiree drug subsidy does not alter the value of the subsidy to firms without taxable income, for plan sponsors with tax liabilities, the tax-free nature of the retiree subsidy increases its value. For example, a tax free subsidy of $668 would be equivalent to a taxable payment of $891 for an employer with a 25 percent marginal tax rate and $1,028 for an employer with a 35 percent marginal tax rate. In comparison, if an employer or union chooses to provide supplemental drug coverage to standard Part D, the indirect subsidy to the employer or union excluding the value of reinsurance is estimated to average about $900 per retiree in 2006. Thus, for plan sponsors that do not have taxable income, the indirect Federal support associated with providing supplemental drug coverage to standard Medicare Part D could be larger than the support they would receive through the Medicare retiree drug subsidy. For plan sponsors that have taxable income, the level of support under the two options may be more comparable, and, depending on a plan sponsor's marginal tax rate and retiree population, could possibly be larger under the Medicare retiree drug subsidy.

In making our assumptions about employer and union sponsored retiree drug coverage, we also took into account that some sponsors currently do not provide drug coverage that has the same or greater actuarial value as Medicare Part D, and many employers provide coverage that (in contrast to Part D) is not subsidized at all. For example, in the Kaiser/Hewitt 2004 survey of large firms with at least 1,000 employees offering retiree health benefits, 5 percent of these firms reported that they believed the actuarial value of their current retiree drug benefit was less than the value of the standard Medicare Part D drug benefit, 4 percent reported that they believed their benefits were equal to Medicare Part D, and 22 percent reported that they did not know how their benefit compared to the standard Part D benefit, while 69 percent reported that they believed their benefits were greater than the standard Part D drug benefit. However, it is important to note that employers responding to the survey could not have been aware of our final approach for comparing the actuarial value of retiree drug coverage with the value of the standard Part D benefit, since the survey was conducted in 2004 before publication of this final rule (''Current Trends and Future Outlook For Retiree Health Benefits: Findings from the Kaiser/Hewitt 2004 Survey on Retiree Health Benefits,'' The Henry J. Kaiser Family Foundation and Hewitt Associates, December 2004, available at *http://www.kff.org*). Furthermore, many employers with coverage that has a high actuarial gross value do not make contributions equal to the Medicare contributions to Part D coverage, so that the employer-based retiree coverage would potentially cost more to the retiree than Part D. For example, the survey found that 19 percent of large firms require new Medicare-age retirees to pay 100 percent of the premium for retiree health insurance and another 11

[6] The relative value of the reinsurance subsidy for catastrophic coverage would be lower for retirees whose employers/unions provide supplemental drug coverage that wraps around the standard Part D benefit. Catastrophic coverage is only available when an individual's true out-of-pocket (TrOOP) expenses exceed a specified threshold, and employers/unions' contributions for supplemental drug coverage would not count toward the TrOOP threshold (thus increasing the total drug spending level at which the retiree would receive catastrophic Part D benefits).

percent require these retirees to pay 61–99 percent—a level of contribution that may not satisfy the ''no windfall'' net test for the retiree subsidy, and thus may be less than the new government subsidy on the Part D benefit. In certain cases, where employers are currently making no premium contribution or a very limited premium contribution for retiree drug coverage, beneficiaries are likely to be better off financially if they enroll in Medicare Part D, since it includes a 75 percent government subsidy of the cost of the insurance coverage. To the extent that beneficiaries without substantial employer/union subsidies enroll in Medicare Part D and to the extent that employers/unions provide additional premium or other financial assistance, the significant financial gain that such retirees would receive by enrolling in the subsidized Medicare Part D benefit would be further increased. Thus, the significant increase in total support (from employers/unions and Medicare) for retiree coverage as a result of the MMA's retiree options in part reflects the fact that many retirees who enroll in Part D plans are likely to obtain significant savings in their drug costs, particularly in future years.

In developing specific numeric assumptions about how employers and unions are likely to respond to the various options Medicare Part D offers for providing prescription drug assistance to retirees, we considered information from a number of experts in the employee benefits consulting industry, as well as recent surveys and studies that have been conducted. Among the 11.4 million beneficiaries we estimate would have retiree drug coverage in 2006 absent the law change, we assume that 86 percent would receive creditable drug coverage from an employer or union plan that is eligible for the Medicare retiree drug subsidy, 3 percent would enroll in a Medicare Part D plan and receive employer or union sponsored enhanced or supplemental drug coverage, and 11 percent would enroll in a standard Part D plan (including those who receive additional premium or other financial assistance from their former employer or union). We note that these assumptions reflect the percentage of beneficiaries whom we estimate will receive drug coverage through the various sources. The percentage of firms choosing the various options will likely be different from the above percentages, as the distribution of beneficiaries across firms that offer retiree drug coverage tends to be concentrated among the largest firms.

Over time, we assume that some employers and unions will transition from providing retiree drug coverage for which they receive the Medicare retiree drug subsidy to providing their own enhanced Part D plan (through waivers), or purchasing enhanced Part D coverage, or offering supplemental drug coverage that wraps around Medicare Part D. Recent surveys suggest significant interest among employers in providing enhanced or supplemental drug coverage that wraps around standard Part D. Employers and unions commonly provide wraparound coverage for Medicare Part A and Part B, either through separate supplemental policies or through arrangements with Medicare Advantage plans, and we anticipate that some employers/unions may prefer using a similar approach with Medicare Part D. In addition, as discussed previously, for some plan sponsors, the indirect subsidy plan sponsors receive by providing enhanced coverage or supplemental drug coverage that wraps around Medicare Part D may be greater in value than the Medicare retiree drug subsidy. While we expect that some employers and unions may want to provide enhanced or supplemental benefits, we anticipate that it may take some time for employers/unions who are interested in doing so to restructure their drug benefits to complement Medicare Part D, and thus these employers and unions may initially elect to obtain the retiree drug subsidy. As discussed in more detail previously, employers and unions that wish to restructure their drug coverage to supplement Medicare Part D have a number of options to consider for providing enhanced or supplemental drug coverage, including the option for an employer or union to obtain a waiver to provide its own enhanced Part D plan. It may take some time for these employers/unions to choose which supplemental coverage option they wish to pursue and make the requisite changes. Consequently, we assume that over time an increasing number of employers/unions would transition from receiving the Medicare retiree drug subsidy to providing their own enhanced Part D plan, purchasing enhanced Part D coverage, or providing separate supplemental drug coverage that wraps around Medicare Part D. Depending upon the amount of time it may take employers/unions to adopt such approaches, it is possible that the provision of wraparound coverage may also be more prevalent in the earlier years of Medicare Part D.

In addition, because some employers have placed caps on their contribution to retiree health benefits, we expect that the number of retiree plans that qualify for the Medicare retiree drug subsidy will decline somewhat over time. Once these plans hit the existing caps that employers have placed on their contributions, the net value of the plans' benefits relative to total drug costs will decline over time and eventually fall below the net value test required to qualify for the Medicare retiree drug subsidy. When this occurs, we anticipate that these employers and unions will likely encourage their retirees to enroll in Medicare Part D and provide either enhanced or supplemental coverage that wraps around Medicare Part D, or additional premium or other financial assistance or some combination of these steps. By doing this, beneficiaries would gain financially since they would receive the more generous Medicare Part D benefit, plus any additional support that the employer or union might offer in terms of wrap around coverage or premium assistance.

Also, due to steps some employers have taken to reduce retiree health benefits for future retirees, such as increasing retiree premium contributions, we anticipate that in future years as new retirees age into the Medicare program, there would be more retirees enrolling in standard Part D (including those with employer or union assistance with the Part D premium). As noted previously, the 2004 Kaiser/Hewitt survey of large employers offering retiree drug coverage found that roughly 20 percent of firms provide new retirees with access only coverage (that is coverage, where the employer makes no financial contribution to the cost of the premium). In situations where employers or unions make no or only a minimal contribution to the cost of retiree drug benefits, beneficiaries would be better off financially if they enrolled in Medicare Part D, since Medicare Part D includes a significant government subsidy. Furthermore, if employers or unions that provide only a very minimal contribution to retiree drug coverage instead offered to put that contribution toward the standard Medicare Part D premium, those retirees would benefit financially from both the subsidized Medicare Part D benefit and their employers/ unions' assistance with premiums. In addition, there has also been a trend toward declining generosity of retiree benefits for current retirees (for example, through increased premiums or cost-sharing), and we expect that this may also result in a slight increase in the number of retirees enrolled in standard Part D.

Due to the various considerations discussed above, among the 11.8 million

beneficiaries that we estimate would have employer or union sponsored retiree drug coverage in 2010 absent the law change, we assume that 61 percent would receive creditable drug coverage from an employer or union plan that is eligible for the Medicare retiree drug subsidy, 20 percent would enroll in Medicare Part D and receive employer or union sponsored enhanced or supplemental drug coverage, and 19 percent would enroll in standard Part D including those who would receive additional premium or other financial assistance from their former employer or union.

Depending on the circumstances of the retiree, all of these types of drug coverage have the potential to reduce retiree lifetime drug costs significantly compared to retiree costs in the absence of the law. Because of the substantial new subsidies and the range of subsidized options available to employers and unions for continuing coverage and enhancing total support for retiree coverage, we conclude that combined payments by employers/unions and Medicare for drug coverage on behalf of retirees will generally be greater—and frequently significantly greater—than they otherwise would have been without the enactment of the MMA. That is, lifetime drugs costs for retirees will generally be lower, and frequently substantially lower, than they otherwise would have been, as a result of strengthened retiree coverage and new assistance with drug costs.

A fifth participation assumption concerns enrollment in the low-income subsidy portion of the program. We estimate that approximately 14.4 million beneficiaries will be eligible for the low-income subsidy in 2006. We assume that a portion of beneficiaries who are eligible for the low-income subsidy (while receiving prescription drug coverage under Part D) will not take up the low-income assistance. We assume 100 percent uptake among full-benefit dual eligibles and 57 percent uptake among all other low-income subsidy eligibles. Among this latter group, we assume 100 percent uptake among those beneficiaries who will be deemed full low-income subsidy eligible and have facilitated enrollment (that is, QMBs, SLMBs, QIs, and beneficiaries with SSI). As noted in the proposed rule, we assume less than full uptake of the low-income subsidy among the remaining low-income beneficiaries based on experience with other means tested programs such as Medicaid and Medicare Savings (QMB/SLMB) programs, which suggests that full take up does not generally occur.

There are several limitations inherent in the assumptions for predicting the specific impacts of a major new program like the Medicare drug benefit. For example, it is difficult to project enrollment rates in this entirely new program, and there is uncertainty about how employers and unions will respond to the retiree drug subsidy or the other approaches available to augment Medicare Part D prescription drug coverage. The assumptions discussed previously reflect our current best estimates, considering the structure of the program, the wide variety of new efforts to educate beneficiaries and facilitate enrollment, and information about participation rates in other types of similar programs where available.

Comment: One commenter asserted that our assumption in the proposed rule that 99 percent of non-low-income and non-actively working beneficiaries would receive drug coverage through a Medicare Part D plan or through an employer or union sponsored health plan that is eligible for the Medicare retiree subsidy was unrealistic, claiming that the late enrollment penalty for Medicare Part D was not sufficient to generate that level of participation. This commenter also asserted that our assumptions did not reflect the potential for selection bias in enrollment in Medicare Part D.

Response: In addition to receiving this comment on our Part D program uptake assumptions, in our efforts to refine our model of Medicare Part D impacts, we also obtained information from industry experts on their expectations of the likely response to Medicare Part D. While we continue to believe that there will be high participation in Medicare Part D, we have revised our uptake assumption downward slightly to reflect what we think is the current best estimate of likely participation in Medicare Part D and we have accounted for selection by assuming graduated uptake rates based on beneficiaries' drug spending levels, as discussed previously.

F. Anticipated Effect of Medicare Part D on Beneficiaries

The Medicare prescription drug benefit is designed to provide all of the nation's Medicare beneficiaries with the opportunity to enroll in a prescription drug benefit that is subsidized by the Medicare program. We believe that giving Medicare beneficiaries access to affordable drug coverage that helps them to pay for their outpatient prescription drugs (which have become an increasingly important component of health care service delivery), and helps beneficiaries to use prescription drugs more effectively, will assist beneficiaries in leading healthier, more productive lives, while improving the effectiveness of the Medicare program. Additionally, we believe that the substantial additional resources that Medicare Part D provides through the retiree drug subsidy and the various opportunities employers and unions have for providing additional coverage that complements the standard Part D drug benefit will make it more affordable for employers and unions to continue providing high quality retiree drug coverage to Medicare-eligible retirees.

The following section contains discussions of: a recap of the Medicare drug benefit's structure, estimates of the average amount of drug spending covered by the Medicare drug benefit and average beneficiary premiums, the anticipated positive effects that the Medicare prescription drug benefit will have on beneficiaries, and a discussion of the anticipated positive effects that the Medicare retiree drug subsidy and other options that are available to employers and unions under Medicare Part D will have on the availability and generosity of retiree drug coverage.

1. Recap of the Structure of the Medicare Part D Drug Benefit

As discussed in more detail in subpart C in the preamble, standard prescription drug coverage under Medicare Part D for 2006 consists of a $250 deductible, 25 percent cost-sharing (or an actuarially equivalent cost-sharing structure) up to an initial coverage limit of $2,250, 100 percent beneficiary cost-sharing after the initial coverage limit until an out-of-pocket threshold of $3,600 is reached, and nominal cost-sharing for expenditures beyond the out-of-pocket threshold (that is, the greater of 5 percent coinsurance or a copayment of $2 for a generic or preferred multiple source drug and $5 for any other drug in 2006, or an actuarial equivalent cost-sharing structure). For each year after 2006, the deductible, initial coverage limit, out-of-pocket threshold, and nominal copayment amounts are indexed to per capita growth in prescription drug expenditures for Part D enrollees, as described in more detail in the preamble.

While we model all of our impact estimates on the defined standard benefit structure, we note that PDP and MA-PD plans have the option of offering actuarially equivalent alternative coverage. In addition, plans may offer enhanced alternative coverage where for an additional premium they offer supplemental drug coverage such as coverage for benefits above the initial coverage limit (that is, coverage of the so-called ''doughnut hole''), and we

anticipate that some plans will offer this coverage.

Beneficiaries who meet certain income and assets requirements qualify for low-income subsidy assistance with cost-sharing and premiums. While the out-of-pocket threshold level is the same for all enrollees, the beneficiary cost-sharing liability covered by the low-income subsidy counts towards the Part D out-of-pocket threshold. Therefore, subsidy-eligible individuals will pay substantially less than all other enrollees before the catastrophic coverage begins. Institutionalized full-benefit dual eligibles pay no cost-sharing. Other full-benefit dual eligibles with income not in excess of 100 percent of the Federal Poverty Level (FPL) face no deductible, have nominal cost sharing of $1 for generic drugs or preferred multiple source drugs and $3 for any other drug up to the out-of-pocket threshold, and receive full coverage for drug costs beyond the out-of-pocket threshold. Other full-benefit dual eligibles with income above 100 percent of FPL and beneficiaries who are not full benefit dual eligibles, but who have income less than 135 percent of FPL and assets up to $6,000 per individual (or $9,000 per couple) in 2006, face no deductible, have nominal cost sharing of $2 and $5 for the respective drugs up to the out-of-pocket threshold, and receive full coverage for costs beyond the out-of-pocket threshold. For other beneficiaries with income less than 150 percent of FPL and assets up to $10,000 per individual (or $20,000 per couple) in 2006, there is a reduced deductible of $50, cost-sharing of 15 percent for costs up to the out-of-pocket threshold, and nominal cost sharing of $2 and $5 for the respective drugs for costs beyond the out-of-pocket threshold. For years after 2006, all aspects of the benefit structure related to the low-income subsidy are indexed to growth in per capita drug spending, except for the nominal copayment amounts for full-benefit dual eligibles with income not in excess of 100 percent of FPL and the low-income assets tests, which are indexed to the Consumer Price Index.

The low-income subsidy also offers beneficiaries substantial help with premiums. Many beneficiaries who receive the low-income subsidy will pay no premium for Medicare drug coverage. Full-benefit dual eligibles and beneficiaries who have incomes up to 135 percent of FPL and who meet the assets test receive a full Federal subsidy of the beneficiary premium—that is, beneficiaries pay no premium as long as they select a PDP or MA-PD that has a premium that does not exceed the greater of the low-income benchmark premium or the lowest PDP premium for basic coverage for the region and as long as they sign up for Medicare Part D within the initial enrollment period or have met creditable coverage requirements. Other beneficiaries receiving a low-income subsidy—those with income between 135 percent and 150 percent of FPL and meeting asset requirements—would face a sliding scale premium based on income.

Medicare Part D also has implications for beneficiaries enrolled in the Program of All Inclusive Care for the Elderly (PACE). PACE programs already provide a comprehensive drug benefit to dual eligible enrollees and to enrollees who only have Medicare coverage. For the dual eligible enrollees, PACE programs will now be receiving funding for prescription drugs through Medicare Part D instead of through the State Medicaid program. PACE enrollees who only have Medicare coverage are today paying the full cost of their drug coverage. As a result of the Federal subsidization of Part D coverage, they will receive substantial premium relief. This lowering of premiums for beneficiaries who only have Medicare coverage may lead to an increase in enrollment in PACE organizations.

2. Estimated total drug spending, spending paid by the Medicare drug benefit, and premiums

a. Summary

Table IV–2 presents estimates for Medicare Part D enrollees of (1) average per capita total drug spending (including spending paid for by the Medicare drug benefit, by the beneficiary, and by any sources of supplemental coverage), (2) average drug spending paid for by the standard Medicare Part D benefit, and (3) the average premium associated with standard Medicare Part D drug coverage. Since beneficiaries who are eligible for the low-income subsidy receive additional assistance with cost-sharing and premiums, we present estimates separately for beneficiaries who do and do not receive the low-income subsidy. A discussion of how these estimates were developed is included in the next section, ''b. Methodology and Assumptions Underlying Estimates.''

For Medicare Part D enrollees who do not receive the low-income subsidy, we estimate that average per capita drug spending in CY 2006 would be $2,260. This projection of drug spending includes cost-management savings discussed in the next subsection, such as price concessions and generic substitution, or utilization effects resulting from the Medicare drug benefit. The Medicare drug benefit would be expected to pay for on average about $1,138 of prescription drug costs, or on average half of total beneficiary drug spending in CY 2006.[7] Beneficiary premiums for defined standard coverage will vary across PDPs and MA-PDs. We estimate that the beneficiary premium to obtain defined standard coverage would be on average about $440 per year in CY 2006. Thus, we estimate that the average monthly premiums would be less than $37. A beneficiary may pay a higher or lower amount depending upon which PDP or MA-PD the beneficiary selects. In CY 2010, drug spending for Part D enrollees who do not receive the low-income subsidy is projected to be $2,945 on average, with the Medicare drug benefit paying for on average $1,490 of prescription drug costs. The average premium in CY 2010 for these beneficiaries is projected to be $580 per year or roughly $48 per month for defined standard coverage.

For enrollees who receive the low-income subsidy, we estimate that average per capita drug spending in 2006 would be $4,359.[8] We estimate that on average the Medicare drug benefit would be expected to pay for about $4,189 of prescription drug costs, or approximately 96 percent of total drug spending. In 2010, these beneficiaries would be expected to spend on average $5,684 per capita on prescription drugs, with the Medicare drug benefit paying for on average about $5,439 of beneficiaries' drug costs. As discussed in the preamble, the low-income cost-sharing amounts vary depending upon a beneficiary's income and assets. Consequently, the share of drug spending paid for by the Medicare drug benefit would vary by subsidy eligibility category, ranging from an average of about 85 percent for the highest-resource subsidy eligibility category (that is, those beneficiaries who qualify for the subsidy under the criteria that they have income less than 150 percent of FPL and assets up to $10,000

[7] We note that $1,138 reflects the average payout of the Medicare drug benefit for non-low-income beneficiaries in 2006. This is different from what the payout would be for a beneficiary with total drug spending equal to average total drug spending for all enrollees. For example, standard coverage under Medicare Part D would payout $1500 for a beneficiary with total spending of $2260. The difference between the average payout versus the payout for a beneficiary with average total drug spending is due to the interaction between the distribution of drug spending and the deductible and cost-sharing structure of the Medicare drug benefit.

[8] Average drug spending for enrollees eligible for the low-income subsidy is higher than for enrollees not eligible for the subsidy because a substantial portion of those eligible for the low-income subsidy are full-benefit dual eligibles, who on average tend to be sicker.

per individual (or $20,000 per couple) in CY 2006) to 98 percent for the most generous subsidy category (that is, full-benefit dual eligibles with income not in excess of 100 percent of FPL). As discussed in the following methodology section, these estimates do not take into account the waiver of cost sharing for institutionalized full-benefit dual eligibles, which further enhances the subsidy for this category of beneficiaries.

As noted previously, many beneficiaries who receive the low-income subsidy receive a full Federal subsidy of the beneficiary premium (that is, the beneficiary pays no premium at all), as long as they enroll in a PDP or MA-PD with a premium that does not exceed the greater of the low-income benchmark premium or the lowest PDP premium for basic coverage for the region and as long as they enroll during the initial enrollment period or have met creditable coverage requirements. For low-income enrollees with income between 135 percent and 150 percent of FPL who face a sliding scale premium based on income, we estimate that the premium will average $220 per year or roughly $18 per month in 2006, and $290 per year or roughly $24 per month in 2010.

Overall, the government is estimated to contribute $1355 to the $1795 cost of standard Part D insurance coverage. In addition, the government will provide further financial assistance for low-income subsidy enrollees—an average of $1863 in low-income cost-sharing subsidies and $420 in premium subsidies.

We note that our total per capita drug spending estimates for the two groups of Part D enrollees—those receiving and those not receiving the low-income subsidy—differ from those presented in the proposed rule. Our current estimate of total per capita drug spending is lower for Part D enrollees not receiving the low-income subsidy and is higher for Part D enrollees receiving the low-income subsidy than our prior proposed rule estimates. The reasons for these changes include use of more recent (2001) Medicare Current Beneficiary Survey (MCBS) data in which spending for non-low-income beneficiaries did not grow as rapidly as predicted using earlier baseline data and benchmarking spending estimates for low-income beneficiaries to Medicaid data.

b. Methodology and Assumptions Underlying Estimates

To estimate beneficiary drug spending for the period CY 2006–2010, we use drug spending data from the 2001 MCBS adjusted for underreporting and trended forward based on projected growth in per capita drug spending based on the National Health Expenditures projections.

In projecting drug spending for enrollees in Medicare Part D, we assume that PDPs and MA-PDs will achieve a certain level of savings due to cost management activities such as negotiation of manufacturer rebates, retail discounts, and other price concessions, and promotion of generic substitution together with other utilization management efforts. We assume discounts and cost-management savings of 15 percent in 2006, 17 percent in 2007, 19 percent in 2008, 21 percent in 2009, and 23 percent in 2010. To take into account that some enrollees in the Medicare Part D drug benefit are likely to have had previous drug coverage from other sources and received some level of discounts and cost-management savings through that coverage, we adjusted the MCBS spending data upward to reflect the full retail price by backing out any assumed discounts and cost management savings and then applied the Part D savings factor. We note that some beneficiaries without drug coverage are currently receiving discounts through the Medicare-approved drug card program. Conceptually, those discounts should also be backed out of drug spending before applying the Part D savings factor; however, because the drug spending data on which our projections are based predate the Medicare-approved drug card program, such an adjustment was not necessary.

Our assumptions related to the cost management savings take into account several factors. Insured products generally obtain lower drug prices than those available to cash paying customers. For example, an April 2000 study prepared by HHS entitled, ''A Report to the President: Prescription Drug Coverage, Spending, Utilization and Prices,'' indicated a significant price differential between individuals paying cash for prescriptions at a retail pharmacy versus individuals with insurance. This difference held true for both the Medicare and non-Medicare populations. According to the study, in 1999 the price paid by cash customers was nearly 15 percent more than the total price paid under prescription drug insurance, including the enrollee cost sharing. For 25 percent of the most commonly prescribed drugs, this price difference was higher—over 20 percent. Such price concessions are envisioned to be an important part of the Medicare drug benefit, as the statute specifically requires PDPs and MA-PDs to provide beneficiaries with access to negotiated prices, which would reflect manufacturer rebates, retail discounts, and other price concessions. Besides these types of price concessions, we also anticipate that PDPs and MA-PDs will achieve savings as a result of other cost management activities such as promotion of generic substitution, which Medicare will help support as well through providing information on opportunities for cost savings to beneficiaries and their health providers. As discussed elsewhere in the preamble, the statute requires PDPs and MA-PDs to put in place a cost-effective drug utilization management program that would include incentives to reduce costs when medically appropriate. We believe that these various efforts are likely to increase use of generics relative to brand-name drugs among Medicare Part D enrollees.

In addition, our drug spending projections assume that changes in beneficiary out-of-pocket costs resulting from the Medicare drug benefit would affect beneficiaries' utilization of drugs. For example, as discussed previously, beneficiaries without drug coverage fill fewer prescriptions and spend less in total on prescription drugs than beneficiaries with drug coverage. Under the Medicare drug benefit, we would expect that drug utilization and spending would increase for beneficiaries without prior drug coverage. Our estimates assume that aggregate beneficiary drug spending (that is, total drug spending for all beneficiaries including those with and without drug coverage prior to 2006) would be 7.2 percent greater in CY 2006 than it otherwise would be, due to reduced out-of-pocket costs resulting from the Medicare drug benefit. Our estimate of the increase in drug spending that results in response to reduced out-of-pocket costs is somewhat lower than our previous proposed rule estimate because we have refined our methodology. For the final rule estimates, we have developed a regression model, where we estimate the demand for prescription drugs as a function of the share of drug costs that are out-of-pocket controlling for the number of physician visits, age, and gender.

Using our estimates of projected drug spending for enrollees in Medicare Part D, we estimate the amount of drug spending that would be paid for by the Medicare drug benefit assuming the defined standard benefit design, separately for enrollees who would and would not receive the low-income subsidy. For enrollees who receive the low-income subsidy, these estimates take into account the differential cost-sharing by income and assets within the

low-income group. However, due to data limitations, our estimates do not take into account the fact that beneficiary cost-sharing is waived entirely for institutionalized full-benefit dual eligibles.

Using the drug spending estimates, we also estimate the statutorily specified share of spending financed through beneficiary premiums for defined standard Part D coverage. For the purpose of this impact analysis, those beneficiaries who are assumed to enroll in Medicare Part D are assumed to do so within their initial enrollment period and face no late enrollment penalty. We also assume that all low-income beneficiaries with income under 135 percent of FPL select PDP and MA-PD plans with a premium that does not exceed the greater of the low-income benchmark premium or the lowest PDP premium for basic coverage for the region, and thus face no beneficiary premium. To estimate the average sliding scale premium, where low-income subsidy enrollees receive a 75 percent premium subsidy (if income is greater than 135 percent of FPL but does not exceed 140 percent of FPL), a 50 percent subsidy (if income is greater than 140 percent of FPL but does not exceed 145 percent of FPL), or a 25 percent subsidy (if income is greater than 145 percent of FPL but less than 150 percent of FPL), we assume a uniform income distribution between 135 percent and 150 percent of FPL. If the income distribution is not uniform, the average sliding scale premium could differ somewhat from our estimates.

We received several comments related to the methodology and estimates in this section.

Comment: One commenter raised concern about the use of Medicare Current Beneficiary Survey data and National Health Expenditure projections to estimate beneficiary drug spending in future years. The commenter questioned the reliability and completeness of self-reported survey data like the MCBS and questioned the use of the NHE projections of per capita prescription drug expenditure growth because these projections are not Medicare specific. The commenter maintained that data from the Federal Employee Health Benefits Program and other public programs that reflect a large number of geographically diverse Medicare beneficiaries should be used for the estimates instead.

Response: We agree with the commenter that there are limitations to the data used to project beneficiary drug spending in future years. We also recognize that data from the Federal Employee Health Benefits Program and other public programs can provide important information about prescription drug spending among Medicare beneficiaries and we have used those data in our other research efforts. However, for the purpose of developing nationally representative costs estimates for Medicare Part D, both CMS and the Congressional Budget Office have relied on the MCBS data. CMS has chosen to use the MCBS because it is the largest nationally representative survey of prescription drug expenditures for Medicare beneficiaries and it has the advantage of being a single data source that provides information on all types of beneficiaries—for example, both beneficiaries with and without prescription drug coverage, beneficiaries with varied income levels, and beneficiaries of different ages and health acuities. The administrators of the survey undertake a number of measures to reduce inaccuracies associated with self-reported data, including supplying respondents with calendars to record drug purchases, requesting that beneficiaries save their drug containers for their next interview, and providing the interviewer with a roster of drugs previously mentioned by the respondent to ensure we are capturing refills. Moreover, we recently completed and published a pharmacy follow-back analysis in which we compared beneficiary-reported drug data to pharmacist-reporting data (''Reporting of Drug Expenditures in the MCBS,'' John A. Poisal, *Health Care Financing Review*, Winter 2003–2004, pp. 23–36). This allowed those who oversee the survey to adjust their estimates to account for survey drug mis-reporting. All of our drug estimates reflect the results from the follow-back study.

With respect to the National Health Expenditures projections, we acknowledge that these projections are national and not specific to the Medicare population. These projections are based on data obtained by our Office of the Actuary (OACT) from a variety of sources, including the National Prescription Audit conducted by IMS Health. OACT adjusts the data from the National Prescription Audit to take into account a number of factors, including benchmarking to the Economic Census and adjusting the data to subtract an estimate of manufacturer rebates provided to health insurers related to insurance coverage for prescription drugs. Since no such projections that take these various factors into account exist specifically for the Medicare population, we believe it is appropriate to use the NHE projections.

Comment: We received a comment from a retiree advocacy group in which they provided independently generated data on the cost of prescription drugs for a group of beneficiaries who currently receive generous drug coverage through large employers and unions. The data were generated by having retirees use the website of an Internet pharmacy to determine the cost of a 90-day supply of the drugs they use. Based on this, the commenter estimated average total drug spending, average drug spending paid for by Medicare Part D, and the average beneficiary premium. The commenter's estimate of average drug spending for its group of retirees was higher than the proposed rule estimate while its estimate of average drug spending paid for by Medicare Part D was lower than in the proposed rule. The commenter's estimate of the beneficiary premium was fairly similar to the proposed rule although the commenter's estimate was slightly lower.

Response: It would not be unexpected that average drug spending for a specific group of beneficiaries may differ from our projections of average drug spending for all Medicare Part D enrollees. However, if on average a specific subgroup of enrollees has higher drug spending, then the average amount of drug spending paid for by the Medicare drug benefit would also be higher for that subgroup of beneficiaries.

As discussed elsewhere, we have based our estimates for Medicare Part D on the MCBS, which is the largest nationally representative survey of prescription drug expenditures for Medicare beneficiaries and which has the advantage of being a single data source that provides information on all types of beneficiaries. The projections based on this data reflect our best estimate of the average impact of Medicare Part D on beneficiaries.

Comment: One commenter took issue with the application of the cost management savings equally to all segments of the Medicare Part D population. The commenter asserted that it is not realistic to expect the same level of savings for low-income subsidy enrollees because their cost-sharing is extremely limited and plans have little ability to incentivize the use of cost effective drugs.

Response: While it is true that low income subsidy enrollees will have minimal cost-sharing, we believe that cost management savings are possible for this population because Part D plans still have other cost management tools available—for example, notably, price concessions for drugs on a plan's formulary, as well as such tools as mandatory generic substitution, step

therapy, and prior authorization. Cost-sharing is only one of many tools available to Part D plans that influence cost management savings.

Comments: Some commenters asserted that they did not believe private price negotiations between Part D plans and drug manufacturers would yield as large savings for beneficiaries as direct government price negotiation (which is prohibited by statute). Some commenters claimed that Medicare Part D plans or PBMs, rather than beneficiaries, would benefit from price concessions negotiated with manufacturers.

Response: We disagree with the commenters. We expect that the private price negotiations between PDP sponsors and drug manufacturers would achieve comparable or better savings than direct price negotiation between the government and manufacturers, as well as coverage options that better reflect beneficiary preferences. This expectation reflects the strong incentives to obtain low prices and pass on the savings to beneficiaries resulting from competition, relevant price and quality information, Medicare oversight, and beneficiary assistance in choosing a drug plan that meets their needs. This is similar to the conclusion of other analyses, for example, CBO's recent statement that ''Most single-source drugs face competition from other drugs that are therapeutic alternatives. CBO believes that there is little, if any, potential savings from negotiations involving those single-source drugs. We expect that risk-bearing private plans will have strong incentives to negotiate price discounts for such drugs and that the Secretary would not be able to negotiate prices that further reduce Federal spending to a significant degree.'' In addition, the provision of relevant price and quality information on each Part D plan through a price comparison website will further promote low prices to beneficiaries.

TABLE IV–2. ESTIMATED AVERAGE ENROLLEE TOTAL DRUG SPENDING, DRUG SPENDING PAID FOR BY MEDICARE DRUG BENEFIT, AND DRUG BENEFIT PREMIUM, CY 2006 AND CY 2010

Estimated Average Annual Drug Spending*	Estimated Average Annual Drug Spending Paid For By the Medicare Drug Benefit**	Estimated	Average Annual
2006			
Enrollees Not Receiving Low-Income Subsidy	$2,260	$1,138	$440
Enrollees Receiving Low-Income Subsidy	$4,359	$4,189	$0 or $220***
2010			
Enrollees Not Receiving Low-Income Subsidy	$2,945	$1,490	$580
Enrollees Receiving Low-Income Subsidy	$5,684	$5,439	$0 or $290***

* Estimated average total drug spending includes spending paid for by the Medicare drug benefit, by the beneficiary, and by any other sources of coverage.

** Average annual drug spending paid for by the Medicare drug benefit reflects on average how much the Medicare drug benefit will payout per beneficiary. This is different from the amount of drug costs the Medicare drug benefit would payout for a beneficiary with average total drug spending, due to the interaction between the distribution of drug spending and the deductible and cost-sharing structure of the Medicare drug benefit. We also note that the average drug spending paid for by the Medicare Part D plan reflects drug costs reimbursed by the plan and does not include PDP or MA-PD administrative costs.

*** These numbers reflect separate premium estimates for two groups of low-income subsidy enrollees. (1) Those low-income subsidy enrollees with income under 135 percent of FPL have a $0 beneficiary premium, as long as they select a PDP or MA-PD with a premium that does not exceed the greater of the low-income benchmark premium or the lowest PDP premium for basic coverage for the region, and as long as they enroll within the initial enrollment period or have met creditable coverage requirements. (2) Low-income subsidy enrollees with income between 135 percent and 150 percent of FPL face a sliding scale premium based on income, which is estimated to average $220 per year in 2006 ($290 in 2010).

2. Qualitative Discussion of Positive Effects of the Medicare Drug Benefit

The purpose of the Medicare prescription drug benefit is to provide all of the nation's Medicare beneficiaries with the opportunity to enroll in a prescription drug benefit that is subsidized by the Medicare program. Outpatient prescription drugs have become an integral component in the delivery of comprehensive, high quality health care services. Giving beneficiaries access to affordable drug coverage, that helps them to pay for their outpatient prescription drugs and helps beneficiaries and their health professionals to use prescription drugs more effectively as part of their overall health care, will enable beneficiaries to lead healthier, more productive lives, while improving the effectiveness of the Medicare program.

a. Enhancement of the Medicare Benefit Package

When the Medicare program was first enacted, outpatient prescription drug coverage was generally not included in private sector health benefit packages. However, over the last two decades, prescription drugs have played an increasingly critical role in health care service delivery. For example, currently, at least one medication is ordered, provided, or continued in approximately 65 percent of all visits to office-based physicians by persons 65 years and over (2001 National Ambulatory Medical Care Survey, National Center for Health Statistics). Prescription drugs have significantly improved the treatment and management of many major conditions—including life-threatening diseases such as stroke (anticoagulant or clot-blocking therapy), heart disease and coronary artery disease (antihypertensive medications, cholesterol-lowering drugs), and cancer (targeted biologics and other agents that modify the course of illness and can be taken orally), as well as disorders that have fundamental impacts on quality of life like psychiatric illnesses (antipsychotics and antidepressants),

osteoporosis (bone-strengthening drugs), and arthritis (anti-inflammatory drugs and other disease-modifying agents)—thereby contributing to longer and healthier lives as well as reductions in other types of medical expenditures such as inpatient admissions and lengths of stay (''The Price of Progress: Prescription Drugs in the Health Care Market,'' J. D. Kleinke, *Health Affairs* 20:5, September/October 2001, available at *www.healthaffairs.org*). Many other significant diseases have also seen improvements in treatment and management, and thus in patient health, as a result of the availability of new medications, including: HIV/AIDS, complex infections, diabetes, asthma and chronic lung diseases, Parkinson's disease, and many less common but serious disorders. With more new medicines in development than ever before, potential future health benefits from better drug therapies are even greater. Medicare Part D will augment the Medicare program's benefit package by making drug coverage, which is currently offered in most private sector health plans, available to all beneficiaries. This represents an important step in modernizing the Medicare program to better meet beneficiaries' needs and respond to changes in health care delivery.

b. Access To Subsidized Prescription Drug Coverage

For the first time in the history of the Medicare program, the Medicare prescription drug benefit will make subsidized prescription drug coverage available to all Medicare beneficiaries. Historically, many Medicare beneficiaries have received prescription drug coverage through a variety of sources, including: employment-based retiree health coverage, Medigap policies with drug coverage, Medicare Advantage plans, Medicaid, and State Pharmaceutical Assistance Programs. These various types of drug coverage have traditionally varied widely in comprehensiveness and cost (for example, many of these policies may not include catastrophic coverage), leaving some beneficiaries at risk for high out-of-pocket costs and related financial access issues even though they have drug coverage. Meanwhile, an estimated 24 percent of Medicare beneficiaries currently do not have any prescription drug coverage at all (based on 2001 Medicare Current Beneficiary Survey data).

In the proposed rule, we stated that by providing substantial additional resources to defray the cost of Medicare drug coverage—including direct subsidy and government reinsurance payments to PDPs and MA-PDs that will cover roughly 75 percent of the total cost of the Medicare drug benefit for all beneficiaries, additional assistance with cost-sharing and premiums for low-income beneficiaries, and new subsidies for the retiree coverage and Medicare Advantage coverage that many beneficiaries receive today—the Medicare prescription drug benefit will make prescription drug coverage more accessible and affordable for beneficiaries. Since we issued the proposed rule, several new independent studies have been published that have examined the financial benefits that are available to beneficiaries through Medicare Part D. In the remainder of this section, we highlight some of the ways that having access to subsidized Part D drug coverage will be helpful to Medicare beneficiaries as a whole, and for specific subgroups within the beneficiary population.

The Medicare prescription drug benefit will provide access to basic subsidized prescription drug coverage for all Medicare beneficiaries, regardless of income, and additional targeted assistance for low-income beneficiaries. We anticipate that beneficiaries who choose to take advantage of the subsidized drug coverage that is available through Medicare Part D by enrolling in a PDP or MA-PD will experience reductions in their out-of-pocket spending for prescription drugs, both in the short-term and over their lifetime, and will also gain generous insurance protection against catastrophic drug costs. Ultimately, we believe that the Medicare prescription drug benefit will significantly reduce the financial burden that beneficiaries may face in obtaining needed outpatient prescription drugs.

Medicare beneficiaries' out-of-pocket spending for prescription drugs has been increasing during the past decade. However, several independent analyses confirm our belief that beneficiaries enrolling in the Medicare drug benefit are likely to receive substantial help through lower out-of-pocket spending. These savings will be associated with Medicare's direct subsidy, low-income subsidy and reinsurance payments (''Estimates of Medicare Beneficiaries' Out-of-Pocket Drug Spending in 2006,'' Jim Mays et. al., Actuarial Research Corporation, and Tricia Neuman et al., The Henry J. Kaiser Family Foundation, November 2004, available at *http://www.kff.org*). Beneficiaries will also achieve savings from the additional price discounts that will be available through the Part D plans (''The Medicare Prescription Drug Benefit: Potential Impact on Beneficiaries,'' Jack Rodgers and John Stell, PricewaterhouseCoopers, prepared for the AARP Public Policy Institute, November 2004, available at *http://research.aarp.org/health/2004_13_rx.pdf*).

These independent analyses suggest that although the level of savings that beneficiaries receive will vary by income and total drug costs, the Medicare drug benefit will enable beneficiaries to achieve savings across all age and health status cohorts. For example, one study consistently found lower out-of-pocket spending for all of the major beneficiary sub-groups analyzed, including age, sex, race, income, place of residence (rural/urban) and health status (Mays, et. al., November 2004).

Although most beneficiaries will experience lower out-of-pocket costs during the first year of the Medicare drug benefit, the available studies suggest that some healthier beneficiaries with low utilization could potentially pay more in premiums than they collect in benefits in 2006 (Mays, et. al., November 2004; King et. al., November 2004; Rodgers et. al., August 2004). However, it is important to note that insurance coverage is purchased to protect against high or unexpected costs. Thus, the value of the Part D benefit should not be measured solely based on savings during any given year; rather, it is more appropriate to compare beneficiaries' out-of-pocket costs with their total lifetime prescription drug expenditures to determine the net savings that beneficiaries will receive through Medicare Part D over their lifetime (King et. al., November 2004). To further illustrate this point, we note that like the existing Medicare Part B benefit, which covers physician care and other outpatient services, the new Medicare drug benefit is voluntary. Under current Medicare Part B coverage, an estimated 30 percent of beneficiaries pay more in premiums than they collect in benefits during any given year; nevertheless, most beneficiaries choose to enroll in Part B when they first become eligible because they know that they will do better over time if they have insurance coverage than if they remain uninsured. The same is true for the new Medicare Part D prescription drug benefit. Younger and healthier beneficiaries who currently have low drug utilization will still be substantially better off over time by enrolling in Medicare Part D. Most beneficiaries who currently have low drug spending will need more costly medicines in the future, as drug utilization and spending tend to increase with age. Moreover, many illnesses can strike unforeseeably, so

that a beneficiary that is healthy during a given year may need an expensive drug the following year. Thus, even if they expect to have no drug spending or modest drug spending in 2006, these beneficiaries will want to join Part D in anticipation of the benefits they will need in the future. This is particularly important because there is a late enrollment penalty for people who do not sign up for Part D, and who do not maintain creditable coverage elsewhere.

Indeed, one study concluded that ''since annual net benefits even for beneficiaries in the youngest age group and in good health exceed the premiums paid, it is readily apparent that over the lifetime of all but the healthiest beneficiaries, benefits will exceed premiums paid for the coverage'' (King et. al., November 2004).

Additionally, millions of beneficiaries who choose to enroll in Medicare Part D will benefit from the availability of catastrophic drug coverage that was lacking in Medigap drug plans, as well as in most Medicare Advantage plans and many employer/union-sponsored plans. A portion of the beneficiary's Part D premium, as well as a portion of the government subsidy, is for this catastrophic protection. In addition to its financial value, this catastrophic coverage also has a psychological value in that even if a given beneficiary's drug spending does not reach the catastrophic coverage threshold during a given year, the beneficiary can still have greater peace of mind in knowing that this valuable catastrophic protection is available to them, should they need it (Mays, et. al., November 2004; Rodgers et. al., August 2004; King et. al., November 2004).

In addition to the Medicare prescription drug benefit, Medicare Part D also provides additional resources to support the continuation of high quality employer and union-sponsored retiree drug coverage. We discuss the anticipated effects of the Medicare retiree drug subsidy and the various other ways that Medicare Part D offers assistance with retiree prescription drug costs to employers and unions in a subsequent section of this impact analysis.

The remainder of this section provides a more detailed description of how different types of Medicare beneficiaries will be helped by the new Medicare prescription drug benefit.

Low-income beneficiaries—As discussed earlier, Medicare Part D makes substantial assistance available to beneficiaries with lower incomes. Altogether, we estimate that more than a third of the Medicare beneficiaries that are expected to enroll in Part D plans in 2006 will receive the low-income subsidy. These 11 million beneficiaries with limited incomes and assets (which includes the full-benefit dual eligibles) will receive substantial additional help from Medicare, with no gaps in coverage and limited or no premiums, deductibles, or co-payments. As discussed elsewhere in this impact analysis, Medicare Part D is estimated to cover on average 96 percent of prescription drug costs for these low-income beneficiaries.

There are three major groups of low-income beneficiaries that will receive additional assistance through the low-income subsidy. About 6.3 million ''dual eligible'' low-income beneficiaries will pay no premium, or a limited premium, no deductible and nominal co-pays of as little as $1 or $3 per prescription. As discussed elsewhere in greater detail, the Medicare drug benefit will pay, on average, 98 percent of dual eligible beneficiaries' drug costs. Additionally, about 1.5 million of these dual eligible beneficiaries are institutionalized, and will be totally exempt from Part D cost sharing, which means that they will not pay any premiums, deductibles, or co-payments. While the nominal cost sharing of the Medicare prescription drug benefit may in some cases be slightly higher than the cost-sharing under a State's Medicaid program, Medicare Part D provides catastrophic drug coverage protection with no cost sharing for all dual eligibles, a benefit that is not currently available in all States. Since this population on average experiences higher drug costs, the catastrophic coverage provided by Part D offers important additional protection to this vulnerable population. We also believe that Medicare Part D is likely to result in more stable prescription drug coverage for low-income Medicare beneficiaries. For many dual eligibles, Medicaid is not a secure source of drug coverage, as eligibility is subject to meeting certain income and resource requirements; as a result, for some dual eligibles, Medicaid only provides intermittent drug coverage. The broader income eligibility criteria for the Medicare Part D low-income subsidy are such that, when compared to Medicaid full-benefit dual eligibility standards, Medicare Part D is likely to result in more stable prescription drug coverage for this population because small income fluctuations will be less likely to jeopardize beneficiaries' eligibility for the subsidized Part D coverage. In addition the duration of eligibility for the low-income subsidy is for one year.

About 3 million Medicare beneficiaries who are not full-benefit dual eligibles, but whose incomes are less than 135 percent of the Federal poverty level ($12,568 for an individual and $16,861 for a couple in 2004) and who have limited assets will also pay only a few dollars per prescription, with no premium, and no deductible under the Part D low-income subsidy. Medicare will also cover 96 percent of these beneficiaries' drug costs, on average.

About 1.6 million beneficiaries with incomes less than 150 percent of the Federal poverty level and assets up to $10,000 (or $20,000 if married) in 2006 will pay 15 percent co-pays with a sliding-scale premium under Medicare Part D, which will cover 85 percent of their drug costs, on average.

Beneficiaries with help from State Pharmaceutical Assistance Programs—States that operate State Pharmaceutical Assistance Programs (SPAPs) have shown a historical commitment to provide the elderly with assistance with prescription drug costs, and are generally showing an interest (for example, through their comments on the proposed rule) in continuing to provide some assistance by working in conjunction with the new Medicare Part D benefit. As noted elsewhere in the preamble, the Act recognized this interest on the part of States through special provisions related to SPAPs. As discussed in greater detail subsequently in this impact analysis, States operating SPAPs which provide subsidized drug coverage to individuals that will be eligible for the Medicare drug benefit will gain substantial savings starting in 2006, when Medicare Part D begins providing very generous coverage for beneficiaries with limited means. As a result of these savings, States may have additional funds, with which they could provide additional coverage that wraps around the Medicare drug benefit if they wish to do so. SPAP assistance with beneficiary cost sharing will count toward the true out-of-pocket cost catastrophic threshold. As a result, this would enable SPAPs to provide as generous or more generous assistance for the beneficiaries who currently receive coverage through these programs, at a lower cost per beneficiary for the States due to the availability of the Medicare drug benefit.

Higher income beneficiaries that do not currently have prescription drug coverage—Non-low income beneficiaries that do not currently have prescription drug coverage will also benefit from the subsidized drug coverage that will be available through Medicare Part D. On average, these beneficiaries will be much better off with Part D coverage than they were

without drug coverage. Indeed, average spending for non-low-income beneficiaries is expected to be about $2,260 in 2006. Compared with not having drug coverage, beneficiaries who spend at least $820 a year (around $70 a month) on prescription drugs in 2006 will see immediate net savings through the Medicare drug benefit. This break-even point actually comes earlier when the discounted prices and other formulary management savings that plans will offer are considered. Beneficiaries spending less than $820 a year on prescription drugs will pay more in premium than they receive in benefits during the first year of the Part D drug benefit. However, a relatively small portion of beneficiaries will fall below the break-even point, largely due to the fact that the Part D premium is highly subsidized, with beneficiaries only paying about a quarter of the total cost of the premium on average. We estimate that about one-fourth (27 percent) of all Medicare beneficiaries will have drug spending below $820 in 2006. However, as discussed earlier, even for these relatively healthy beneficiaries, an unexpected illness could result in large and unanticipated drug costs, and annual prescription drug spending levels are expected to rise as people age, such that these beneficiaries will be much better off enrolling in Part D when they first become eligible to do so, and avoiding the late enrollment penalty. As noted previously, an estimated 30 percent of beneficiaries pay more in premiums under current Medicare Part B coverage than they collect in benefits during any given year. Nevertheless, most beneficiaries choose to enroll in Part B when they first become eligible because of its insurance value—they know that they will do better over time if they have insurance coverage than if they remain uninsured. The same is true for the new Medicare Part D prescription drug benefit.

Beneficiaries that currently have Medicare Advantage—In July 2004, approximately 4.2 million beneficiaries were enrolled in general Medicare Advantage Plans (that is, those not operating under an employer waiver), and about 82 percent of these beneficiaries (3.4 million) had some prescription drug coverage through their Medicare Advantage plan. However, most beneficiaries that currently have drug coverage through Medicare Advantage plans do not have a drug benefit that is as generous as the Medicare Part D standard benefit. For example, around 34 percent had coverage for generic drugs only, about 48 percent had coverage for both brand and generic drugs, and almost all beneficiaries in these plans had annual coverage limits of $2,000 or less, while only about 2 percent of the beneficiaries in Medicare Advantage plans had unlimited brand and generic drug coverage. Medicare Part D will give all beneficiaries access to subsidized brand and generic drug coverage and catastrophic coverage through Part D plans, including MA-PDs, as well as additional assistance for low-income beneficiaries. We expect that the combination of the new Medicare-subsidized Part D drug benefit, as well as the availability of rebates for Medicare Advantage Plans that are related to the provision of Medicare Part A and Part B services, and the attractiveness of drug coverage to beneficiaries will result in Medicare Advantage plans offering prescription drug premiums and benefit designs that are more advantageous to beneficiaries than the existing prescription drug offerings in the current Medicare Advantage market.

Beneficiaries that currently have drug coverage through a Medigap plan—The Medicare Part D prescription drug benefit will also provide savings for beneficiaries in comparison to existing Medigap insurance policies that include drug coverage. The new Medicare prescription drug coverage offers a much better value to beneficiaries than Medigap plans, where the enrollee must pay the full cost of the premium (which is not subsidized by the Federal government) and has no catastrophic protection against high prescription drug costs. By comparison, the Medicare drug benefit provides beneficiaries with comprehensive drug coverage at a lower cost, with the beneficiary paying only about 25 percent of the Part D premium. These savings occur at all spending levels. For example, at a drug spending level of $1,000 a year, beneficiaries who switch from Medigap H and I plans will save over $800 a year in premiums and cost-sharing, and those in plan J will save over $1,300 a year in premiums and cost-sharing by enrolling in Part D. Similarly, a beneficiary who spends $3,000 a year on drugs will typically save about $1,300 a year in premiums and cost sharing by switching to the new Medicare drug benefit from a Medigap H or I plan, and save almost $1,700 a year by switching from a Medigap J plan. Additionally, it is important to note that enrollees who switch from Medigap drug coverage into a Part D prescription drug plan will be able to keep their other Medigap benefits, such as payment of deductibles and coinsurance for doctor and hospital care, while paying lower premiums since their drug coverage will no longer be included in the Medigap plan. They will also be able to switch into two new Medigap benefit packages that will allow purchasers to insure against catastrophic costs for benefits covered under traditional Medicare and, together with the new drug benefit, allow beneficiaries to insure against catastrophic expenses for hospital, doctor, and prescription drug costs. Since all beneficiaries face some risk of catastrophically high bills for these services, these are important additions to the choices available to beneficiaries to manage their costs and potential financial exposure.

Beneficiaries that currently have employer- or union-sponsored coverage—As discussed elsewhere in this impact analysis, for well over a decade the availability and generosity of employment-based retiree health coverage has been eroding, particularly for future retirees. Medicare Part D, including the retiree drug subsidy and the other options it gives employers and unions for providing additional drug coverage that complements the standard Part D drug benefit, will help to counteract this trend by increasing the financial support that is available to employers and unions for retiree drug coverage. We discuss the anticipated effects of the Medicare retiree drug subsidy and the various other ways that Medicare Part D offers assistance with retiree prescription drug costs to employers and unions in a subsequent section of this impact analysis.

Overall, both our analysis and the analyses of several independent researchers have found that the new Medicare drug benefit will provide substantial help to millions of beneficiaries. However, we did receive some comments expressing concerns about how Medicare Part D will affect access to prescription drugs for certain beneficiary subpopulations.

Comment: We received numerous comments from beneficiary advocacy groups, States, and others expressing concern about the potential for dual eligible beneficiaries to experience coverage gaps if they do not enroll in a Part D plan prior to January 1, 2006 (when their primary prescription drug coverage will be transitioned from Medicaid to Medicare). These commenters stated that dual eligibles are particularly vulnerable due to their extensive and complex medical needs and limited financial resources, and that such coverage gaps could interfere with their ability to obtain medically necessary prescription drugs.

Additionally, various commenters noted that it will be particularly difficult to educate the dual eligible population about the relatively complex array of choices that are inherent in the new Part D drug benefit due to a variety of factors, including cognitive impairments (which may make it difficult for some dual eligibles to select a Part D plan, including those who are disabled, mentally ill, and/or institutionalized), limited proficiency with written English, and general poor health status. A few commenters also asserted that the potential for various different actuarially equivalent benefit designs under Part D could contribute to beneficiaries' difficulty in comparing Part D plans and making an informed choice among the options that are available to them. Some commenters expressed concern that dual eligible beneficiaries could be exposed to late enrollment penalties if they enroll in a Part D plan after the initial enrollment period has ended, which could represent an added financial burden for individuals that are on a fixed income. Some commenters also expressed concern that the provision allowing Part D plans to disenroll individuals whose behavior is disruptive could cause additional gaps in drug coverage and exposure to late enrollment penalties that could disproportionately affect beneficiaries with mental illness or cognitive difficulties. Commenters asserted that interruptions in access to needed prescription drugs could ultimately potentially have a negative impact on health outcomes and costs for dual eligibles and other beneficiaries with HIV/AIDS, mental illness, or developmental disabilities, as well as for beneficiaries that are institutionalized in skilled nursing facilities. For this reason, several commenters recommended either delaying implementation of Part D for dual eligibles to ensure a smooth transition; delaying implementation of the late enrollment penalty for dual eligibles; or auto-enrolling dual eligibles into Part D plans by Fall 2005 (with the ability to change plans) to avoid coverage gaps. Additionally, some commenters also suggested auto-enrolling beneficiaries that are enrolled in Medicare Savings Programs, as well as other low-income subsidy-eligible beneficiaries into Part D plans. Finally, some commenters recommended increased funding for SHIPs, AAAs, and States to provide an extensive network of local, face-to-face, culturally and linguistically competent counseling services to notify and educate the dual-eligible population about the low-income subsidy, and improve beneficiaries' overall comprehension of and enrollment into Part D plans.

Response: We share the commenters' concerns about the importance of facilitating a smooth transition to Medicare Part D for dual eligibles, and ensuring access to necessary prescription drug coverage for vulnerable populations. As discussed elsewhere, we have modified the final rule to ensure that auto-enrollment of dual eligibles will begin as soon as the eligible Part D plans are known prior to January 1, 2006. Additionally, given the significant savings that will be available to beneficiaries through the low-income subsidy, our final rule also includes facilitated enrollment provisions for all other beneficiaries who are determined or deemed eligible for the low-income subsidy. It is important to note that for low-income beneficiaries, the Part D benefit design will be fairly standardized due to the cost-sharing subsidies.

Also, as discussed in the preamble, we anticipate making every effort to provide beneficiaries with information to assist them in considering whether they should change Part D plans after they have been auto-enrolled and as part of the facilitated enrollment process. For example, we anticipate working with SHIPs, States and a broad array of public, voluntary, and private community organizations serving Medicare beneficiaries to assist dual eligibles and other beneficiaries (including targeted efforts among historically underserved populations) in understanding the various options that are available to them under Medicare Part D. We also anticipate that the special enrollment period provisions in the final rule will help to ensure that dual eligibles and other beneficiaries are able to change to a PDP or MA-PD that better meets their needs. We have also made additional revisions in the final rule to provide additional protections for vulnerable individuals, such as the mentally ill, who potentially might face involuntary disenrollment from a PDP due to disruptive behavior. Ultimately, as discussed earlier, we believe that Medicare Part D will improve access to and stability of generously subsidized drug coverage for many dual eligibles and lower income beneficiaries due to the broader income eligibility criteria that are associated with the Medicare Part D low-income subsidy, which means that small income fluctuations will be less likely to jeopardize beneficiaries' eligibility for coverage. In addition, the duration of eligibility for the low-income subsidy is for one year.

Comment: We also received numerous comments from beneficiary advocacy groups and others expressing concern that some beneficiaries with extensive and complex medical needs that enroll in PDPs and MA-PDs could be required to switch their medications due to a given Part D plan's formulary restrictions. Several commenters stated that there is a possibility that a beneficiary's current prescription drugs may not be included on their Part D plan's formulary, or may be included in a formulary tier that has higher cost-sharing requirements, because PDPs and MA-PDs will only be required to include at least two drugs from each therapeutic class on their formularies, and will not have any limits on their application of tiered co-payments under Medicare Part D (including the ability to use different tiers for different classes of drugs, and to make changes in tiers during the plan year). These commenters stated that many beneficiaries need immediate and ongoing access to medically necessary and therapeutically appropriate medications, which often may not be interchangeable with other drugs in the same therapeutic class—including dual eligibles; institutionalized beneficiaries; beneficiaries with HIV/AIDS, mental illness, developmental disabilities, or other life-threatening and pharmacologically complex conditions; and beneficiaries in subpopulations where there is data suggesting that specific drugs may be more efficacious than others (for example, based on gender, ethnicity or disease category)—and expressed concern that the Part D appeals process could cause delays in these beneficiaries receiving timely access to needed medications. Commenters also asserted that various other cost-control mechanisms can potentially delay beneficiaries' access to necessary and appropriate treatment, including dispensing limits, prior authorization requirements, therapeutic substitution, step therapy, and fail first provisions. Some commenters also suggested that Part D formulary cost-sharing requirements could be particularly burdensome for certain beneficiaries, including dual eligibles whose States do not currently require co-payments for prescription drugs and institutionalized beneficiaries (who could be subject to out-of-network costs if they obtain their drugs through a long-term care pharmacy that has an exclusive contract with the facility where they reside and provides value-added therapeutic management services, but is not part of their Part D plan's pharmacy network). Some commenters

also expressed concern that Part D plans may not actively solicit the inclusion of I/T/U pharmacies in their networks, noting that in some areas, I/T/U pharmacies may be the only facilities capable of providing medication therapy management services to certain American Indian / Alaska Native beneficiaries due to language and cultural barriers. Additionally, several commenters expressed concern that some mentally ill patients could be switched to less effective medications and experience painful withdrawal symptoms because benzodiazepines and barbiturates are excluded from being Part D drugs. Finally, a substantial number of commenters requested that CMS designate certain groups of beneficiaries—including dual eligibles; institutionalized beneficiaries; and beneficiaries with HIV/AIDS, mental illness, developmental disabilities, or other life-threatening and pharmacologically complex conditions—as special populations that are protected from the potential effects that formulary restrictions could have on their access to medically necessary prescription drugs through the inclusion of alternative or open formularies and other special provisions and exemptions.

Response: We agree with commenters' concerns about the importance of continuity of care and access to medically necessary drugs for vulnerable populations. The preamble considers the various issues that were raised in the comments relating to special populations and Part D plans' formulary restrictions, and discusses the steps we are taking to be responsive to these concerns. For example, although Part D plans will not be required to include every Part D drug on their formularies, we will require Part D plan formularies to include adequate access to a broad range of drugs used to treat diseases for which drugs exist. Additionally, we will comprehensively review Part D plans' proposed benefit designs—including their tiered cost-sharing formulary structures, P&T committee structure and utilization, utilization management policies and processes, and exceptions and appeals processes—to ensure that they provide an adequate benefit that generally complies with all applicable standards under Part D.

As discussed in the preamble, we will also review Part D plan formularies to ensure that plans do not discriminate against certain classes of Part D eligible individuals by adopting a benefit design (including any formulary or tiered formulary structure) that would substantially discourage enrollment by certain beneficiaries. We believe that our review of Part D plans' benefit designs, including their utilization management policies and processes, will address commenters' concerns regarding access to Part D drugs for vulnerable populations and ensure that Part D plans' benefit designs do not discriminate against certain groups of beneficiaries.

In addition to the safeguards noted above, as discussed in the preamble, we have also modified the final rule to include a requirement that Part D plans establish an appropriate transition process for new enrollees whose current drug therapies may not be included in the Part D plan's formulary. We expect that a plan's transition process would address procedures for medical review of non-formulary drug requests and, when appropriate, a process for switching new plan enrollees to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination. We will review the Part D plans' proposed transition processes as part of our overall benefit package review process.

We have also modified the final rule to clarify that Part D plans must disclose information about any utilization management procedures that they may use as part of the formulary information that they must disseminate to beneficiaries. We believe that this provision will assist beneficiaries in making informed choices during the enrollment process in determining which Part D plan will best meet their needs.

Additionally, as discussed elsewhere in the preamble, we believe that our approach of providing for any willing pharmacy contracts tailored to long-term care pharmacies that serve institutionalized populations will encourage the participation of long-term care pharmacies in the Part D plans' networks, and thus help to assure that institutionalized beneficiaries will continue to have access to these pharmacies, while also providing for increased competition in this area. Also, in what we anticipate are those limited instances where a beneficiary's Part D plan does not have the long-term care pharmacy servicing the beneficiary's particular long-term care facility in its network, then the beneficiary is eligible for a special enrollment period that will enable them to switch plans. Should such a change in Part D plans be necessary and involve a transition period, our rules also provide that non-routine use of an out-of-network pharmacy is permitted when the beneficiary cannot reasonably access a network pharmacy. We note that the final rule provides that CMS will pay the out-of-network differential for appropriate non-routine use of out-of-network pharmacies on behalf of all full low-income subsidy individuals and will pay amounts above the statutory cost-sharing limit for partial low-income subsidy-eligible Part D enrollees.

We have used a similar approach in addressing concerns relating to access to I/T/U pharmacies. As discussed elsewhere in the preamble, we have added a provision to our final regulations requiring Part D plans to offer contracts to all I/T/U pharmacies in their service areas, and to include a special addendum to their standard contracting terms and conditions in order to account for the special circumstances of I/T/U pharmacies.

Finally, we expect that some Medicare beneficiaries will continue to have access to drugs excluded under Medicare Part D, such as benzodiazepines, through Part D plans or State Medicaid plans. First, Medicare Part D allows PDPs and MA-PDs to provide drugs that are specifically excluded from being Part D drugs if they do so as supplemental benefits through enhanced alternative coverage. We believe that some beneficiaries with chronic conditions will choose to enroll in Part D plans that offer enhanced alternative coverage. Additionally, under Medicaid, States will be able to, at their discretion, provide coverage for a drug that is an excluded Medicare Part D drug.

c. Improved Compliance with Treatment Regimens

Available data suggest that not having drug coverage, combined with high drug expenses, may cause some beneficiaries to either not have their prescriptions filled or have them filled less often because they are not financially able to purchase outpatient prescription drugs. Because the Medicare prescription drug benefit will reduce affordability barriers associated with obtaining outpatient prescription drugs by reducing both the costs of drug treatment and beneficiaries' payments, we believe it will help to improve beneficiaries' compliance with their drug treatment regimens.

There is evidence that some beneficiaries, particularly those without drug coverage, do not fill some prescriptions ordered by their physicians and skip doses to make their drugs last longer due to cost concerns. For example, a study of Medicare beneficiaries in eight States found that among those without drug coverage, 25 percent reported not filling a prescription due to cost, while 27 percent reported skipping doses to make

drugs last longer. These rates of ''noncompliance'' with physician prescribing orders were more than double the rates reported among beneficiaries with drug coverage (Dana G. Safran, et. al., ''Prescription Drug Coverage And Seniors: How Well Are States Closing the Gap?'' Health Affairs Web Exclusive W253, July 2002, *http://content.healthaffairs.org/cgi/reprint/hlthaff.w2.253v1.pdf*).

Furthermore, analysis of data from the 2001 Medicare Current Beneficiary Survey (MCBS), a nationally representative sample of Medicare beneficiaries shows that Medicare beneficiaries without drug coverage fill fewer prescriptions than those with drug coverage. Overall, beneficiaries without drug coverage, on average, self-report filling 37 percent fewer prescriptions (18) than those with drug coverage (29). While some of this difference in utilization likely reflects differences in health status and other beneficiary characteristics, this phenomenon holds true even among groups of beneficiaries with large numbers of chronic conditions. For beneficiaries with five or more chronic conditions, those without drug coverage self-report, on average, filling approximately 38 prescriptions a year compared to beneficiaries with drug coverage, who self-report filling, on average, 50 prescriptions.

Finally, a study in the December 2001 issue of the *Journal of General Internal Medicine* found that certain characteristics, such as minority ethnicity, and low income (defined as income less than $10,000) significantly increase the risk that individuals without drug coverage will restrict their use of medications by, for example, skipping doses or avoiding taking medication altogether. For example, the odds of medication restriction in minority subjects were higher among those with no drug coverage than among those with full drug coverage. Similarly, the odds of medication restriction were higher in low-income subjects with no drug coverage than in those with full drug coverage. (Michael A. Steinman, et al., ''Self-restriction of Medications Due to Cost in Seniors without Prescription Coverage,'' 16 Journal of General Internal Medicine 793–799, Dec. 2001). Thus, comprehensive coverage is particularly likely to have an impact on prescription drug use among disadvantaged populations.

d. Improved Health and Reduction of Adverse Health Effects

Not filling prescriptions, skipping doses, or cutting pills in half are referred to in medical literature as ''medication noncompliance,'' and can have adverse health effects. We believe that by reducing financial barriers associated with obtaining outpatient prescription drugs and encouraging beneficiary compliance with their drug treatment regimens, the Medicare prescription drug benefit will reduce the occurrence of adverse health events and lead to overall improvements in beneficiaries' health.

Medication noncompliance can lead to worsening health problems and the need for additional health care services. For example, a study of prescription drug noncompliance among disabled adults found that about half of the individuals reporting medication noncompliance due to cost reported experiencing one or more health problems as a result, including pain, discomfort, disorientation, change in blood pressure or other vital signs, having to go to a doctor or emergency room, or being hospitalized. (Jae Kennedy and Christopher Erb, ''Prescription Noncompliance Due to Costs Among Adults with Disabilities in the United States,'' American Journal of Public Health, July 2002). This same study cited other research indicating that medication noncompliance is a clinical problem, particularly related to chronic illnesses such as hypertension, and has been found to be a predictor of hospital admissions and emergency room visits in other studies.

Similarly, another study found that limiting access to medications among low-income, elderly Medicaid patients increased rates of admission to nursing homes. The study analyzed Medicaid recipients aged 60 years or older who took three or more medications per month and at least one maintenance drug for chronic diseases. Limiting affordable access to prescription drugs for this population (through a reimbursement cap on medications) increased rates of admission to nursing homes. The authors concluded that for the sicker patients in the study, the limitation on medication more than ''double[d] the rate'' of admission in comparison to a group whose medications were not limited. (Stephen B. Soumerai et al., ''Effects of Medicaid Drug-Payment Limits on Admission to Hospitals and Nursing Homes,'' 325 *New England Journal of Medicine* 1072, 1074, 1991).

There is also evidence suggesting that the use of specific drugs may reduce adverse health events, utilization of other health care services, and related costs for certain groups of patients. For example, a recent study found that the use of statins in cholesterol-lowering drug therapy reduced the incidence of coronary disease-related deaths by 24 percent in elderly men and women (ages 70 to 82) with a history of, or risk factors for, vascular disease, and also reduced the incidence of non-fatal heart attacks and fatal or non-fatal strokes in these patients (''Pravastatin in Elderly Individuals at Risk of Vascular Disease (PROSPER): A Randomised Controlled Trial,'' *Lancet* 2002, 360:9346, 1623–1630).

Similarly, the Heart Outcomes Prevention Evaluation (HOPE) study has found that antihypertensive drug therapy reduced the combined risk of cardiovascular death, heart attack and stroke by 22 percent in approximately 9,000 high-risk middle-aged and elderly patients (ages 55 and older), with $871,000 in net estimated savings associated with direct hospitalization and procedural costs for this cohort of patients over the first 4 years of the study, and also significantly reduced the risk of adverse cardiovascular outcomes by 25 to 30 percent in a broad range of high-risk middle-aged and elderly patients with diabetes mellitus (See ''Drug Therapy and Heart Failure Prevention,'' Editorial, Jennifer V. Linseman, PhD, and Michael R. Bristow, MD PhD, *Circulation* 107:1234, American Heart Association, 2003; ''Economic Impact of Ramipril on Hospitalization of High-Risk Cardiovascular Patients,'' Cathryn A. Carroll, PhD MA MBA BSPharm, *The Annals of Pharmacotherapy*, Volume 37, No. 3, pp. 327–331; and ''Effects of Ramipril on Cardiovascular and Microvascular Outcomes in People With Diabetes Mellitus: Results of the HOPE Study and MICRO-HOPE Substudy, Evaluation (HOPE) Study Investigators, *Lancet* 355 (9200):253–259, 2000).

While there is evidence that the use of certain prescription drugs may be cost-effective for specific groups of patients (in the sense that they result in net health care cost savings or produce health improvements at relatively low cost), thus far it has been difficult to generalize the results of these drug-specific studies more broadly to estimate the potential health care cost savings or morbidity or mortality reductions in the context of an overall Medicare prescription drug benefit. First, the findings from available cost-effectiveness analyses in the literature suggest that while some prescription drugs may lead to short-term or long-term reductions in net health care costs, other prescription drugs may lead to net increases in health costs (for example, as a result of adverse drug reactions which require additional health care services). Second, the Medicare prescription drug benefit will improve access to prescription drugs for a

broader patient population than is typically included in the available studies in the literature, which may affect the potential cost-effectiveness of certain drugs. For example, while the literature suggests that the use of statin drugs for lowering blood cholesterol levels in patients with existing heart disease is relatively cost-effective, using these drugs to preventively lower blood cholesterol levels in patients that do not have heart disease may be less cost-effective (see ''Are Pharmaceuticals Cost-Effective? A Review Of The Evidence,'' Peter J. Neumann, Eileen A. Sandberg, Chaim M. Bell, Patricia W. Stone, and Richard H. Chapman, *Health Affairs* 19:2, March/April 2000; and ''The Price of Progress: Prescription Drugs in the Health Care Market,'' J. D. Kleinke, *Health Affairs* 20:5, September/October 2001 available at *www.healthaffairs.org*).

In addition to the anticipated reductions in adverse health events associated with anticipated improvements in prescription drug compliance, we believe that many elements of the Medicare prescription drug benefit—including quality assurance, electronic prescribing, better beneficiary information on drug costs and ways to reduce drug costs (for example, through generic substitution), and medication therapy management which are designed to improve medication use and reduce the risk of adverse events, including adverse drug interactions—will also improve beneficiaries' health outcomes. We believe that these improvements will occur through enhanced beneficiary education, health literacy and compliance programs; improved prescription drug-related quality and disease management efforts; and ongoing improvements in the information systems that are used to detect various kinds of prescribing errors—including duplicate prescriptions; drug-drug, drug-allergy and drug-food interactions; incorrect dosage calculations, and problems relating to coordination between pharmacies and health providers. We also believe that additional reductions in errors and additional improvements in prescription choices based on the latest available evidence will occur over time as the electronic prescribing provisions of the MMA are implemented (T*o Err is Human: Building A Safer Health System*, Institute of Medicine of the National Academies, 1999, pp. 191–193, *www.iom.edu* or *www.nap.edu*).

Ultimately, we believe that the evidence supports our conclusion that making prescription drugs more available and affordable will help beneficiaries to live healthier, more productive lives. We also believe that expanding prescription drug coverage will reduce adverse health events and Medicare program spending on more costly services for some beneficiaries, and will be particularly important for beneficiaries with limited means who are more likely to forego beneficial prescription drugs when they do not have coverage. However, the effect on aggregate Medicare program spending across all beneficiaries is difficult to ascertain. At this time, there have not been studies that have found evidence that expansions of drug coverage across a large population, as will occur under the Medicare drug benefit, yields aggregate health care cost savings. Furthermore, there have been mixed results on the impact of coverage on the cost-effectiveness of care involving certain individual drugs in general, and in differing patient populations. Thus, the extent to which the Medicare drug benefit may lead to reductions in Medicare spending for other health care services in the aggregate across all beneficiaries is difficult to predict. Additional research will be needed to further examine and quantify these potential effects. For example, we are currently conducting a demonstration study on the extent to which coverage of oral medicines reduces the use of professionally-delivered medicines and the associated physician and health care services that are currently covered in Part B. We are very interested in developing further evidence on the best ways to encourage outcome improvements and overall health care cost reductions through drug coverage. For example, we are currently collaborating with AHRQ and other experts to identify priorities for developing better evidence and increasing value in the use of outpatient medications, and intend to develop further evidence as part of the implementation of the drug benefit.

In the proposed rule, we requested comments related to how outcome improvements and overall health care cost reductions related to drug coverage can be incorporated into the implementation of the drug benefit.

Comment: We received a comment from a quality organization which stated that when administered appropriately, a prescription drug benefit can affect care across the spectrum, from preventing infection or disease to managing or reversing the impact of chronic disease, and controlling the cost of overall care; however, a poorly managed drug benefit can worsen the health of beneficiaries, raise costs, and potentially negatively affect public health. The commenter went on to state that prescription drugs are a critical element of an evidence-based benefit package, and that administration of a drug benefit must simultaneously guard against potential underutilization of needed drugs and over utilization of inappropriate drugs, both of which have the potential to negatively affect quality and costs for the individual and for society as a whole. Another quality organization stated that medication therapy management program services are a vital component for ensuring that Medicare beneficiaries receive their Part D benefits in a safe and effective manner. Several quality organizations provided recommendations relating to Part D plan quality assurance measures and systems, encouraged us to develop quality and performance measures for assessing the services provided by PDPs and MA-PDs, and offered to assist us in developing requirements and performance measures. Additionally, we received a number of comments that included examples of successful medication therapy management programs and described methods for measuring outcomes for asthmatic, diabetic, and hypertensive patients. Additionally, one quality organization commenter urged us to standardize the format, terms, definitions, and types of information that PDP sponsors will use in describing their quality assurance measures and systems and medication therapy management programs in the plan information they disseminate to beneficiaries.

Response: We appreciate the information that commenters provided relating to incorporating quality improvements and potential cost reductions into the implementation of the Medicare drug benefit. We agree that effective medication therapy management programs and quality assurance measures and systems can help to improve beneficiaries' health outcomes, and ultimately reduce health care costs, and will continue to look at this issue closely. As mentioned in the preamble, we intend to work with various stakeholders to develop appropriate quality elements and utilization measures, and incorporate them into Medicare Part D where appropriate.

4. Positive Effects of the Medicare Retiree Drug Subsidy and Other Employer/Union Options for Providing Prescription Drug Assistance

The Medicare prescription drug benefit and retiree drug subsidy represent additional funding sources that can help employers and unions continue to provide high quality drug

coverage for their retirees. In this section, we describe the Medicare retiree drug subsidy and the various other ways that Medicare Part D offers financial assistance with retiree prescription drug costs to employers and unions. We also discuss some of the potential effects that these options will have on the availability and generosity of retiree drug coverage for Medicare-eligible retirees.

We anticipate that these new sources of support will have many important positive benefits for the quality and security of drug coverage for retirees. Overall, we believe that the implementation of Medicare Part D, including the Medicare retiree drug subsidy and the other opportunities it affords employers and unions for providing continued prescription drug assistance to their Medicare retirees, will result in combined aggregate payments by employers/unions and Medicare for drug coverage on behalf of retirees that are significantly greater than they otherwise would have been without the enactment of the MMA. Furthermore, we believe that the Medicare prescription drug benefit and retiree drug subsidy represent a particularly important strengthening of health care coverage for future Medicare-eligible retirees, given the erosion in the availability and generosity of employment-based retiree coverage for future Medicare beneficiaries that has already been taking place.

a. Overview of the Medicare Retiree Drug Subsidy

The positive benefits for retiree coverage from the new retiree drug subsidy program are related to the subsidy payments it will make available to sponsors of employer and union plans that provide high quality retiree drug coverage, the special tax-favored status of the subsidy payments that will be made to the qualified retiree health plan sponsors, and the flexibility in using the subsidy to support retiree coverage. The retiree drug subsidy program has highly flexible rules and stands as an additional option that permits employers and unions to continue providing drug coverage to their Medicare-eligible retirees while retaining their current plan designs that are at least equivalent to the standard Part D benefit, and receiving a Federal subsidy that reduces the cost of providing this coverage. We note that employers and unions that want to participate in the retiree drug subsidy program also retain the option of providing regular supplementation to Medicare Part A and Part B benefits through arrangements with Medicare Advantage organizations offering a MA only plan without the Part D benefit, while still qualifying for the retiree drug subsidy program by arranging for an employer or union-sponsored retiree drug benefit through a separate private contract with the MA organization.

The intent of the Medicare retiree drug subsidy is to offer qualified retiree prescription drug plans financial assistance with a portion of their prescription drug costs and thereby ''help employers [to] retain and enhance their prescription drug coverage so that the current erosion in coverage would plateau or even improve'' (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Conference Report, p. 53). By making a tax-free subsidy for 28 percent of allowable prescription drug costs attributable to the portion of each qualifying retiree's gross prescription drug costs that is between the cost threshold and cost limit (that is, drug spending between $250 and $5,000 for 2006) available to qualified retiree prescription drug plans, the Medicare retiree drug subsidy significantly reduces the financial liabilities associated with employment-based retiree drug coverage and encourages employers and unions to continue assisting their retirees with prescription drug coverage.

To provide a rough estimate of the per capita retiree drug subsidy, we used MCBS data on prescription drug spending for retirees with employment-based coverage, adjusted for under-reporting, and trended these data forward based on the projected growth rate in prescription drug spending from the National Health Expenditures projections. We then applied 28 percent to the drug spending between $250 and $5,000 to approximate the average annual retiree drug subsidy for 2006. This calculation yielded an estimated per capita retiree drug subsidy amount of $668 in 2006. The per capita subsidy amount was calculated across all beneficiaries in qualified retiree prescription drug plans, including both those who do and do not have spending high enough to qualify for a Medicare retiree drug subsidy payment. In the proposed rule, we sought comment on the completeness and accuracy of our MCBS-based projections for valuing the retiree subsidy. While we did not receive any comments specifically relating to the use of MCBS data for valuing the retiree drug subsidy, we did receive comments about the use of MCBS data more generally (see section D of this impact analysis). As discussed in more detail previously, we acknowledge that there are limitations associated with using MCBS data; however, we believe that the MCBS offers the best data available for making these estimates because it is the largest nationally representative survey of prescription drug utilization and costs for Medicare beneficiaries.

The Medicare retiree drug subsidy is excluded from the taxable income of the plan sponsor (just as the Medicare subsidy provided to beneficiaries through the Medicare prescription drug benefit is excluded from the taxable income of the beneficiary). While the tax-free nature of the retiree drug subsidy does not affect the value of the subsidy to firms without taxable income, the tax-free nature of the Medicare retiree drug subsidy generally increases its value to plan sponsors that are subject to taxation. As indicators of the value of this tax subsidy, we provide some estimates of the equivalent values of a taxable subsidy for employers at several corporate income tax rates. For corporations with taxable incomes, marginal tax rates generally range from 15 percent to 35 percent. According to estimates by the Congressional Research Service, the weighted average effective tax rate for corporations that pay taxes is approximately 28.5 percent (Congressional Research Service, ''Weighted Effective Total Tax Rates on the Corporate and Noncorporate Sectors,'' cited in the Congressional Budget Office's letter and report to the Honorable Don Nickles, February 24, 2004, see *www.cbo.gov*). Combining this tax rate and the estimated $668 average per capita subsidy amount for 2006, we estimate that the $668 tax-free retiree drug subsidy amount would be equivalent to a taxable subsidy of $934 for employers subject to taxation. The equivalent taxable subsidy for any particular employer with taxable income would, of course, vary depending on its specific marginal tax rate. For example, the tax-free $668 average retiree drug subsidy amount would be equivalent to about $891 of taxable income for employers with a marginal tax rate of 25 percent and about $1,028 of taxable income for employers with a marginal tax rate of 35 percent.

Our implementation of the retiree drug subsidy program is guided by the following four policy goals: 1) maximizing the number of Medicare-eligible retirees with high quality employer or union-provided retiree drug coverage, and maximizing the generosity of their coverage; 2) avoiding financial windfalls in the retiree drug subsidy program by ensuring that plan sponsors contribute at least as much to retiree drug coverage as Medicare pays them as a subsidy; 3) minimizing

administrative burden while maximizing flexibility for employers and unions; and 4) fulfilling our fiduciary responsibility by limiting overall budgetary costs. We have taken a number of steps to be responsive to the concerns that were raised in the comments relating to the retiree drug subsidy program. We believe that the flexibility that we have provided relating to actuarial equivalence, plan definition, qualifying covered retirees, payment methodology, and data reporting requirements will make it easier for employers and unions to continue offering their existing retiree drug plans to Medicare-eligible retirees, while qualifying for the retiree drug subsidy.

b. Overview of Additional Options Available to Employers and Unions Through Medicare Part D

As indicated earlier, in addition to the ability to obtain Medicare retiree drug subsidy payments for sufficiently generous drug coverage, Medicare Part D also gives employers and unions a variety of other options for continuing to assist their Medicare-eligible retirees in obtaining more generous drug coverage. For example, employers and unions that are supporting retiree coverage now could also choose to provide additional drug coverage by using the new Medicare Part D subsidy directly (that is, encouraging their retirees to enroll in a Medicare Part D plan which includes a significant government subsidy for the standard benefit) with the employer/union providing additional coverage over and above the standard Part D benefit that maintains or exceeds the generosity of their current benefit designs. This can be achieved by either: 1) arranging for a PDP or MA-PD Part D plan to provide enhanced benefits to their retirees; 2) arranging for a PDP or an MA-PD under a waiver to offer a customized plan that is exclusive to the employer or union's retirees; 3) choosing through a waiver to become a Part D plan for their retirees that offers enhanced benefits (this is equivalent to offering a self-insured benefit); or 4) providing separate supplemental drug coverage that wraps around a Part D plan (similar to the typical employer and union policies that wrap around Medicare benefits under Part A and Part B). In addition to the various options that are available for providing additional retiree drug coverage in coordination with a Part D plan, employers and unions also have the opportunity to assist their Medicare-eligible retirees in paying all or part of their Part D premiums.

Under these approaches for coordinating employer or union-sponsored retiree drug coverage with Part D, the employers/unions' costs associated with providing retiree drug benefits are reduced on a dollar-for-dollar basis by the amount that Medicare subsidizes Part D plans. For example, we estimate that employers and unions that choose to provide enhanced or separate supplemental drug coverage that wraps around Part D will achieve, on average, a minimum of $900 per beneficiary of savings in 2006.

For Medicare Advantage Part C, we have broad authority to waive rules that hinder the design, enrollment in, or offering of employer plans to Medicare eligible beneficiaries. We believe that this waiver authority, which has also been extended to Part D, can assist PDPs and MA-PDs in designing prescription drug benefits that are offered exclusively to employers for their retiree populations, and make it easier for employers to contract with (or become) PDPs and MA-PDPs to provide enhanced benefits to their retirees that supplement the standard Part D benefit (for example, additional assistance with cost sharing).

We anticipate providing considerable flexibility in the waiver process for PDPs and MA-PDs that are offered exclusively to employers. As discussed in the preamble, we will be using a streamlined approach for implementing employer group waivers that allows maximum flexibility for employers to retain retiree prescription drug coverage. As part of this process, we will include details on the types of waivers that we will consider in guidelines, and we will address additional waiver requests from specific employers or plans on a flow basis. Additionally, we note that once waivers have been granted, they will be available to all similarly situated employers or unions, thus maximizing the number of employers that will be able to benefit from the flexibility of the waiver process.

We are also committed to easing the transition to employer/union participation in providing separate supplemental coverage that wraps around Part D. Employers and unions that choose this option will need to coordinate their wraparound benefits with the standard Part D benefit, a function that can be performed by the employer or union's insurer or third party administrator. As discussed more fully in the preamble, CMS will play a role in facilitating coordination of benefits and the tracking of TrOOP. We are considering the most efficient way of assisting in coordinating benefits and TrOOP tracking, including through the establishment of a TrOOP facilitation contractor, contractors, or a blend of approaches. We will provide more details of our solution in this regard in CMS guidance to be released before the statutory deadline of July 1, 2005. We believe that the TrOOP facilitation process will make it easier for employers and unions to offer supplemental coverage that wraps around Part D.

Finally, it is important to note that since the final rule includes a two-prong actuarial equivalence test for qualifying for the retiree drug subsidy, as discussed in subpart R of the preamble, there may be some employers or unions that provide retiree drug coverage that is creditable on a gross value basis but, for example, are not making sufficient contributions toward the financing of the benefit to qualify for the retiree drug subsidy on a net value basis. These employers and unions can choose at any time to modify their existing retiree drug benefit designs to supplement Part D. Under this circumstance, as discussed in subpart B of the preamble, the Medicare retirees would be eligible for a special enrollment period for Medicare Part D because their retiree drug coverage no longer meets the criteria for creditable coverage. The special enrollment period provision would enable these employers/unions to work with their retiree populations and the new Part D plans to achieve a smooth transition and ensure that their Medicare-eligible retirees would not be subject to late enrollment penalties when they enroll in Part D. We believe that the availability of special enrollment periods provides important additional flexibility and time to employers and unions as they evaluate the various options that are available to them under the Medicare drug benefit and retiree drug subsidy.

c. How Employers and Unions Are Likely To Respond To The Options That Are Available To Them Under The MMA

While there is considerable uncertainty about the choices that employers and unions will make regarding the form of prescription drug assistance that they may choose to provide for their Medicare-eligible retirees, we believe that employers and unions will generally continue to provide prescription drug assistance to their retirees and that Medicare Part D will make it more affordable for them to do so.

First, as we noted in the proposed rule, with the decline over the years in the number of employers/unions offering retiree health insurance coverage, it is likely that many of the remaining employers and unions who

continue to offer such coverage directly are likely those employers/unions who have a contractual commitment or other interest in maintaining that coverage.

Second, although employers and unions' responses to Medicare Part D and the retiree drug subsidy are expected to play out over the next few years, initial signals suggest that there has been a positive response to the Medicare retiree drug subsidy. Several major employer associations have praised the MMA for giving businesses flexibility in deciding how their retiree health plans will work in relation to the Medicare prescription drug benefit, and for offering employers and unions a 28 percent Medicare retiree drug subsidy payment that would not be taxed for plan sponsors who continue to provide high quality retiree coverage (''ECOM Applauds Historic Passage of Medicare Reform Legislation,'' Employers' Coalition on Medicare press release, November 25, 2003, *www.employersandmedicare.org*; ''Chamber Praises Congressional Action on Medicare Reforms,'' U. S. Chamber of Commerce, November 25, 2003, *www.uschamber.com*).

Additionally, several major corporations issued 2003 annual reports that included estimates suggesting that they will collectively experience an $11.8 billion reduction in their accumulated postretirement benefits obligation that will occur over time due to the Medicare subsidy payments they anticipate receiving under the Medicare retiree drug subsidy program (''Expected Cost Savings From Medicare Act May Top $11.8 Billion'', Lingling Wei, Dow Jones Newswires, The Wall Street Journal, March 22, 2004, available at *www.wsj.com*). Although some of these companies may have needed to revise their initial estimates to reflect the Financial Accounting Standards Board's (FASB) Final Staff Position on accounting for the effects of the Medicare retiree drug subsidy payments, which was effective for financial statements for periods beginning after June 15, 2004 (''FASB Staff Position Number FAS 106–2, Accounting and Disclosure Requirements Related to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003,'' posted May 19, 2004, available at *www.fasb.org*) and the provisions of this final rule, these initial reports suggest that some employers are already planning to take advantage of the substantial savings that are available to them under Medicare Part D.

However, given the uncertainty that exists about the future choices that employers and unions will make we requested comments about how employers and unions are likely to view the various options that are available under Medicare Part D for assisting them in continuing or enhancing their retiree health benefits. Specifically, we were interested in comments on the factors that will affect employers' and unions' choices between applying for the retiree drug subsidy, wrapping around Part D coverage, qualifying as an enhanced Part D plan directly, or using an enhanced PDP or MA-PD plan to provide enhanced coverage to their retirees. This information will assist us in understanding how these options can be designed together to maximize the increase in availability of high quality drug benefits for retirees. The following sections summarize the major issues relating to employers and unions' likely responses to the various options available to them under the MMA that we discussed in the proposed rule, as well as the comments that we received relating to these issues.

i. Major Factors That Will Affect Employers And Unions' Responses To The Options That Are Available To Them Under The MMA

In the proposed rule, we identified several factors that could potentially influence employers and unions' responses to the opportunities for continuing to provide high quality retiree drug benefits that are available to them through the retiree drug subsidy and the various options that are available for coordinating their coverage with Part D.

For example, we noted that the Medicare retiree drug subsidy is excluded from the taxable income of the plan sponsor (just as the Medicare subsidy provided to beneficiaries through the Medicare prescription drug benefit is excluded from the taxable income of the beneficiary). While the tax-free nature of the retiree drug subsidy does not affect the value of the subsidy to firms without taxable income, the tax-free nature of the Medicare retiree drug subsidy generally increases its value to private sector employers that are subject to taxation. For example, as noted previously, the tax-free $668 average retiree drug subsidy amount would be equivalent to about $891 of taxable income for employers with a marginal tax rate of 25 percent and about $1,028 of taxable income for employers with a marginal tax rate of 35 percent.

We also stated that based on published employer surveys, reports from employers and benefit consultants, and other available sources of evidence, we expect that some employers and unions will choose to provide prescription drug assistance to their Medicare-eligible retirees in the form of enhanced benefit packages through Part D plans or separate wraparound coverage. In both cases, the employer/union contributions would augment Medicare's subsidized coverage under Part D. We noted that many employers and unions currently do this relative to Medicare Part A and Part B coverage, either through separate supplemental policies or through arrangements with Medicare Advantage plans. In fact, the Medicare retiree drug subsidy represents a new type of arrangement for employers and unions relative to the interaction of their retiree coverage with Medicare. Thus, some employers and unions may prefer to interface with the new Medicare prescription drug benefit in a manner similar to their supplementation of the basic Medicare Part A and Part B benefits. We also stated that we expect that many of the employers and unions that choose to provide drug coverage through or in coordination with Part D will also choose to pay some or all of their retirees' Part D premiums. Since the Medicare Part D drug benefit includes a direct Federal subsidy, these approaches would allow employers and unions to continue to provide a benefit package of similar or greater generosity compared to their existing arrangements while potentially lowering their prescription drug costs.

We also noted that another important factor that will affect whether employers or unions will use the retiree drug subsidy is whether their contribution to the retiree coverage is sufficient to qualify for the retiree drug subsidy, and if it is not currently sufficient, whether they will increase the generosity of their contribution in order to receive the cash and tax value of the subsidy. We suggested that such increased contributions could be in the financial interest of some employers and unions because they could qualify for the value of the full subsidy by making an additional incremental contribution of less than the full value of the subsidy, thereby achieving net savings. However, we also stated that providing enhanced benefits or separate wraparound coverage in coordination with Part D may also be an attractive option to employers and unions that may not be eligible for the Medicare retiree drug subsidy because their retiree drug benefits, as currently structured, are not actuarially equivalent to the standard Medicare Part D drug benefit. In both cases, these employers/unions could use their contributions to augment Medicare's subsidized coverage under

Part D, and thereby provide a more generous benefit to their Medicare-eligible retirees.

Comment: We received several public comments from employers and employer groups that supported the MMA and proposed rule's overall approach of encouraging employers and unions to continue providing retiree health coverage, while providing flexibility and minimizing administrative burdens. Several of these comments indicated that employer and union retiree health plan sponsors' responses to the various options that are available to them under the Medicare drug benefit and retiree drug subsidy will be affected by a variety of factors, including: the timeframe of CMS regulation and guidance; the degree of flexibility in the retiree drug subsidy program (for example, relating to the actuarial equivalence methodology, application process, plan sponsor and qualifying covered retiree definitions, payment methodology and frequency, and subsidy payment allocation requirements); the amount of flexibility in the waiver process for employer-sponsored PDPs and MA-PDs; the financial incentives and degree of administrative burden associated with the various options; the timely availability of feasible PDP and wraparound options in the market; and employers and unions' own internal timeframes and processes required to make benefit design changes.

We also received several comments suggesting that plan sponsors' responses to the various options that are available to them under the MMA, including whether or not they will choose to accept the retiree drug subsidy, may vary according to the type of employer or union plan. For example, one commenter stated that small, self-insured employers might find that the cost of obtaining an actuarial attestation may exceed the value of the retiree drug subsidy payments that they would receive. Similarly, a few commenters stated that employer/union plan sponsors and insurers offering fully-insured retiree health plans might have difficulty tracking claims at the individual plan sponsor level for purposes of meeting the retiree drug subsidy program's data submission and record retention requirements.

Additionally, a few public sector employer commenters stated that the definition of plan sponsor that was being used in the proposed rule did not seem to be broad enough to allow some public retirement systems to qualify for the retiree drug subsidy. Two public sector employer commenters suggested that some governmental entities may be discouraged from obtaining the retiree drug subsidy because its tax-free nature does not provide an additional financial incentive to non-taxable plan sponsors that provide retiree health benefits. Also, one public employer group commenter requested that we assure through final regulations or the waiver process that State and local government plans have the same opportunity to directly sponsor a PDP or MA-PD as other employer/union plan sponsors.

Finally, a few commenters expressed concerns that retiree health plans with limited employer/union contributions—including some State and local government retiree health plans and many church plans that require their retirees to contribute in excess of 50 percent of the cost of prescription drug coverage—might have difficulty qualifying for the retiree drug subsidy if a net-value test is used in determining actuarial equivalence.

Response: In recognition of the considerable diversity that exists within the employer and union community, the MMA gives employers and unions several options for accessing the new financial resources that Medicare Part D makes available for assisting them in continuing to offer high quality retiree drug coverage. For example, employers and unions have the option of continuing to provide drug coverage that is at least actuarially equivalent to the standard Part D benefit for their Medicare-eligible retirees as a primary insurer, and receiving a direct retiree drug subsidy that reduces the cost of providing this coverage. As discussed in more detail in subpart R, to qualify for the retiree subsidy, plans must meet a two-prong test for actuarial equivalence, which includes a net-value test. We chose this definition of actuarial equivalence for the retiree subsidy because we believe it best achieves our goals of maximizing the number of beneficiaries retaining employment-based retiree drug coverage while not creating windfalls to sponsors.

Employers and unions, including those that do not qualify for the subsidy, have several other options under Medicare Part D for providing prescription drug assistance to their retirees. For example, employers and unions can choose to offer drug coverage that maintains or exceeds the generosity of their current benefit designs by providing additional coverage that complements the standard Part D prescription drug benefit, effectively becoming a secondary insurer that uses the Part D benefit to subsidize the costs of their Medicare-eligible retirees' drug coverage. As discussed earlier, this coordination can be achieved by: 1) arranging for a PDP or MA-PD Part D plan to provide enhanced benefits to their retirees; 2) arranging for a PDP or an MA-PD under a waiver to offer a plan that is exclusive to the employer's retirees; 3) choosing through a waiver to become a Part D plan that offers enhanced benefits; or 4) providing separate supplemental drug coverage that wraps around a Part D plan (similar to policies that wrap around Medicare benefits under Parts A and B). We recognize that some of the options that are available through the Medicare drug benefit and retiree drug subsidy may be more attractive to certain employers/unions than other options. However, we believe that these options give employers and unions a wide variety of opportunities for continuing to provide a generous level of retiree coverage.

Our implementation of the various options that are available to employers and unions under the Medicare drug benefit and retiree drug subsidy for continuing to offer high quality prescription drug coverage to Medicare-eligible retirees at a lower cost is guided by four policy goals: 1) maximizing the number of Medicare-eligible retirees with high quality employer or union-provided retiree drug coverage, and maximizing the generosity of their coverage; 2) avoiding financial windfalls in the retiree drug subsidy program by ensuring that plan sponsors contribute at least as much to retiree drug coverage as Medicare pays them as a subsidy; 3) minimizing administrative burden while maximizing flexibility for employers and unions; and 4) fulfilling our fiduciary responsibility by limiting overall budgetary costs. The preamble considers the issues that were raised in the comments from employers, unions, and other related entities and describes the policy decisions that we made relating to these issues, balancing the various policy goals in an effort to achieve the maximum increase in support for retiree health coverage as existing employer and union contributions are augmented by new financial support from the Medicare prescription drug benefit and retiree drug subsidy. We have taken a number of steps to be responsive to the concerns that were raised in the comments. Similarly, we are exploring options for increasing flexibility in employers' and unions' ability to directly sponsor PDPs or MA-PDs. For example, as discussed in the preamble, we have provided flexibility in the payment methodology and data submission requirements related to retiree drug subsidy payments to plan sponsors with insured benefits.

In addition, where appropriate, the potential impact of these various policy decisions has been factored into the projection assumptions for the impact analysis, as discussed elsewhere in this impact analysis.

ii. Potential Effect of Factors Unrelated to Medicare on Employer and Union Behavior

In the proposed rule, we noted that although the Medicare prescription drug benefit and retiree drug subsidy represent additional funding sources for employment-based retiree drug coverage that can help employers and unions to retain drug coverage for their retirees, there are also a number of economic forces unrelated to Medicare that will play a role in employers' and unions' decision making regarding both the availability and the generosity of employment-based retiree health coverage. Many of the economic forces behind the ongoing erosion of retiree health benefits that are discussed subsequently in this impact analysis may continue to give employers and unions a financial incentive to reduce the costs associated with providing retiree health coverage. The Employee Benefit Research Institute (EBRI) has estimated that additional declines in retiree drug coverage could potentially continue to occur, particularly for future retirees, ''due to existing business, accounting, and cost trends,'' regardless of changes in the Medicare program (EBRI Special Analysis prepared for Senator Charles E. Grassley, Dallas L. Salisbury and Paul Fronstin, Employee Benefit Research Institute, July 18, 2003, available at *www.ebri.org*).

Comment: We received one comment from a retiree advocacy group suggesting that the recent Equal Employment Opportunity Commission (EEOC) ruling could significantly affect employer/union behavior relating to retiree health benefits for Medicare-eligible retirees.

Response: As noted above, several economic and non-economic forces that are not related to the Medicare retiree drug subsidy and the other opportunities that are available for coordinating employer/union-sponsored coverage with Part D could potentially influence employers' and unions' decisions about the availability and generosity of retiree health benefits for Medicare-eligible retirees. We agree that the recent EEOC ruling is a non-Medicare related factor that could potentially affect employers' and unions' behavior concerning retiree drug coverage. In that ruling, the EEOC approved a proposed final rule that would allow ''employers and labor organizations to offer retirees a wide range of health plan designs that incorporate Medicare or comparable State health benefit programs without violating the ADEA.'' EEOC states that its proposed final rule would enable employers and unions to supplement a retiree's Medicare coverage or take advantage of the tax-free retiree drug subsidy without having to demonstrate that the drug coverage they provide to their Medicare-eligible retirees is identical to the drug coverage that they offer to their early retirees. There is considerable uncertainty about how the EEOC's ruling will ultimately affect employer and union behavior (see EEOC web site, *http://www.eeoc.gov/policy/regs/retiree_benefits/*).

Similarly, the Governmental Accounting Standards Board (GASB, which develops accounting standards for State and local governments) recently issued Statement No. 43, Financial Reporting for Postemployment Benefit Plans Other Than Pension Plans and Statement No. 45, Accounting and Financial Reporting by Employers for Postemployment Benefits Other Than Pensions, which will require State and local governments to begin reporting the long-term costs of their retiree health benefit liabilities on an accrual basis and will encourage them to begin setting aside money in trust funds to cover the future costs of providing benefits to their retirees (''GASB Issues Standards to Improve Postemployment Benefit Plan Reporting,'' May 11, 2004 and ''GASB Issues Statement That Addresses Employer Reporting of Postemployment Benefits Other Than Pensions,'' August 2, 2004, see GASB web site, *http://www.gasb.org/news/index.html*). Some experts have speculated that the GASB standards could put additional financial pressures on State and local governments to reduce their financial liabilities by making changes in their retiree health benefits; however, others have noted that some State and local governments may find it difficult to make such changes due to legislative and collective bargaining considerations, or may not opt to make such changes due to labor relations considerations.

Additionally, while there is some uncertainty relating to their potential impact on employer and union behavior, factors such as existing caps on retiree health benefits that have been instituted by some plan sponsors, and demographic trends could also potentially influence employer and union decision making concerning retiree health benefits. Furthermore, as discussed elsewhere, the availability and generosity of retiree health coverage had been declining for more than a decade prior to enactment of the MMA, particularly for future retirees, and available evidence suggests that this erosion is continuing to occur (primarily in the form of increasing retirees' share of premiums and increasing eligibility restrictions for future retirees) due to ongoing financial pressures on employers (Comments made during discussion of the Medicare Payment Advisory Commission (MedPAC) Supplement to the Kaiser/HRET Survey, Transcript of MedPAC Public Meeting, November 16, 2004, see MedPAC web site, *http://www.medpac.gov/public_meetings/transcripts/1104_allcombined_transc.pdf*).

iii. Employers And Unions Have Not Yet Decided How They Will Respond

In the proposed rule, we noted that some employers and unions have not yet decided whether they will apply for the Medicare retiree drug subsidy, and are considering the various other options that are available for providing prescription drug assistance to their Medicare-eligible retirees (See Press Releases and Statements, Press Room of the Employers' Coalition on Medicare, available at www.employersandmedicare.org). We also noted that at the time that the proposed rule was published, most publicly traded companies had chosen to defer recognizing the effects of the Medicare retiree drug subsidy payments pending receipt of additional accounting and regulatory guidance. However, we noted that available evidence suggests that numerous large companies that offer employment-based retiree prescription drug coverage anticipate continuing to provide this coverage and accepting the Medicare retiree drug subsidy payments.

Comment: We received comments suggesting that most employers and unions have not yet decided how they will respond to the options that are available to them under the Medicare drug benefit and retiree drug subsidy. However, a few commenters did provide some information about employers' and unions' future plans. For example, two public sector employer commenters expressed a desire to continue providing their current retiree health benefits and receive the retiree drug subsidy. Similarly, a retiree advocacy group comment included information about a private employer that plans to separate its retiree drug coverage from its other retiree health coverage so that its Medicare-eligible retirees can choose between remaining in the employer's retiree drug plan or enrolling in a Part D plan, and plans to stop offering retiree drug coverage in a few years when the value of its retiree drug benefit becomes

lower than the value of the standard Part D benefit due to existing financial caps that the company had placed on its contribution to the costs of retiree coverage.

Response: Recent anecdotal information from various benefit consultants, researchers, and other experts suggests that many employers and unions have not yet determined how they will respond to the options that are available under the Medicare drug benefit and retiree drug subsidy, due to uncertainty about some of the details relating to how these options will be implemented.

However, in spite of employers and unions' uncertainty, some early evidence suggests that many employers and unions are likely to continue providing prescription drug assistance to their Medicare-eligible retirees. Recent surveys that included questions related to the Medicare drug benefit and retiree drug subsidy suggest that the vast majority of current Medicare-age retirees are likely to continue receiving some form of prescription drug assistance from their former employers/unions—either primary drug coverage that qualifies for the retiree drug subsidy, enhanced or supplemental coverage that wraps around the standard Part D benefit, or assistance with paying Part D premiums—and that few beneficiaries with retiree drug coverage were likely to lose their employment-based retiree drug benefits and/or retiree health benefits. The surveys suggest that many employers are likely to continue to assist their retirees by taking advantage of the financial support for retiree drug coverage that is available through the retiree drug subsidy and other options for coordinating with Part D, rather than ceasing to provide prescription drug assistance for their Medicare-eligible retirees (Comments made during discussion of the Medicare Payment Advisory Commission (MedPAC) Supplement to the Kaiser/HRET Survey, Transcript of MedPAC Public Meeting, November 16, 2004, see MedPAC web site, *http://www.medpac.gov/public_meetings/transcripts/1104_allcombined_transc.pdf*; Kaiser/Hewitt 2004 Survey on Retiree Health Benefits).

iv. Employers' And Unions' Responses May Change Over Time

Comment: We received several comments suggesting that employers' and unions' responses to the various options that are available to them under the Medicare drug benefit and retiree drug subsidy may change over time. For example, a benefit consultant stated that many plan sponsors will initially be attracted to accepting the retiree drug subsidy because this decision may be the easiest course administratively; however, as time goes on, it may be more attractive for employers and unions to consider modifying their retiree drug plans to supplement and coordinate with Part D. This benefit consultant also anticipated that the typical employer/union plan will provide retiree drug benefits that are better than Part D in 2006, but suggested that this pattern is likely to reverse over time. This commenter stated that the value of employment-based coverage for future retirees may well be less than the value of the highly-subsidized standard Part D coverage, suggesting that as plan sponsors' retiree populations begin to include more future retirees (who may be disproportionately affected by the economic caps that some companies have placed on their contributions to the cost of retiree coverage), this could result in a gradual shift in the average generosity of employment-based plans, thus making the option of supplementing the Part D benefit a more attractive approach for providing retiree drug coverage.

Similarly, we received a comment suggesting that another factor that may contribute to changes in employer and union behavior over time relates to the effect of financial caps that some employers have placed on their contributions to retiree health benefits in response to rising costs and the implementation of Financial Accounting Statement No. 106 (FAS 106). Specifically, as employers' contribution levels reach these caps, their retiree drug plans may no longer qualify for the retiree drug subsidy, or their retiree drug plans could become less valuable than the new Medicare drug benefit.

In addition, several commenters stated that employers and unions typically require a lead-time of at least one year to implement benefit design changes (and even longer in the case of church plans), and may not have sufficient advance information that would enable them to take full advantage of the various options that are available to them under Medicare Part D by 2006. For example, two commenters indicated that although employers are very interested in the option of wrapping around Medicare Part D coverage, they do not yet see arrangements in the marketplace that they feel would make this option feasible, such as the availability of cross-regional PDP and MA-PD offerings.

Response: In responding to the various options that are available to them under the Medicare drug benefit and retiree drug subsidy, employers and unions have two major choices. They will either need to determine whether they want to continue to offer creditable coverage that qualifies for the retiree drug subsidy and remain the primary insurer for their Medicare-eligible retirees' drug coverage, or whether they want to become a secondary payer that offers additional coverage that complements the Medicare Part D, with Medicare acting as the primary insurer. In developing this final rule, we have sought to provide significant flexibility in implementing the various options that are available to employers and unions under the Medicare drug benefit and retiree drug subsidy. We believe that this approach will help us to maximize the number of employers and unions that are able to take advantage of the various options available under the Medicare prescription drug benefit and retiree drug subsidy for retaining and enhancing their retiree drug coverage.

As discussed earlier, it is also important to note that an employer or union that provides retiree drug coverage that is creditable on a gross value basis but, for example, is not making sufficient contributions toward the financing of the benefit to qualify for the retiree drug subsidy on a net value basis can choose at any time to modify its existing benefit design to supplement Part D. Under this circumstance, as discussed in subpart B of the preamble, the Medicare retirees would be eligible for a special enrollment period for Medicare Part D because their retiree drug coverage no longer meets the criteria for creditable coverage. The special enrollment period provision would enable these employers and unions to work with their retiree populations and the new Part D plans to achieve a smooth transition and ensure that their Medicare-eligible retirees would not be subject to late enrollment penalties when they enroll in Part D. We believe that the availability of special enrollment periods provides important additional flexibility and time to employers and unions as they evaluate the various options that are available to them under the Medicare drug benefit and retiree drug subsidy.

However, we recognize that employers and unions will not be making their decisions in a static environment; rather, many of the environmental factors that will affect their decisions will continue to change over time, including the impact of rising health care costs and financial caps on employer contributions to retiree health coverage, demographic shifts in employers' and unions' retiree populations (as more of the future

retirees who may have less generous benefits than the current retirees begin to retire), and changes in a plan sponsor's financial position. Additionally, as discussed in the proposed rule, we believe that some employers and unions may prefer to provide coverage that interfaces with Medicare Part D in much the same way that they supplement the basic Medicare Part A and Part B benefits, and we acknowledge that they may require some additional lead-time to implement this option. Moreover, anecdotal information from various benefit consultants, researchers, and other experts suggests that some employers/unions that initially choose to accept the retiree drug subsidy may move to a wraparound option a few years later (Comments made during discussion of the Medicare Payment Advisory Commission (MedPAC) Supplement to the Kaiser/HRET Survey, Transcript of MedPAC Public Meeting, November 16, 2004, see MedPAC web site, *http://www.medpac.gov/public_meetings/transcripts/1104_allcombined_transc.pdf*).

For these reasons, we believe that it is likely that some employers' and unions' responses to the various options that are available to assist them in providing high quality drug coverage under the Medicare drug benefit and retiree subsidy may change over time—either in the aggregate or for specific retiree subpopulations. As discussed earlier, we have updated our enrollment estimates to reflect this potential change in employer and union behavior over time. We believe that these enrollment estimates are the best available given the considerable amount of uncertainty surrounding the possible responses of current plans to the many options that are available to them for interacting with Part D.

d. Anticipated Effects of the Medicare Retiree Drug Subsidy Program and Part D Assistance for Retirees on the Availability and Generosity of Retiree Drug Benefits

We also requested comments on how choices by employers and unions relating to the retiree drug subsidy, wrapping around Part D coverage, qualifying as an enhanced Part D plan directly, or using an enhanced PDP or MA-PD plan will affect retirees' net payments for drugs and other health services.

Comment: We received several comments from retiree advocacy groups and unions, which stated that the implementation of Medicare Part D will pose several potential risks for retirees with regard to the availability and generosity of their employment-based coverage, and requested that the final rule include additional retiree protections. Specifically, these commenters stated that Medicare-eligible retirees have a risk of: losing their current generous employer or union-sponsored retiree drug coverage; experiencing significant increases in out-of-pocket costs; not making the best choice for receiving prescription drug coverage due to confusion about the multiple options that are available to them; being exposed to the late enrollment penalty; and experiencing reduced access to newer drugs due to Part D formulary limitations. We also received comments from two employer groups suggesting that there is a risk for disabled beneficiaries in active worker plans (although they are in a non-work status) to receive less generous drug coverage if they are not deemed as being qualifying covered retirees for purposes of the retiree drug subsidy. Finally, one employer group commenter suggested that some retirees that choose to enroll in Part D plans could lose their other retiree health benefits because many employers may require their retirees not to enroll in a Part D plan as a condition of eligibility for the employer's qualified retiree health plan.

Response: A variety of factors will affect employers' and unions' decisions about how to respond to the various options that are available to them under the Medicare drug benefit and retiree drug subsidy. These decisions will ultimately affect the nature of the retiree drug benefits that will be available to current and future Medicare-eligible retirees. As discussed elsewhere, the availability and generosity of retiree health coverage had been declining for more than a decade prior to enactment of the MMA, particularly for future retirees, and available evidence suggests that this erosion is continuing to occur (primarily in the form of increasing retirees' share of premiums and increasing eligibility restrictions for future retirees) due to ongoing financial pressures on employers. For example, according to comments made by a researcher from the Health Research and Educational Trust, the cost of retiree health benefits has increased by 56 percent since 2000, and 27 percent of Medicare-eligible retirees receive their benefits from firms that have more Medicare-eligible retirees than active workers (Comments made during discussion of the Medicare Payment Advisory Commission (MedPAC) Supplement to the Kaiser/HRET Survey, Transcript of MedPAC Public Meeting, November 16, 2004, see MedPAC web site, *http://www.medpac.gov/public_meetings/transcripts/1104_allcombined_transc.pdf*).

In the context of this continuing erosion in the availability and generosity of retiree coverage, the Medicare drug benefit and retiree drug subsidy make considerable new financial resources available to assist employers and unions in continuing to offer high quality retiree health benefits. Employers and unions have considerable latitude in making changes in their existing retiree health benefit designs unless they have made a specific promise to maintain these benefits in their formal written plan documents, collective bargaining agreements, or other contractual commitments; or in the case of public employers, unless they have other statutory or regulatory constraints on their ability to make such changes. This has always been the case, and continues to be the case with the enactment of the MMA. However, we believe that the substantial additional resources that Medicare Part D provides through the retiree drug subsidy and the various options that employers and unions have for coordinating with Part D can help to counteract some of the financial pressures that have been contributing to the trends toward erosion in retiree health benefits by making it more affordable for employers and unions to continue providing high quality retiree drug coverage. Additionally, as discussed earlier, available evidence suggests that the majority of current Medicare-age retirees are likely to continue receiving prescription drug assistance from their former employers and unions—either in the form of primary drug coverage that qualifies for the retiree drug subsidy, enhanced or supplemental coverage that wraps around the standard Part D benefit, or assistance with paying Part D premiums—and that very few beneficiaries are likely to lose their employer or union-sponsored retiree drug benefits altogether.

The preamble describes the policy decisions that we made relating to the various options that are available to employers and unions under Medicare Part D, in an effort to balance our various policy goals and to achieve the maximum increase in support for retiree health coverage. We have taken a number of steps to be responsive to the concerns that were raised in the comments that we received relating to the proposed rule. For example, we believe that the flexibility that we have provided relating to actuarial equivalence, plan definition, qualifying covered retirees, payment methodology, and data reporting requirements will

make it easier for employers and unions to continue offering their existing retiree drug plans to Medicare-eligible retirees, while qualifying for the retiree drug subsidy. In cases where employers and unions choose to provide additional retiree drug benefits through separate wraparound coverage that supplements Part D, or enhanced benefits through Part D plans, they can coordinate this additional coverage with Part D in such a way that they can continue providing generous retiree drug benefits at a lower cost, while ensuring that their retirees do not experience significant changes in their out-of-pocket spending.

Additionally, given that approximately 30 percent of the large private sector firms (that is, firms with 1,000 or more employees) that currently offer retiree health coverage to new Medicare-age retirees require those retirees to pay 61 to 100 percent of the cost of their retiree health premiums, based on findings from the 2004 Kaiser/Hewitt Survey on Retiree Health Benefits, some retirees are likely to experience a significant reduction in their out-of-pocket costs by enrolling in the government-subsidized Part D plans. We also note that many beneficiaries' current employer/union-sponsored coverage includes various features that are similar to Part D, including the use of tiered formularies, which may help to minimize potential disruptions associated with switching from an existing employment-based retiree drug plan to a Part D plan (''Current Trends and Future Outlook For Retiree Health Benefits: Findings from the Kaiser/Hewitt 2004 Survey on Retiree Health Benefits,'' The Henry J. Kaiser Family Foundation and Hewitt Associates, December 2004, available at http://www.kff.org).

Additionally, as discussed earlier, it is also important to note that an employer or union that provides retiree drug coverage that is creditable (on a gross value basis) can choose at any time to modify its existing benefit design to supplement Part D. Under this circumstance, the Medicare retirees would be eligible for a special enrollment period for Medicare Part D because their retiree drug coverage no longer meets the criteria for creditable coverage. Thus, the special enrollment period provision would enable these employers and unions to work with their retiree populations and the new Part D plans to achieve a smooth transition and ensure that their Medicare-eligible retirees would not be subject to late enrollment penalties when they enroll in Part D.

We anticipate working closely with employers, unions, and advocacy groups to assist beneficiaries that have employment-based drug coverage in understanding the various choices that are available to them under Part D and choosing the option that will provide them with the best value, given their particular circumstances. Ultimately, we believe that Medicare Part D, including the retiree drug subsidy and the other options it gives employers and unions for providing drug coverage, will help to counteract the trend toward erosion in retiree health benefits by significantly increasing the amount of financial support that is available to employers and unions for retiree drug coverage, and by providing important support for recent retirees and future retirees that may have less generous employer/union support.

Overall, we believe that the implementation of Medicare Part D, including the Medicare retiree drug subsidy and the other opportunities it affords employers and unions for providing continued prescription drug assistance to their Medicare retirees, will result in combined aggregate payments by employers/unions and Medicare for drug coverage on behalf of retirees that are significantly greater than they otherwise would have been without the enactment of the MMA. Furthermore, we believe that the Medicare prescription drug benefit and retiree drug subsidy represent a particularly important strengthening of health care coverage for future Medicare-eligible retirees, given the erosion in the availability and generosity of employment-based retiree coverage for future Medicare beneficiaries that has already been taking place.

e. Historical Trends in the Availability and Generosity of Retiree Drug Coverage

As additional background, we provide a discussion of trends in the availability and generosity of employer-sponsored retiree drug coverage, based on data from several different sources. We note that there are a limited number of data sources relating to retiree coverage, and some of these data sources may not be directly comparable to one another due to differences in the scope of analysis (for example, overall retiree health benefits versus specific information on retiree drug coverage), unit of analysis (for example, retirees versus firms, or firms versus establishments), as well as differences in the age groups, types of retirees (current versus future), and employer sizes that are being analyzed. For these reasons, caution should be exercised in making comparisons across the various data sources that are cited in this section.

As noted previously, employer-sponsored insurance has been an important source of drug coverage for many Medicare beneficiaries. For example, the trend in retiree health coverage for older Medicare beneficiaries (ages 70 and older) was essentially flat between 1996 and 2000 (''Employer-Sponsored Health Insurance and Prescription Drug Coverage for New Retirees: Dramatic Declines in Five Years,'' Bruce Stuart et al, Health Affairs, July 23, 2003, available at www.healthaffairs.org). However, for well over a decade, the availability and generosity of employer-sponsored retiree health coverage has been eroding, particularly for future retirees. The level of employer-sponsored retiree health coverage has been relatively stable for the nation's current retirees during recent years. However, the apparent stability of benefits has been changing for future retirees. We believe that certainly absent the new law, these trends would have continued. In enacting the law, the Congress hoped that the opportunities available to employers and unions under the Medicare prescription drug benefit and retiree subsidy would help to ameliorate the erosion in retiree health coverage. Overall, we do expect that the implementation of Medicare Part D, including the Medicare retiree drug subsidy and the other opportunities it affords employers and unions for providing continued prescription drug assistance to their Medicare retirees, will result in combined aggregate payments by employers/unions and Medicare for drug coverage on behalf of retirees that are significantly greater than they otherwise would have been without the enactment of the MMA.

From 1988 to 1991, the percentage of firms with 200 or more workers offering health benefits to active workers that also offered retiree health benefits declined substantially from 66 percent to 46 percent (KPMG Survey of Employer-Sponsored Health Benefits: 1988, 1991, cited in Kaiser/HRET 2004 Annual Survey of Employer-Sponsored Health Benefits, available at www.kff.org) due to the implementation of Financial Accounting Statement No. 106 (FAS 106) as well as increasing costs. FAS 106, which was published in December 1990, required companies to make significant changes in the way that they accounted for future retiree health benefits on their balance sheets for fiscal years ending after December 15, 1992 (''Retiree Health Benefits: Trends and Outlook,'' Paul Fronstin, Employee Benefit Research Institute (EBRI) Issue Brief No. 236, August 2001; ''Statement

of Financial Accounting Standards No. 106: Employers' Accounting for Postretirement Benefits Other Than Pensions,'' Financial Accounting Standards Board, December 1990, available at *www.fasb.org/pdf/fas106.pdf*). The percentage of large employers offering retiree health coverage has continued to decline during the past decade (General Accounting Office (GAO), ''Retiree Health Benefits: Employer-Sponsored Benefits May Be Vulnerable To Further Erosion,'' May 2001, available at *www.gao.gov*). However, the recent declines have been more gradual than what occurred during the early 1990s, with less than 40 percent of the nation's large firms with 200 or more workers that offer health benefits to active workers also offering retiree health benefits in 2003 (Kaiser/HRET 2004 Annual Survey of Employer-Sponsored Health Benefits, available at *www.kff.org*).

Many of the changes in availability of retiree health coverage in the past decade have primarily affected future retirees, rather than current retirees. (Fronstin, August 2001). For example, the percentage of large employers with 500 or more employees offering retiree health benefits to new Medicare-age (that is, ages 65 and older) retirees decreased from 40 percent in 1993 to 20 percent in 2004 (data from the National Survey of Employer-Sponsored Health Plans, 2004 cited in a press release entitled ''US health benefit cost rises 7.5 percent in 2004, lowest increase in five years,'' Mercer Human Resource Consulting, November 22, 2004, available at *www.mercerhr.com*). As a result, new retirees are less likely to have employer-sponsored retiree drug coverage than current retirees.

Availability of retiree health coverage varies depending on the type of employer. Employers with union workers are more likely to offer retiree coverage than employers without union workers. Similarly, public sector employers are more likely to offer coverage to retirees than private sector employers. (Kaiser/HRET 2004 Annual Survey of Employer-Sponsored Health Benefits, available at *www.kff.org*; ''How States Are Responding to the Challenge of Financing Health Care for Retirees,'' Jack Hoadley, Henry J. Kaiser Family Foundation, September 2003, available at *www.kff.org*.)

Availability of retiree health coverage also varies according to the size of the employer. Larger employers are more likely to offer retiree health coverage than smaller employers. For example, in 2004, 36 percent of the nation's private sector firms with 200 or more workers that offered health benefits to active workers also offered retiree health coverage to pre-age 65 and/or Medicare-age retirees (Kaiser/HRET, 2004). However, very few smaller employers offer retiree health insurance. Recent surveys have found that only 3 to 10 percent of the nation's smaller private sector firms (3 to 199 workers) that offer health benefits to active workers also offer retiree health coverage (Kaiser/HRET 2001, 2002, 2003 and 2004 Annual Surveys of Employer-Sponsored Health Benefits, available at *www.kff.org*).

Larger employers account for the majority of the beneficiaries with employer-sponsored retiree coverage. In 2001, data from the Medical Expenditures Panel Survey indicate that less than 1 percent of the nation's smallest private establishments (those with a ''firm size,'' or total number of employees for the entire firm, of less than 50 employees) offered health insurance to Medicare-age retirees, compared with 37 percent of the nation's largest private sector establishments (those with a firm size of 1,000 or more employees). As a result, within the private sector, the largest firms (1,000 or more employees) covered approximately 90 percent of the Medicare-age retirees who had employer-sponsored retiree coverage, while smaller firms (fewer than 1,000 employees) covered only 10 percent of these retirees.

In an effort to control costs, many employers have been changing their benefit packages (for example, reducing the benefit that is offered and/or increasing the amount that the retiree has to pay), resulting in gradual erosion in the generosity of this coverage over time. For example, since the mid–1990s, some employers have made changes in eligibility for retiree health coverage (for example, age and service requirements), reduced their subsidization of retiree health costs (by increasing retirees' share of premiums and increasing retirees' co-payments and deductibles), placed caps on the employer contribution to retiree health costs (aggregate or per beneficiary), or changed their health benefit designs to a defined contribution structure (Fronstin, August 2001; GAO, May 2001). Because many employers have identified prescription drug costs as a major contributor to rising retiree health benefit costs, they have adopted cost control measures in an effort to manage their retiree prescription drug costs (Kaiser/HRET, 2004).

The intent of Medicare Part D and the retiree drug subsidy is to provide employers and unions with a set of highly flexible options that are designed to make it more affordable for them to continue providing high quality prescription drug assistance to their Medicare-eligible retirees. As discussed earlier, the MMA Conference Report indicates that by lowering the cost of providing retiree drug benefits and providing financial incentives for employers and unions to maintain this coverage for their Medicare-eligible retirees through Medicare Part D and the retiree drug subsidy, it is hoped that the erosion in the availability of employment-based retiree drug coverage will plateau or even improve.

Overall, we expect that the implementation of Medicare Part D, including the Medicare retiree drug subsidy and the other opportunities it affords employers and unions for providing continued prescription drug assistance to their Medicare retirees, will result in combined aggregate payments by employers/unions and Medicare for drug coverage on behalf of retirees that are significantly greater than they otherwise would have been without the enactment of the MMA. Furthermore, the Medicare prescription drug benefit and retiree drug subsidy represent a particularly important strengthening of health care coverage for future Medicare-eligible retirees, given the erosion in the availability and generosity of employment-based retiree coverage for future Medicare beneficiaries that has been taking place.

G. Anticipated Effect on the Federal Budget

The following section presents estimates of the effect of Medicare Part D on net Federal budgetary spending. As indicated previously, there is a great deal of uncertainty related to making these estimates. However, we believe that these estimates provide a reasonable representation of the likely net Federal budgetary effects of the Medicare Part D program.

We expect that the Medicare drug benefit will affect several components of the Federal budget. Specifically, we anticipate that it will increase Federal spending on Medicare benefits and decrease Federal spending on Medicaid benefits (as dual eligibles' drug coverage is shifted from Medicaid to Medicare). The net effect of these changes on Federal spending is estimated to be about $49 billion in CY 2006 and $68 billion in CY 2010, with the total net effect estimated to be about $293 billion over the period from 2006–2010. We note that these estimates are slightly higher than those presented in the proposed rule due largely to the higher per capita spending estimates for the

low-income subsidy enrollees as discussed in section F.2 of this impact analysis. Table IV–3 provides year-by-year estimates of the net Federal budgetary effects[9] of Medicare and Medicaid benefit spending. We discuss these effects subsequently, as well as the expected impacts of the Medicare drug benefit on Federal administrative costs for Medicare, Medicaid, and the Social Security Administration.

1. Federal Medicare Spending

We estimate that the net Federal budgetary effect of Medicare benefit spending related to Medicare Part D, including the Medicare retiree drug subsidy program, will be nearly $61 billion in CY 2006 and nearly $365 billion over the five-year period from CY 2006–2010. The estimated $365 billion in additional net Federal spending over the five-year period is made up of approximately $419 billion in Federal Medicare spending on direct government subsidies, government reinsurance payments, low-income subsidies, and retiree drug subsidies, with an offset of nearly $55 billion in additional Medicare revenues received from States to partially compensate for Medicare coverage of dual eligibles' drug costs (overall, we estimate States will save due to reduced Medicaid spending, as is explained subsequently).[10]

In addition, CMS expects to incur administrative expenses related to the Medicare drug benefit. Implementing a new program of the size and scope of the Medicare drug benefit requires substantial implementation expenses, including extensive computer and other systems changes. Estimates of CMS administrative costs for these activities will be incorporated in the forthcoming President's Budget.

2. Federal Medicaid Spending

As a result of Medicare Part D, there is expected to be a reduction in net Federal spending on Medicaid benefits for the period CY 2006–2010, with the reduction estimated to be about $11 billion in CY 2006 and about $72 billion over the five-year period from CY 2006–2010.

With the Medicare program providing drug coverage to dual eligibles who had previously received drug coverage through Medicaid, State Medicaid spending on prescription drugs will be reduced, and as a result Federal spending on Medicaid matching payments will also be reduced. We estimate reduced Federal Medicaid spending on prescription drugs for full-benefit dual eligibles of about $13 billion in CY 2006 and about $84 billion during the five-year period from CY 2006–2010.

The reduction in Federal spending for Medicaid prescription drug benefits will be partially offset by an increase in Federal Medicaid spending for newly enrolled dual eligibles. As discussed in more detail in the State impacts section, the additional benefits available to low-income beneficiaries through Medicare Part D and our related outreach activities are likely to raise awareness of other benefits available to such individuals through Medicaid, including Medicare Savings (QMB/SLMB) programs, and lead to higher enrollment in these programs. We assume that 1.1 million more Medicare beneficiaries will enroll in Medicaid, including Medicare Savings (QMB/SLMB) programs, in CY 2006 as a result of the Medicare drug benefit. As discussed later in the State impacts section, we estimate that a larger share of these beneficiaries will receive benefits as QMB/SLMB individuals than will receive full Medicaid benefits. Among beneficiaries that are eligible for, but not enrolled in Medicaid and the Medicare Savings Program, we assume a smaller new enrollment rate among those beneficiaries that are eligible for full Medicaid benefits, because we believe that if these beneficiaries were likely to sign up for the full Medicaid benefits package, most would have done so already. We assume a somewhat higher new enrollment rate for those beneficiaries that are eligible for QMB/SLMB benefits. We estimate Federal matching payments for State Medicaid expenditures for these beneficiaries will be about $2 billion in CY 2006, and total about $12 billion during the five-year period from CY 2006–2010.

In addition, the Medicare drug benefit has implications for Federal spending on Medicaid administrative costs. The statute gives responsibility to State Medicaid programs as well as the Social Security Administration (SSA) for conducting eligibility determinations for low-income benefits under Part D. In addition, States are required to provide us with data for the purpose of calculating the amounts States are required to pay Medicare to compensate for a portion of full-benefit dual eligibles' drug costs. These and other State administrative activities related to Medicare Part D will generate State administrative costs, as discussed in more detail in the State section of the impact analysis. We estimate that the Federal share of these net costs will be $39 million in FY 2004, $73 million in FY 2005, and average $67 million from FY 2006–2010.[11] These net costs reflect savings from reduced State claims processing workload as dual eligibles' drug coverage is shifted from Medicaid to Medicare.

3. SSA Administrative Costs

SSA will incur administrative costs associated with its responsibilities under the MMA. SSA is developing and executing an outreach plan to educate beneficiaries about the low-income subsidy assistance that is available under Medicare Part D. To assist beneficiaries with their requests for subsidy assistance, SSA is developing simplified application, appeal, and redetermination forms. SSA has responsibility for determining eligibility for the low-income subsidy, performing reviews of determinations based on requests for appeal, and redetermining eligibility. To do this, SSA must develop computer systems, regulations, and internal SSA instructions for processing applications, appeals, and re-determinations. In addition, SSA is developing training materials for State employees so that they can use SSA's simplified application form and application process, and is conducting data exchanges with CMS and other Federal Agencies necessary for making eligibility determinations. Estimates for SSA administrative costs for these activities will be incorporated in the forthcoming President's Budget.

[9]–We note that the estimated net Federal budgetary effect of Medicare subsidy payments excludes changes to governmental receipts (that is, tax collections) because we do not have sufficient data to estimate these effects at this time.

[10] For the purpose of this impact analysis, we do not assume any additional Medicare costs or savings related to risk corridors. We also do not assume any savings on Part A and Part B benefits.

[11] For the purpose of this impact analysis, we do not assume any additional Medicare costs or savings related to risk corridors. We also do not assume any savings on Part A and Part B benefits.

TABLE IV–3. ESTIMATED NET FEDERAL BUDGETARY EFFECTS OF MEDICARE AND MEDICAID BENEFIT SPENDING, CY 2006–2010 (BILLIONS OF DOLLARS)

	2006	2007	2008	2009	2010	2006–2010
Net Effect of Medicare Benefit Spending Related to Medicare Part D						
Federal Spending Related to Medicare Part D, Including the Retiree Subsidy	69.7	76.2	83.3	91.0	99.2	419.3
State Payments to Partially Offset Medicare Drug Costs for Dual Eligibles	-9.0	-9.9	-10.9	-11.9	-13.0	-54.7
Subtotal	60.6	66.2	72.5	79.1	86.1	364.6
Net Effect of Medicaid Benefit Spending						
Additional Federal Matching Payments for Newly Enrolled Dual Eligibles	2.0	2.2	2.5	2.7	2.9	12.3
Reduction in Federal Matching Payments for Medicaid Drug Expenditures for Dual Eligibles	-13.3	-14.9	-16.6	-18.5	-20.7	-84.0
Subtotal	-11.3	-12.7	-14.1	-15.8	-17.8	-71.7
Net Federal Budgetary Effects of Medicare and Medicaid Benefit Spending	49.3	53.6	58.4	63.3	68.3	292.9

Note: Positive numbers denote increased spending; negative numbers denote reduced spending (that is, savings). Numbers may not sum to totals due to rounding and exclude effects on Federal tax revenues.

H. States

1. Overall State Budgetary Impacts

We estimate that, as a result of Medicare Part D, States will realize net savings of $7.9 million over the CY 2006–2010 period, as shown in Table IV–4. Estimated State savings range from approximately $1.0 billion in CY 2006, increasing each year during the five-year period, to reach about $2.2 billion by CY 2010. The estimated $7.9 billion in net State savings over the five-year period are made up of $72.6 billion in State savings related to Medicare Part D that are partially offset by $64.8 billion in State costs related to Medicare Part D. We note that our estimates of State savings are slightly lower than those presented in the proposed rule because our current estimate of the overall impact on States includes an estimate of State administrative costs while our previous estimate had not.

We estimate that States will save approximately $73 billion from CY 2006 to 2010 as the Medicare Part D drug benefit and Medicare retiree drug subsidy provide financial support for the prescription drug costs of full-benefit dual eligibles, State retirees, and participants in State prescription drug assistance programs. The vast majority of these State savings ($63.4 billion) are the result of Medicare Part D replacing drug coverage for full benefit dual eligibles that would otherwise be paid for by Medicaid. States offering qualified retiree prescription drug coverage to their own former employees (and their spouses and dependents) will also achieve savings due to the Medicare retiree drug subsidy and the other options Part D offers employers and unions for providing retirees with prescription drug coverage at lower costs. We estimate these savings to be $6.3 billion from CY 2006 to CY 2010. In addition, States that operate prescription drug assistance programs, as well as States with Pharmacy Plus programs, will also realize additional savings as Medicare Part D displaces a portion of their spending on prescription drug coverage for enrollees ($3 billion from CY 2006 to CY 2010). We discuss the estimated savings for State prescription drug programs in more detail in a separate section later in this analysis.

The estimated $73 billion in State savings, discussed previously, will be partially offset by approximately $65 billion in State costs related to Medicare Part D over the period CY 2006–2010. The largest component of these costs are State payments to the Federal government to defray a portion of the Medicare drug expenditures for full-benefit dual eligibles, estimated at about $54.7 billion from CY 2006–2010. As discussed in the preamble, the States and the District of Columbia are required to make these monthly payments beginning January 1, 2006. It is important to note that the data sources and methodology used to estimate these State payments for the purpose of this impact analysis differ somewhat from those that will be used, as stipulated by statute and described in more detail in subpart S of the preamble, to calculate the actual State payment amounts for 2006. The expenditure data that will be used to calculate the actual State payment amounts are not yet available. Thus, for the purpose of this impact analysis, we relied on MCBS as the data source to produce an estimate of aggregate State payments.

Another component of these costs is increased State Medicaid spending due to increased Medicaid enrollment. We anticipate that in the process of outreach and applying for the Part D low-income subsidy, some beneficiaries will learn of their eligibility for other low-income assistance such as Medicaid or Medicare Savings (QMB/SLMB) programs and choose to enroll in these programs. We estimate that about 1.1 million additional beneficiaries will enroll in Medicaid or the Medicare Savings programs in CY 2006. We assume that a larger share of these beneficiaries will receive benefits as QMB/SLMB individuals than will receive full Medicaid benefits, with 21 percent of the new enrollees estimated to receive full Medicaid, 20 percent to receive QMB benefits, and 59 percent to receive SLMB benefits. We assume a smaller new enrollment rate among those beneficiaries that are eligible for

full Medicaid benefits, because we believe that if these beneficiaries were likely to sign up for the full Medicaid benefit package, most would have done so already. We assume a somewhat higher new enrollment rate for those beneficiaries that are eligible for QMB/SLMB benefits. Because there are currently more beneficiaries eligible for but not enrolled in the SLMB program than the QMB program, new enrollees into the SLMB program make up the majority of the estimated 1.1 million new enrollees. We estimate that State Medicaid spending on benefits for these 1.1 million individuals will be about $9.1 billion over the five-year period from CY 2006–2010.

Also included in our estimate of State costs is the effect of the MMA's prohibition on States imposing taxes on premiums related to Part D coverage. As a result of this prohibition, we estimate that States will realize reduced premium tax revenues of approximately $504 million over the period CY 2006–2010.

States will also incur administrative costs related to Medicare Part D. We estimate that these State costs will be $39 million in FY 2004, $73 million in FY 2005 and average $90 million per year from FY 2006–2010 (after receiving Federal matching payments). In FY 2004 and 2005, we anticipate that States will incur costs on data file cleanup (to enable States to provide us with information on dual eligibles). In addition, in FY 2005, we estimate that States will incur costs for development of State eligibility determinations systems for Part D and for processing eligibility determinations for individuals who apply for the low-income subsidy through the State during the early stages of the low-income subsidy application period. In FY 2006–2010, we expect that the bulk of States' administrative costs will be associated with processing Part D applications, re-determinations, and appeals; and State screening of Part D low-income subsidy applicants for eligibility for the Medicare Savings programs. The additional administrative costs during FY 2006–2010 will be partially offset by State savings on claims processing costs, as dual eligibles' prescription drug claims will no longer be processed by States. We note that our estimates of State administrative costs are somewhat lower than those cited in the proposed rule because, as discussed subsequently, we anticipate that SSA will play a substantial role in the eligibility determinations process for the low-income subsidy, lessening the burden on States. We anticipate that prior to implementation of Medicare Part D, States will incur costs related to the data file preparation work necessary to provide us with information on which beneficiaries are full dual eligibles, QMBs, SLMBs, or QIs. States are required, effective with CY 2003 and all subsequent MSIS data submittals, to provide accurate and complete coding to identify the numbers and types of Medicaid and Medicare dual eligibles, with CY 2003 data submittals required to be completed by December 31, 2004. In accordance with the statute, this final rule also requires States to submit an electronic file, beginning effective August 2005, and each subsequent month, that identifies each full benefit dual eligible enrolled in the State for each month.

As discussed in the preamble, we will send notices of eligibility to all deemed low-income subsidy eligible individuals, relieving States of the financial burden of sending notices to these beneficiaries. We will also educate Medicare beneficiaries, including dual eligibles, through a variety of methods about prescription drug coverage under the new Part D benefit, which we expect would eliminate the need for States to carry out this function.

The statute gives responsibility to State Medicaid programs as well as the Social Security Administration for conducting eligibility determinations for low-income benefits under Part D. As a result, States will need to develop an eligibility determinations system for processing Part D low-income subsidy applications. However, States have considerable flexibility in designing the system in a manner that would be most cost-effective given their existing eligibility determination processes and the likelihood that SSA will process a substantial number of applications. We anticipate that SSA will have a substantial role in processing Part D eligibility determinations, which will considerably reduce State costs related to processing Part D applications. SSA will be conducting an extensive outreach campaign to inform low-income Medicare beneficiaries about the Medicare Part D low-income subsidy assistance and inform them that they can apply for the low-income subsidy through SSA. In addition, as discussed in the preamble, we are encouraging States to consider using the SSA application form and process as their default approach for processing low-income subsidy applications. While States would have to develop a process to determine eligibility for an individual who requests a ''State'' determination as opposed to an ''SSA'' determination, States may use the SSA low-income subsidy application in order to reduce the administrative burden associated with sending notices and processing appeals and re-determinations. With SSA performing a substantial role in eligibility-processing, States would also be relieved of a significant burden in verifying information reported on low-income subsidy applications. As a result, States could focus most of their attention on assisting individuals with completing the SSA application, and screening and enrolling individuals in the Medicare Savings Program.

We also note that States are generally responsible for issuing licenses to health insurers. While some new PDP plans will require new licenses, the States charge fees for licensing and the States already have the mechanisms in place to handle these new license applications. Furthermore, licensing would not affect current insurers that want to become PDPs if these insurers are already licensed as insurers in a given State; the PDP would simply be a new line of business for these insurers. Thus, we do not estimate any cost implications for the States associated with licensing insurers.

Comment: Several States noted that they did not believe they would realize net savings as a result of Part D. These States commented that their costs would exceed their savings. In addition, some States pointed out that the characteristics of their situation, in terms of such issues as savings for retirees, existence of a SPAP, administrative costs associated with low-income eligibility determinations, or new Medicaid enrollments, would mean that their particular State costs would exceed savings from Medicare Part D.

Response: Based on our estimates, we believe that, in aggregate, State savings will exceed State costs over the 5 year period, CY 2006–2010. Our best estimate, based on available data, is that generally States will realize net savings from the implementation of Medicare Part D, and these savings will increase over time, as shown in Table IV–4. We estimate that States will save approximately $7.9 billion from CY 2006 to CY 2010 as the Medicare Part D drug benefit and Medicare retiree drug subsidy provide financial support for prescription drug costs of full-benefit dual eligibles, State retirees, and participants in State prescription drug assistance programs. The vast majority of these State savings are the result of Medicare Part D replacing drug coverage for full benefit dual eligibles that would otherwise have been paid for by Medicaid (about $63 billion from CY 2006 to CY 2010).

Comment: Several States asserted that exempting Medicare Part D prices from Medicaid best price will have a negative financial effect on States. In addition, several States also asserted that Medicare Part D will reduce their drug price negotiating power for the non-dual population.

Response: As noted elsewhere in the preamble, we do not have the statutory authority to modify the best price provisions of the Medicaid best price statute and the exemption of Part D under the MMA. However, we do not believe that the exemption of PDP and MA-PD prices from ''best price'' will adversely affect best price compared with what it would have been in the absence of Medicare Part D. We expect that price negotiations by PDPs and MA-PDS with drug manufacturers will lead to price concessions for beneficiaries. Nevertheless, the expected increase in drug use among the Medicare population, due to the expansion of drug coverage, will make it less likely that manufacturers will respond by raising their prices to other lines of business. Consequently, we expect that there would be minimal, if any effect, on best price.

In terms of the impact on States' negotiating power with drug manufacturers, we believe that States would remain large volume purchasers of prescription drugs even after the dual eligible beneficiaries transition to Part D coverage. Furthermore, a number of States have joined purchasing pools to increase their market power in an effort to reduce their Medicaid spending on prescription drugs. As such, we believe that the States would maintain their bargaining power with drug manufacturers and that there would be minimal impact on their ability to negotiate price concessions.

Comment: Two States noted that the estimate of net State savings should include administrative costs.

Response: The estimate of State administrative costs is included in the estimate of net State savings, as shown in Table IV–4.

Comment: One State wanted us to clarify whether we included the estimated fiscal impact of the following programmatic and administrative State costs: (1) additional compliance responsibilities with HIPAA and privacy rule notice of practice provisions; (2) Certificates of Coverage requirements; (3) educating staff; (4) coordinating the State pharmacy programs (and systems) with the PDPs for purposes of medication management programs; and (5) educating dual eligibles on Medicare Part D.

Response: Our estimates of State administrative costs take into account staff training activities. We have not included new costs for HIPAA, the privacy rule notice of practice provisions, or Certificates of Coverage because we do not agree that the MMA imposes additional compliance responsibilities on States in these areas. In terms of the costs of educating beneficiaries, we did not include these costs in our estimate as we believe they will be negligible, for several reasons. First, SSA will be conducting an extensive outreach campaign to inform low-income Medicare beneficiaries about the Medicare Part D low-income subsidy assistance and inform them that they can apply for the low-income subsidy through SSA. Second, CMS will send notices of eligibility to all deemed low-income subsidy eligible individuals, relieving States of the financial burden of sending notices to these beneficiaries. Third, CMS will educate Medicare beneficiaries, including dual eligibles, through a variety of methods about prescription drug coverage under the new Part D benefit, which we expect would lessen the need for States to carry out this function.

As discussed elsewhere in the preamble, we recognize that SPAPs and States have an interest in acquiring access to prescription drug utilization data for purposes of their medical and case management activities. We are continuing to work on means to practically expedite data sharing. As noted previously, although we do not have the authority to require data exchanges between Part D plans and the States, we will strongly encourage Part D plans to independently share data on these shared enrollees with State Medicaid plans consistent with the HIPAA Privacy Rule provisions for the sharing of protected health information with another covered entity for that entity's health care operations.

Comment: Two States noted that we underestimated the administrative cost estimates for States to conduct low eligibility determinations under Part D. One State noted that, due to the complexity of the new drug benefit and the incidence of cognitive impairment in the dual eligible population, the figure of $100 million is underestimated and should be reconsidered. Similarly, another State noted that if the States are required to determine low-income subsidy eligibility for low-income individuals other than Medicaid and Medicare Savings Program recipients, there will be additional costs to the States. The State asserted that the significant costs include system changes necessary to do the eligibility determinations and to issue notices to beneficiaries and notify CMS; the cost of applications, forms, and information material; the cost of writing and maintaining a policy manual; the cost of developing training materials and training staff; and the cost of new positions, space, and supplies for new staff needed to do determinations. This State noted that these costs will be even higher if the States are required to process automatic enrollments and if each State must coordinate subsidy eligibility determination processes with SSA.

Response: We recognize that States will incur costs associated with the eligibility determinations for Medicare Part D benefit. In developing our State administrative cost estimates related to eligibility determinations, we took into account the costs of developing eligibility systems; developing training materials; processing Part D applications, re-determinations, and appeals; screening and enrolling beneficiaries in Medicare Savings programs; and notifying CMS about beneficiaries determined eligible for the Part D low-income subsidy. In estimating these costs we included the cost of staff time, benefits, overhead, and training involved. We did not include State costs for auto-enrollment as CMS will be responsible for that function. We have estimated total State administrative costs (after receiving Federal matching payments) of $39 million in FY 2004, $73 million in FY 2005 and on average $90 million per year from FY 2006–2010. The vast majority of these costs are for the eligibility determinations process described above. While we recognize that States will incur significant costs related to eligibility determinations, we believe that our estimates represent a reasonable assessment of these costs. As noted previously, we anticipate that SSA's role in processing Part D low-income subsidy eligibility determinations will considerably reduce State costs related to processing Part D low-income subsidy applications. SSA will be conducting an extensive outreach campaign to inform low-income beneficiaries about the Medicare Part D low-income subsidy assistance and inform them that they can apply for the low-income subsidy through SSA. In addition, we are encouraging States to consider using the SSA application form and process as their default approach for processing low-income subsidy applications. While States would have to develop a process to determine eligibility for an individual who

requests a ''State'' determination as opposed to an ''SSA'' determination, States may use the SSA low-income subsidy application in order to reduce the administrative burden associated with sending notices and processing appeals and re-determinations. With SSA playing a substantial role in eligibility-processing, States would also be relieved of a significant burden in verifying information reported on low-income subsidy applications. In addition, while States must develop a process to support eligibility determinations when specifically requested of them, States have flexibility in designing the system in a manner that would be most cost-effective given their existing eligibility determination processes and the likelihood that SSA will process a substantial portion of Part D low-income subsidy applications.

2. State Prescription Drug Assistance Programs

As mentioned previously, one of the components of our estimate of net State savings resulting from Medicare Part D is savings on State Pharmaceutical Assistance Programs (SPAPs). We estimate that SPAPs spend roughly $1.45 billion of State only resources on prescription drug assistance for 1.2 million individuals, based largely on FY 2002 data. Five States account for approximately 87 percent of the SPAP spending, and have approximately 77 percent of the enrollment. For Medicare beneficiaries who have income less than 135 percent of the Federal Poverty Level (FPL) and assets valued up to $6,000 per individual (or $9,000 per couple) in 2006, Part D offers comprehensive drug coverage with a full Federal subsidy for the beneficiary premium and only nominal cost-sharing. Thus, SPAP expenditures on this group of Medicare beneficiaries will be mostly displaced by the Medicare prescription drug benefit. We estimate that the savings that will accrue to States as a result of Medicare Part D displacing SPAP expenditures for low-income beneficiaries will be approximately $600 million per year, or about $3 billion over the five-year period from CY 2006–2010.

States with SPAPs have shown a commitment to assisting their low-income residents with drug costs. As of Spring 2004, twenty States were operating SPAPs that provide subsidized drug coverage to individuals who will be eligible for Medicare Part D. We anticipate that many of these States will choose to continue providing financial assistance with drug expenditures, because they can achieve the same or a greater level of assistance for their beneficiaries at a lower cost to the States. Part D provides States with a number of options for continuing their provision of prescription drug assistance to Medicare beneficiaries, if they choose to do so. States, for example, have the flexibility to restructure their SPAP programs to wrap around the Part D benefit and pay deductibles and cost sharing for beneficiaries, with the State's assistance counting toward the Medicare Part D annual out-of-pocket threshold triggering protection against catastrophic drug costs. States can also provide assistance by paying for Part D premiums for beneficiaries. As part of their SPAPs, States also have the flexibility to make arrangements with PDPs and MA-PDs to provide enhanced Part D benefits.

Comments: The comments from States did not indicate a preferred option for restructuring their SPAP benefits in relation to Medicare Part D. One commenter indicated that given the proposed system for coordination of benefits, it seems likely that SPAPs will structure their benefit design to wrap around Medicare Part D. However, another commenter stated that choosing a wraparound benefit design would entail significant administrative and information systems costs.

Response: We are uncertain at this time what actions States will take to structure their SPAP benefits in relation to Part D. Part D provides States with a number of options for continuing their provision of prescription drug assistance to Medicare beneficiaries (for example, wrapping around Medicare Part D, or paying for some portion or all of premiums, including buying enhanced coverage). While we recognize that SPAPs will incur administrative costs in modifying their programs, we do not have enough information to quantify those costs. Currently, SPAPs have varying levels of administrative costs and their choices will influence the size of their future operating costs. For example, if SPAPs choose to provide premium assistance in contrast to a wraparound design, then their administrative costs might be lower than an operational design that would require ongoing processing of claims. We believe that we have provided flexibility for the States to restructure their SPAP programs to best serve the needs of their enrollees. We expect that regardless of how States choose to alter their SPAP benefits to work in relation to Part D, States will achieve savings as Part D coverage replaces benefit spending previously financed by SPAPs. Even though States will incur administrative costs in adapting the structure of their programs in relation to Part D, the benefit savings will far exceed administrative costs as administrative costs represent a small share of expenses associated with providing prescription drug coverage.

In the proposed rule, we invited States to provide specific enrollment and expenditure data by FPL for their State and any State-specific savings estimates they may have developed, as well as comments on improvements in our methodology. However, the public comments did not include estimates of SPAP enrollment and expenditure data by FPL, nor did the comments include State-specific savings estimates. Additionally, we did not receive any comments on our methodology for estimating potential savings from SPAP expenditures. Several States with SPAPs have publicly stated that they are realizing savings from the Medicare approved drug discount card and transitional assistance program. We anticipate that Medicare Part D will bring even larger savings for SPAP programs.

We retain the same methodology for estimating savings related to SPAP programs as we used in the proposed rule. We believe that we are presenting a conservative estimate of the displacement of SPAP expenditures, because our assessment does not include any potential State savings for SPAP enrollees at income levels above 135 percent of FPL. States that choose to restructure their programs to complement Medicare Part D can still achieve savings because of the substantial Medicare displacement of SPAP spending for low-income beneficiaries as well as for individuals who enroll in Part D and do not qualify for the low-income subsidy.

We also note that, as discussed elsewhere in the preamble, Section 1860D–23(d) of the Act provides for the payment of transitional grants to States with Pharmaceutical Assistance Programs of up to $62.5 million in each of fiscal years 2005 and 2006. On October 28, 2004 HHS announced the awards to States for fiscal Year 2005. In addition, the statute provides the authority (Section 1860D–23(a) of the Act) for the Secretary to establish requirements for effective coordination between Part D plans and SPAPs. For further discussion related to coordination of benefits, see the section on coordination of benefits under Administrative Costs.

To estimate potential SPAP savings resulting from Medicare Part D expenditures, we focus our analysis on SPAP expenditures that may be spent on individuals with income below 135

percent of FPL. We are primarily relying on State-published data that describe SPAPs and their eligibility standards (sources such as State government websites, program annual reports, and Governor's budget documents). Our ongoing work with States also provides us with certain information regarding enrollment and expenditures under SPAPs. Unless we have adequately detailed State-published data on SPAP expenditures for enrollees by income, we use the Census Bureau's Current Population Survey (CPS) data to help us estimate SPAP spending on beneficiaries with income under 135 percent of FPL.

We recognize that our methodology has significant limitations and that our estimates are imprecise. For example, our analysis does not take into account the effect of the Medicare Part D assets test and does not include an estimate of potential savings for SPAP enrollees with income greater than 135 percent of FPL. We believe that States, with their own internal data and resources, are in the best position to project individual State-level impacts.

3. Pharmacy Plus Waiver Programs

Four States under Medicaid section 1115 waivers operate Pharmacy Plus demonstration programs that provide assistance to Medicare beneficiaries with the cost of prescription drugs. Expenditures for these services receive Federal matching payments in the same manner as do services for full benefit Medicaid beneficiaries. In the proposed rule, we noted that due to the special treatment SPAPs receive relative to the TrOOP, States that operate Pharmacy Plus programs and beneficiaries enrolled in those programs could benefit financially by States restructuring their Pharmacy Plus programs to use a State only SPAP design to wrap around Medicare Part D. We sought comments on this issue and welcomed further data and analyses from States.

Comment: One State that operates a Pharmacy Plus waiver program responded to our request for comments. The State indicated that it does not plan to restructure its Pharmacy Plus program as a SPAP. The State commented that its pharmaceutical assistance programs provide its residents with benefits that are more generous than Medicare Part D. It provided comparative scenarios based on illustrative beneficiary spending levels and stated that beneficiaries in its State would be better off financially under the current arrangement. One beneficiary advocacy group agreed with the State's point-of-view. The public comments did not contain any other data or analysis on the issues we raised in the proposed rule regarding Pharmacy Plus Waiver programs.

Response: The State's comments compare a current benefit design with the structure of the standard Medicare Part D benefit, which will be implemented in January 2006, but assumes no State supplementation to the Medicare benefit nor does it include the special Medicare low-income subsidies that will be available to certain populations. Medicare Part D will provide a generous package of prescription drug coverage. While State Medicaid programs will no longer be able to claim Federal financial participation for those drugs after January 1st, 2006, we assume that States that developed special pharmaceutical assistance programs may be interested in continuing to provide financial assistance to these beneficiaries. The final rule provides that Pharmacy Plus programs can continue with Federal match after January 1, 2006, under certain circumstances. As indicated elsewhere in the Preamble, any State that operates a Pharmacy Plus demonstration program must determine whether it is feasible to continue that Pharmacy Plus program by submitting a revised budget neutrality calculation for the demonstration. We will review the revised budget neutrality calculation and approve or disapprove the continuation of the Pharmacy Plus demonstration for the period when Part D is effective.

Under the Statute, there is a financial incentive favoring States that provide Medicare beneficiaries direct financial assistance for the purchase of prescription drugs. As noted elsewhere in the preamble, Section 1860D–2(b)(4)(C)(ii) of the Act only allows a person or a SPAP to make payments that will count toward TrOOP for an individual Part D enrollee. However, as previously discussed, Pharmacy Plus waiver programs are not considered to be SPAPs. Therefore, Pharmacy Plus program expenditures cannot be counted towards the calculation of TrOOP. As noted earlier, the Pharmacy Plus Waiver Programs could be modified to take advantage of the incentive set by statute.

Given these considerations, we continue to believe that generally States would benefit by restructuring their prescription drug programs using a State-only SPAP design that wraps around Medicare Part D, rather than continuing their Pharmacy Plus programs. Depending on the State and the nature of the population, we believe that generally States could realize savings relative to their current Pharmacy Plus spending levels while protecting program participants from higher out-of-pocket costs. To be conservative, State savings estimates for these four Pharmacy Plus programs have not been included in our estimates of overall State savings, and would be in addition to net State savings presented in this analysis.

TABLE IV–4. PROJECTED STATE SAVINGS AND COSTS DUE TO THE MEDICARE DRUG BENEFIT AND RETIREE DRUG SUBSIDY, CY 2006–2010 (BILLIONS OF DOLLARS)

	2006	2007	2008	2009	2010	2006–2010
Savings						
Reduction in State Medicaid Spending	-10.0	-11.2	-12.5	-14.0	-15.6	-63.4
State Savings on Drug Costs for Retired State Workers	-1.0	-1.2	-1.3	-1.4	-1.5	-6.3
Savings for State Pharmacy Assistance Programs	-0.6	-0.6	-0.6	-0.6	-0.6	-3.0
Costs						
State Payments to the Federal Government for Full-Benefit Dual Eligibles	9.0	9.9	10.9	11.9	13.0	54.7
State Spending for New Medicaid Enrollees	1.5	1.6	1.8	2.0	2.2	9.1

TABLE IV–4. PROJECTED STATE SAVINGS AND COSTS DUE TO THE MEDICARE DRUG BENEFIT AND RETIREE DRUG SUBSIDY, CY 2006–2010 (BILLIONS OF DOLLARS)—Continued

	2006	2007	2008	2009	2010	2006–2010
Lost Revenue from Prohibition on Taxes on Premiums for Part D Coverage	0.06	0.08	0.10	0.12	0.14	0.50
State Administrative Costs*	0.09	0.09	0.09	0.09	0.09	0.45
Net Savings/Costs	-1.0	-1.3	-1.5	-1.8	-2.2	-7.9

Note: Positive numbers denote increased spending; negative numbers denote reduced spending (that is, savings). Numbers may not sum to total due to rounding.

* Prior to 2006, States are estimated to incur administrative costs related to Medicare Part D of $39 million in FY 2004 and $73 million in FY 2005.

I. Administrative Costs

There are four major areas of administrative costs associated with Medicare Part D that will be incurred by the private and public sector that merit separate discussion. These areas include the costs of PDPs and MA-PDs administering the Medicare prescription drug benefit, the cost of creditable coverage disclosure notices that the MMA requires be provided to Medicare beneficiaries and to CMS, the administrative costs associated with certain coordination of benefits as required by the MMA, and the administrative costs for employers and unions associated with obtaining the Medicare retiree drug subsidy. The following provides a detailed discussion of each of these areas.

1. Prescription Drug Plans and MA-PD Plans

The administrative cost estimates are based on taking into account the normal fixed costs associated with administering a prescription drug benefit, for example, such functions as claims processing, responding to customer inquiries, information dissemination, appeals processes, pharmacy network negotiations and contracting, and drug manufacturer negotiations and contracting. In addition, we assume ''risk-premium'' costs associated with risk-based insurance products that require companies to maintain certain levels of financial reserves. The other factor taken into account when developing our estimate is that PDPs and MA-PDs will likely incur slightly higher administrative costs during the initial few years of the Part D benefit due to start-up costs related to implementation and initial operations for a new benefit, for example more marketing and enrollment activities. We also assume that entities that will participate as PDPs will have already made the necessary changes to be HIPAA compliant because of the other business arrangements they will have been functioning in prior to choosing to participate as a PDP under the Medicare drug benefit program.

As is typically done with insurance products, we express the average administrative costs as a percentage relative to net standard benefit expenses. This percentage is commonly referred to as the ''administrative load.'' We estimate that the average administrative load will be 12.7 percent in CY 2006, with this declining slightly over time, and reaching 11.9 percent in CY 2010. The administrative load is expected to decline slightly over the period for two reasons: (1) administrative costs are expected to grow at a somewhat slower rate than PDP and MA-PD plans' prescription drug costs and (2) initial administrative start-up costs associated with implementation are expected to phase out in the first few years of operations.

Our estimates for administrative costs are similar to those seen in the general health insurance market. Our administrative load of 12.7 percent in 2006 translates into administrative costs being about 11.2 percent of total Part D plan expenditures (including both benefits and administrative costs). This is similar to the share of total health plan spending accounted for by administrative costs in the private sector. For example, as CMS reported in its ''Health Care Industry Market Update on Managed Care,'' Blue Cross Blue Shield health plans had average sales, general and administrative (SG&A) expenses ranging from 12 percent in 1999, 11.7 percent in 2000, 11.3 percent in 2001, and 10.9 percent in the first half of 2002. Similarly, in examining our Medicare Advantage plans data we see variation in administrative costs, for example newer plans (less than 5 years) seem to have higher administrative costs (11 percent) than older plans (7 percent).

The MMA also requires PDPs and MA-PDs to pay a user fee to help offset ongoing beneficiary education and enrollment costs relating to the Medicare prescription drug benefit, which represents an expansion of the user fees that are currently required of MA plans. As discussed earlier in this preamble, the MMA authorizes up to $200 million for beneficiary education and enrollment activities in FY 2006 and thereafter, reduced by the fees that will be collected from MA organizations and PDP sponsors in that fiscal year. Our rough estimates of the user fees for beneficiary education and enrollment costs in CY 2006 are approximately $21 million for PDPs and $34 million for MA organizations, with the remainder (approximately $144 million) being the government's share. These estimates are slightly different from those presented in the proposed rule and reflect our updated estimates for the Medicare Advantage program and Part D. While the user fees will actually be collected on a fiscal year basis, we believe that these estimates, which are based on calendar year data, provide a reasonable estimate of what the magnitude of these user fees will be during a given fiscal year. We assume that the cost of these user fees will be built into the administrative cost structure of the PDPs and MA-PDs, and will therefore be reflected in bids. We note that these user fees represent a minuscule percentage of the estimated total payments to MA organizations and PDP sponsors under the Medicare program.

2. Disclosure Notice Requirements

A number of entities that provide prescription drug coverage to Medicare beneficiaries such as Medigap plans, private and public sector employer or union sponsored plans that provide drug coverage to Medicare beneficiaries who are retired or who are active workers, State Medicaid Pharmacy Plus programs, State Pharmacy Assistance programs (SPAPs), and the Indian Health Service—are required to provide at certain times disclosure notices to beneficiaries on whether the drug coverage they provide equals or exceeds the actuarial value of standard Part D coverage. As discussed in the preamble,

certain entities that provide Part D coverage that is by definition creditable coverage (that is, PDPs and MA-PDs) will not be required to provide disclosure notices. Additionally, as discussed previously, States will not need to provide disclosure notices to full-benefit dual eligibles, as this will be handled through our process of deeming these beneficiaries as being eligible for the low-income subsidy.

The largest cost for providing these disclosure notices is expected to occur in the months preceding the implementation of the drug benefit in January 2006. Thereafter, notices will need to be provided by these entities prior to each subsequent Part D annual coordinated election period (AEP), if there is a change in creditable coverage status, or upon request by the individual. Also, firms that provide drug coverage to active workers will have to provide disclosure notices in the future to those active workers who become new Medicare beneficiaries. In an effort to reduce the burden associated with providing these notices, we have revised our final regulations to allow notices of creditable and non-creditable status to be provided with other information materials that these entities distribute to beneficiaries (rather than separately) and, as discussed in the preamble, we anticipate providing model language for both types of notices.

With the exception of Medigap insurers and group health plans that provide drug coverage only to Medicare beneficiaries who are active workers (and not retirees), implementation of the Medicare prescription drug benefit and the retiree drug subsidy is expected to produce net savings to public and private sector entities that provide drug coverage to Medicare beneficiaries. For SPAPs, State Pharmacy Plus programs, the Indian Health Service (IHS), and private sector and State/local government group health plans that provide retiree drug coverage, we estimate that the cost of creditable coverage disclosure notices will be about $18 million in CY 2005, with anticipated savings from the implementation of Medicare Part D expected to far exceed the disclosure notice costs for each of these entities. We note that the estimated disclosure notice cost for these entities has decreased from our previous estimate in the proposed rule because we are allowing most entities (with the exception of Medigap plans) to include disclosure notices with other existing plan materials (instead of requiring a separate notice) and CMS will be handling the disclosure notices for full-benefit dual eligibles through our process of deeming these beneficiaries as being eligible for the low-income subsidy.

For Medigap insurers and employer/union group health plans that offer coverage only to beneficiaries who are active workers, not retirees, the cost of providing disclosure notices is estimated to be approximately $62 million in CY 2005 (which translates into an average of roughly $151 per employer/union that offers drug coverage to Medicare beneficiaries who are active workers and about $11,050 per Medigap insurer).

We anticipate that annual disclosure notice costs in years after 2005 will generally be significantly lower. For example, while entities will be required to provide disclosure notices prior to each Part D annual coordinated election period, they will be able to include these notices in their existing plan materials with minimal modifications unless there has been a change in their creditable coverage status. Similarly, while group health plans that provide drug coverage to active workers will also need to provide disclosure notices to the more limited number of new beneficiaries who age into the Medicare program, they will also be able to include these notices in their existing plan materials at minimal cost.

We anticipate that most of the disclosure notice costs in years after 2005 will be related to changes in benefit design and/or creditable coverage status among employer and/or union-sponsored plans providing coverage to active workers and retirees. For example, we estimate that some group health plans providing coverage to active workers will incur costs in the event that their plan has a substantial change in its benefit structure that makes a reconfirmation of their creditable coverage status appropriate, as well as in the event of a change in their creditable coverage status. Similarly, we anticipate that there will be some disclosure notice costs associated with changes in creditable coverage status among employer/union-sponsored retiree plans that choose to transition from providing coverage that qualifies for the retiree subsidy to providing coverage that complements the Medicare drug benefit. Additionally, we anticipate that a small number of beneficiaries will request an additional copy of their creditable coverage disclosure notice during any given year, which may need to be sent separately from the other plan materials that the various entities normally provide to their participants.

We estimate maximum costs of roughly $8 million to $9 million per year for disclosure notices during the period CY 2006–2010. We note that the estimated disclosure notice cost for years after 2005 has increased somewhat from our previous estimate in the proposed rule because in addition to the estimated costs associated with creditable coverage status changes and reconfirmations relating to active worker plans, we have also included costs associated with plan sponsors providing notices to Medicare retirees in the event of a change in status and costs associated with providing additional copies of notices to a small number of individual beneficiaries upon request. For private sector and State/local government group health plans that provide retiree drug coverage, we estimate that the maximum cost of creditable coverage disclosure notices will be about $3 million per year during the period CY 2006–2010 (including costs associated with change of creditable coverage status notices and costs associated with providing additional notices to individuals upon request). For Medigap insurers and employer/union group health plans that offer coverage only to beneficiaries who are active workers, the cost of providing disclosure notices is estimated to be approximately $5 to $6 million per year during the period CY 2006–2010.

In brief, we take the following approach to estimate the cost of disclosure notices. For the various entities that are required to provide disclosure notices, the circumstances of these different types of coverage and how they will relate to the new Medicare prescription drug benefit differ. Consequently the nature of the disclosure notice and any associated actuarial valuation will vary. Beyond the cost of the actuarial valuation are the costs of preparing and mailing the notices. We generally base our cost estimates on wage data from the Department of Labor for an actuary and for administrative personnel, adjusted to 2005 and loaded for compensation, overhead, general administration and fee, with additional adjustments for wage growth in subsequent years.

In terms of the basic costs of preparing and mailing the disclosure notices, we assume that each entity required to provide these notices expends 8 hours for developing the notice (with one exception described below), 1 hour for providing a copy of the notice to CMS, 1 hour per 60 notices for providing separate notices to beneficiaries in the case of Medigap plans, approximately 5 minutes per notice for providing separate additional

copies of the notices to individual beneficiaries upon request, and negligible costs for incorporating notices into existing plan materials that are provided to beneficiaries (since these plan materials are already being disseminated to their participants). The one exception to this relates to group health plans that provide drug coverage only to Medicare beneficiaries who are active workers, not retirees. We assume these entities expend less time developing the notice (2 hours) because we expect that this service is likely to be provided to them by insurers or health plan administrators, who we anticipate will spread the cost of this service across many plan sponsors.

In terms of the time involved in performing the actuarial valuation that forms the basis of the disclosure notices, we anticipate that it will vary somewhat by the type of entity providing the notice. As discussed subsequently in the section on administrative costs for the retiree drug subsidy, our estimates of the time involved in doing actuarial valuations were informed by discussions held with actuaries in our Office of the Actuary and other industry experts. With respect to SPAPs and State Pharmacy Plus programs, we expect that the actuarial assessment is not likely to be complex, and that the disclosure notice will likely focus on how the State program will work with the new Medicare drug benefit. We assume that each SPAP and State Pharmacy Plus program would expend on average 2 hours for actuarial work. With respect to the Indian Health Service, we expect that the actuarial assessment is not likely to be complex since the coverage is likely to be creditable; we assume that the IHS would expend less than 6 hours for actuarial work.

We believe that the notice requirement related to Medigap drug policies will be relatively straightforward. In accordance with section 104 of the MMA, we are developing a model disclosure notice for Medigap insurers in consultation with the NAIC. For standardized Medigap plans, we anticipate that the actuarial work involved in developing these notices will be minimal. As discussed elsewhere in the preamble, we believe that standard Medigap plans H and I are not creditable and that it is very unlikely that plan J would be creditable. In the case of the pre-standardized policies, the nature of the actuarial valuation and the level of effort involved will likely vary with the nature of the benefit package. For the purpose of this analysis, we assume 6 hours on average per Medigap insurer for actuarial valuations, taking into account that those with pre-standardized plans may do more extensive actuarial valuations.

Employer or union-sponsored retiree health plans that apply for the Medicare retiree drug subsidy will have to perform an actuarial valuation for the purpose of their application. We assume that those plans will simply use the actuarial valuation that was developed for the retiree subsidy application for the disclosure notices. We note that the first prong of the retiree drug subsidy program's actuarial equivalence test requires plan sponsors to compare the gross value of their drug benefit with the value of the standard Part D benefit (which is the same comparison that they will need to make for disclosure notice purposes). Thus, we assume nominal costs for the actuarial valuation related to the disclosure notices. Estimates of the administrative costs related to applying for the Medicare retiree subsidy, including the actuarial valuation, are discussed elsewhere in this document.

We anticipate that employer or union-sponsored retiree health plans that do not choose to apply for the retiree drug subsidy will need a minimal amount of time to compare the value of their drug benefit with the value of the standard Part D benefit, and expect that these employers/unions will be able to use the simplified actuarial methods that we anticipate developing and publishing for comparing a sponsor's plan with the standard Part D benefit, as discussed in subpart R of the preamble, in making this comparison. For these reasons, we assume that each of these plan sponsors will on average incur expenses for one-quarter of an hour of actuarial time. As discussed in more detail subsequently, this relatively low number reflects our assumption that the insurers and PBMs will build actuarial models that can determine creditable coverage status for multiple plans with similar benefit designs in a relatively automated fashion, and that they will spread the associated costs across many plan sponsors.

In addition, in future years, employer or union sponsored plans that offer retiree coverage may incur costs associated with changes in creditable coverage status. For those entities that experience such changes, we use the same assumptions relating to the time involved in doing the actuarial valuation, developing the notice, and notifying CMS and beneficiaries as for the initial creditable coverage notices, with adjustments for future growth in wages. It is important to note that there is uncertainty relating to the number of firms that will apply for the retiree drug subsidy versus providing enhanced or supplemental prescription drug coverage that complements Medicare Part D, especially since approximately 90 percent of the retirees with employment-based coverage are concentrated in 10 percent of the firms that provide this coverage. Given this uncertainty, we take the approach of estimating the maximum possible cost associated with disclosure notice activities for these firms.

Disclosure notices are also required of group health plans that provide drug coverage to active workers who are Medicare beneficiaries (that is, beneficiaries for whom Medicare is the secondary payer). It is very difficult to know how many firms that provide health insurance to their active workers have a Medicare beneficiary in their workforce. We have estimated roughly as an upper bound that there may be as many as 400,000 firms that provide drug coverage to at least one Medicare beneficiary who is an active worker. We emphasize that this is a very rough estimate that extrapolates from data from a number of sources (including an IRS, SSA, CMS data match, Census data, BLS data, and a Kaiser survey). We note that our rough estimate of the number of employers that may be providing coverage to Medicare beneficiaries that are active workers has decreased from our previous estimate that was included in the proposed rule, because we had inadvertently included employers with fewer than 20 employees who are exempt from Medicare Secondary Payer requirements in the prior estimate.

We anticipate that many of these employers that provide drug coverage to beneficiaries who are active workers are purchasing standard health insurance products from insurers that sell these plans to numerous purchasers, and that the cost of the actuarial valuation for purposes of confirming that this coverage is creditable will be spread across a relatively large number of employers or third party purchasers. While self-insured employers may have more distinct health plan benefit structures, we believe that it is likely that their health plan administrators would be able to achieve economies of scale by building actuarial models that can serve multiple clients. In addition, the cost of the valuation for those employers and unions that also offer retiree drug coverage could potentially be incorporated into the costs required to do an actuarial valuation for both types of coverage and thus there may be some economies of scale (particularly since some employers and unions' retiree plans provide coverage that is

similar to the coverage that is available in their active worker plans). Additionally, we expect that these employers/unions and their insurers or plan administrators will be able to use the simplified actuarial methods described above in comparing their drug coverage to the standard Part D benefit. For these reasons, we assume that each of these employers/unions will on average incur expenses for one-quarter of an hour of actuarial time. This relatively low number reflects our assumption that insurers and PBMs will build actuarial models for determining creditable coverage in an automated fashion that will be able to accommodate different cost-sharing structures with minor modification, and that they will spread the fixed cost associated with building these models across many employers and unions. Consequently, the estimated one-quarter of an hour of actuarial time represents the estimated share of the cost for those systems that will be passed on to each employer.

In years after 2005, employers that provide drug coverage to Medicare beneficiaries who are active workers are likely to expend some additional time related to disclosure notices, but we anticipate this time will be substantially less than in 2005. In subsequent years, we anticipate that these employers will provide disclosure notices to their workers who age into the Medicare program and continue working. In addition, it is possible that a portion of these employers may alter their drug benefit design to such an extent that a reconfirmation of their creditable coverage status may be appropriate. We assume that those active workers who become new Medicare beneficiaries each year will receive disclosure notices as part of existing plan materials that these employers normally provide to their employees, that about 25 percent of the firms providing coverage to beneficiaries who are active workers will need to obtain a new actuarial valuation on their benefit design per year, and that about 1 percent of the firms providing coverage to beneficiaries who active workers will have a change in creditable coverage status that requires them to provide a notice to CMS as well as a notice to beneficiaries in their plan materials in any given year. As discussed previously, we anticipate that the disclosure notice cost per employer that offers drug coverage to Medicare beneficiaries who are active workers (and not retirees) will be relatively small—$151 per employer on average in CY 2005 and we expect less in future years.

Finally, we anticipate that a minimal number of beneficiaries will request an additional copy of a creditable coverage disclosure notice in any given year. Specifically, we estimate that approximately 5 percent of the beneficiaries receiving coverage through group health plans for active workers, and retiree health plans that participate in the retiree drug subsidy program will request an additional copy of their disclosure notice in any given year. Similarly, we estimate that approximately 5 percent of the beneficiaries that choose to continue receiving creditable drug coverage through Medigap plans will request an additional copy of their disclosure notice in any given year (we assume that most beneficiaries that have Medigap drug coverage will enroll in Part D because most Medigap coverage is not creditable). Finally, we estimate that a smaller percentage (1 percent) of the beneficiaries in retiree health plans that choose not to participate in the retiree drug subsidy program will request an additional copy of their disclosure notice in any given year because we anticipate that most of the beneficiaries in these plans will already be enrolled in Part D (since many of these employers/unions are likely to have drug coverage that complements the standard Part D benefit). In cases where individuals request an additional copy of the creditable coverage disclosure notice, we assume that the entity will give the beneficiary a copy of the same disclosure notice that it has already incorporated into its plan materials. Therefore, we do not assume that these entities will incur an additional cost associated with developing a new disclosure notice for this purpose; however, as discussed previously, we conservatively estimate that these entities will incur a nominal cost in disseminating this information to beneficiaries upon request.

We believe that the changes that we have made in the final rule related to allowing various entities to provide notices of creditable and non-creditable coverage status with other existing plan materials that are distributed to beneficiaries (rather than separately), providing model language for both types of notices, and allowing employers and unions to use simplified actuarial methods to determine the actuarial equivalence of their drug coverage to the Part D benefit will help to reduce the administrative burden associated with the disclosure notice requirements, while also ensuring that beneficiaries receive the information they will need to make an informed decision about enrolling in Part D.

3. Coordination of Benefits Under Employer And Union-Sponsored Plans and SPAPs

We are required under the statute to establish requirements for coordination of benefits between Medicare PDPs and MA-PDs and other insurers including SPAPs, Medicaid programs, group health plans, FEHBP, military coverage including TRICARE, and other coverage CMS may specify. Ensuring accurate and timely coordination of benefits is important for tracking the true out-of-pocket limit, a cornerstone of the benefit design. This will necessitate that an efficient and effective operational framework be established to track beneficiary out-of-pocket expenditures.

Section 1860D–23(a) of the Act authorizes the Secretary to establish procedures and requirements to promote the effective coordination of benefits between a Part D plan and an SPAP with respect to payment of premiums and coverage, and payment for supplemental prescription drug benefits. In addition, as specified at section 1860D–24(a) of the Act, we will apply coordination of benefit requirements to other prescription drug plans including group health plans, the Federal Employees Health Benefits Program (FEHBP), military coverage (including TRICARE), Medicaid (including a plan operating under a waiver under section 1115 of the Act), and other coverage that we specify.

The elements to be coordinated include enrollment file sharing, claims processing, payment of premiums for both basic and supplemental drug benefits, third-party reimbursement of out-of-pocket costs, application of protection against high out-of-pocket expenditures (defined in section 1860D–2(b)(4) of the Act), and other administrative processes and requirements that we specify. As required by the statute, we will establish procedures before July 1, 2005, to ensure the effective coordination of benefits between Part D plans and SPAPs and third party coverage.

As discussed more fully in the Preamble, we plan to play a role in ensuring that benefits are coordinated and TrOOP is tracked. We intend to establish an efficient and effective process for handling coordination of benefits and tracking of the TrOOP by the Part D plans, consistent with the statute and the guidance we will issue. We are considering how best to facilitate these processes, including through the establishment of a TrOOP facilitation contractor, contractors, or some type of blended approach. We also plan to

facilitate TrOOP by leveraging coordination of benefits processes currently in place under Medicare, and by creating an on-line eligibility file query to assist pharmacies in directing claims to the correct payer. As discussed, we will provide guidance on the specific processes for coordinating claims prior to July 1, 2005. We believe the coordination effort will reduce the confusion that could result for multiple payers being involved in payment of an individual claim. We believe that a coordination of benefits and TrOOP facilitation effort will ease the burden on Part D plans especially, but also on pharmacists and ultimately on beneficiaries since it will help ensure that claims involving multiple payers are paid correctly, accurately, and as timely as possible.

Section 1860D–24(a)(3) of the Act permits the Secretary to impose user fees on plans (but not on SPAPs) for the transmittal of benefit coordination information under Part D. We are also provided authority to retain a portion of these user fees to offset costs we incur in providing for the coordination of benefits. Costs incurred may include items such as the necessary infrastructure, system security, and outreach and education activities related to TrOOP. We plan to provide more detailed information regarding the user fee, including the amount and collection processes in CMS guidance to be issued prior to July 1, 2005. However, we plan to charge no more than $1 per annum in 2006 for each beneficiary enrolled in a Part D plan to provide for funding of a Part D coordination of benefits and TrOOP facilitation process, and we expect that the fee will be considerably less. This cost is expected to be collected from plans at a rate of 1/12 of $1 per month for each enrolled beneficiary. We expect that these small costs will be reflected in plan administrative costs as part of their bids.

We believe that a maximum of $1 per year per enrolled beneficiary is a relatively modest sum, given the value of the coordination of benefits function to Part D plans, beneficiaries, pharmacists, and secondary payers. The user fee represents a small fraction of the total expense of administering the Part D benefit. Indeed, the $1 per enrollee per year maximum user fee amount is quite small when considered on a per claim basis, given the sheer volume of Part D claims expected in 2006. We believe that imposing a user fee to cover the expenses involved in coordinating benefits and facilitating accurate TrOOP tracking is more cost effective and convenient for Part D plans than having the plans plan for, implement, and perform these functions independently.

Pharmacies have much to gain by having a coordination of benefits effort as described more fully in the Preamble. Pharmacies have a great interest in ensuring that claims are paid correctly and quickly at the point of sale. We expect that pharmacies will have an on-line eligibility file query capability to facilitate situations where the pharmacy is lacking information in order to bill the appropriate payer. Having an electronic source of payer information on customers with multiple insurances will be a valuable service to pharmacies. While the advent of the Part D benefit will require pharmacies to electronically submit a portion of claims to more than one insurer, the cost of doing so will be quite small in comparison to the positive effect on pharmacies of the Part D benefit (including increased sales of prescriptions and increased foot traffic in the ''front end'' of the store).

The majority of commenters supported the option of having a TrOOP facilitator assist us in ensuring that benefits coordination and TrOOP facilitation is performed. We believe that this support underscores the value of the function to plans, pharmacies, and beneficiaries. We are currently considering the best approach for all parties concerned. We are prepared to have a role in coordinating benefits and tracking TrOOP, as explained more fully in the Preamble, since this approach is effective and is supported by commenters. CMS is considering facilitating TrOOP in many ways, including through the establishment of a TrOOP facilitation contractor, contractors, or a blended approach. We will continue to work with the parties involved to pursue an approach that makes the most sense for plans, pharmacies, and beneficiaries. We will continue discussions and will issue details and guidance prior to July 1, 2005.

4. Estimated Administrative Costs in Applying for Retiree Drug Subsidy

Qualified retiree prescription drug plans that choose to accept the Medicare retiree subsidy will incur some administrative costs associated with obtaining the subsidy.

As discussed earlier in the preamble, sponsors will have to submit to CMS an application for the Medicare retiree drug subsidy, including an attestation that the actuarial value of the prescription drug coverage under their retiree plan or plans is at least equal to the actuarial value of defined standard prescription drug coverage under Medicare Part D. The attestation must be certified by the attesting actuary, and the application must be signed by the plan sponsor (or a plan administrator designated by the sponsor). As part of this application, employers and unions are also required to provide other information including data about the eligible covered Medicare retirees in their plan or plans, as well as a signed sponsor agreement. In addition, entities accepting the Medicare retiree drug subsidy payments will have to report certain prescription drug cost data for the purpose of receiving subsidy payments and maintain records for purposes of audit and oversight by CMS. We also note that employer and union sponsored health plans that provide drug coverage to beneficiaries are required to provide, at certain times, creditable coverage disclosure notices to beneficiaries. These notices are required regardless of whether the plan sponsor applies for a subsidy, and consequently the costs of these notices are discussed in the section of this analysis on disclosure notices.

In developing the rule, we have tried to minimize the administrative burden associated with the operation of the retiree subsidy program. We want to establish an efficient administrative structure that provides maximum flexibility for qualified retiree prescription drug plans, while at the same time providing for an appropriate level of financial accountability that assures the accuracy of payments and safeguards the interests of beneficiaries, consistent with our fiduciary responsibility.

For purposes of the ''Collection of Information Requirements'' section and the accounting statement in this rule, we have developed an estimate of the time and aggregate employer/union costs involved in the various administrative functions associated with employers and unions obtaining the Medicare retiree subsidy including: subsidy application requirements, including performing the actuarial valuation; preparing and coordinating the plan(s)' enrollment files and other information databases to identify the eligible Medicare retiree population and other relevant information; assembling the application; reporting data and information (for example, data on prescription drug costs for the purpose of receiving subsidy payments); and record retention. We base our cost estimates on 2005 wage data for an actuary, computer programmer, and administrative personnel loaded for compensation, overhead, general administration, and fee.

a. Application for Retiree Drug Subsidy Including Actuarial Attestation

In applying for the subsidy, sponsors of qualified retiree prescription drug

plans are required to provide to us an attestation that the actuarial value of the prescription drug coverage in each such plan is at least equal to the actuarial value of defined standard Medicare Part D prescription drug coverage. Sponsors of qualified retiree prescription drug plans will need to submit this attestation on an annual basis, and submit an updated attestation if there is a change during the year that materially affects actuarial value of their drug coverage. As discussed earlier in the preamble, a material change means any change that potentially causes a plan to no longer meet the actuarial equivalence test (these submissions would not be required when non-material changes are made to the coverage).

One factor in the cost of actuarial attestation is that one actuarial model can potentially be used to analyze multiple plans' benefit designs that, for example, are similar in design but use different co-payments or have different levels of beneficiary premium contributions. We believe it is likely that various entities that work with employer/union sponsored group health plans (such as employee benefit consultants, actuarial firms, insurance companies, or PBMs) are likely to develop such models and spread the development costs across numerous clients, lessening the cost to any one employer/union. In addition, we believe it is likely the entities that develop actuarial models and pass the costs onto employers/unions will likely amortize over time the fixed costs of model development.

Besides the fixed costs of developing an actuarial model, each actuarial valuation will likely require some individual time by an actuary. That analysis time may vary depending on the complexity of the plan offered by the employer/union. Given that some employers (particularly large employers) may often offer multiple plans (benefit options) which may involve multiple valuations, we expect that the actuarial time would vary across employers.

To develop assumptions about the time and costs involved, we had discussions with actuaries in our Office of the Actuary and other industry experts. From these discussions, we developed a range of time estimates for preparing actuarial models, taking into consideration: the use of actual plan data if it is available and credible, the time to conduct the analyses, the issue of economies of scale in the use of one model to analyze multiple plans, and the time involved in preparing the written attestation report. Based on these discussions, our preliminary estimate is that total time involved in developing one actuarial model and preparing an analysis and report on one plan could generally range from 6 to 40 hours. For the purpose of this analysis, we assume that on average employer/union sponsored retiree health plans incur costs for the actuarial valuation in the initial year ranging from 2 hours of actuarial time for very small firms (assuming that the entity that performs the actuarial valuation spreads the cost of developing an actuarial model across a large number of clients and amortizes the costs over time) to 60 hours for very large firms that offer multiple plans (benefit options) and require significant specialized analysis. Based on these assumptions and taking into account the time involved for firms of different sizes, we estimate that the cost of the actuarial valuation would on average be in the range of about 1.8 percent of the value of the retiree subsidy.

In addition to the actuarial valuation, plan sponsors applying for the retiree subsidy will need to prepare the application and related enrollment data and information on retirees, and sign the sponsor agreement. We anticipate that the time involved in preparing the application and required enrollment information will vary by firm size, with the average time ranging from 5 hours for the smallest firms with 6 retirees on average to 382 hours for the largest firms with more than 1,500 retirees on average. In addition, we assume a half hour for signing the sponsor agreement. As discussed elsewhere, some of the information needed on eligible beneficiaries may not be routinely available to plan sponsors and consequently for initial start-up some level of effort may be needed to obtain this information. We have been conservative in our assumptions to reflect this possibility. It is important to note that a significant portion of the time involved would be a one-time expense. Based on these assumptions, we estimate that on average across large and small firms, the cost involved in preparing the application and related enrollment information (excluding the actuarial work) and signing the agreement would be in the range of about 2.9 percent of the value of the subsidy. It is important to note that after the first year, we believe these costs will decline as the initial work associated with identifying the eligible population will have been accomplished and as employers/unions and their agents gain more experience with the program.

b. Reporting

In order to obtain the subsidy, sponsors of qualified retiree prescription drug plans will need to submit certain data to CMS and maintain certain records. If a sponsor elects to receive monthly or quarterly retiree subsidy payments or an interim annual retiree subsidy payment, the plan sponsor must submit aggregated gross cost data, an estimate of the difference between these gross costs and allowable costs (based on expected rebates and other price concessions), and any other data CMS may require upon submission of data for payment at each of the time intervals elected by the sponsor, with a final reconciliation within 15 months after the end of the plan year. For final reconciliation purposes, sponsors must submit total gross cost data segregated per qualifying covered retiree; actual rebates, discounts or other price concessions received for such costs; and any other data CMS may require, within 15 months after the end of the plan year. In addition, plans sponsors are required to provide on a monthly basis an update to their enrollment file (for example, accretes and deletes). Because prescription drug data and records are highly automated, there are significant economies of scale related to data reporting requirements, which we believe will lessen the cost to any one employer/union group health plan. We anticipate that insurers, PBMs, and third-party administrators will incur initial fixed costs in modifying their current claims processing systems to track prescription spending data in the required format to be submitted for payment purposes. We believe there would be substantial economies of scale in making these systems changes, as we anticipate that an entity (such as a third party administrator or insurer) could generally use the same approach for numerous clients. We also anticipate that entities that work with group health plans (such as insurers, PBMs, third-party administrators, actuarial firms, and employee benefit consultants) will incur fixed costs associated with developing a methodology for rebate allocation and modifying their systems to allocate rebates accordingly. We believe that it is likely that these entities would generally use a similar approach for allocating rebates and making systems modifications for its clients and would spread the fixed development costs across those clients. While we recognize that there will be some individual client specific work necessary for rebate allocation, we believe it is likely that certain aspects of this process such as developing a general rebate allocation method and general approach to systems changes would provide economies of scale. In addition, since some of these same entities will likely be developing

systems to track costs and allocate rebates for both the Medicare retiree drug subsidy and the Medicare Part D program, we believe it is likely that there may be some overlap in the initial development phases of this work for some of these entities that may provide additional economies of scale.

In the initial year, we estimate that plan sponsors will incur costs equal to about 0.8 percent of their expected subsidy payments due to the fixed costs associated with developing methodologies and modifying systems to generate the required cost data and allocate rebates. As noted previously, we assume a relatively low amount of cost per plan sponsor because we anticipate that entities that work with group health plans (such as insurers, PBMs, actuarial firms, and employee benefits consultants) will spread the fixed costs associated with this work across many clients. With respect to costs associated with developing the infrastructure to provide a monthly enrollment update, we believe that the systems and procedures needed to do this would have already been developed as part of the plans sponsors work identifying qualified retirees during the initial application process, and consequently, those costs have been included in our prior cost estimate in that area. In terms of the costs associated with generating the required cost data and enrollment data (once the systems have been developed and tested), we assume that the average number of hours of staff time involved in submitting the drug cost data and enrollment data will range from 12 hours (for a very small firm that we assume submits cost data annually) to 56 (for a very large firm that we assume submits cost data monthly). Based on these assumptions and taking into account the time involved for firms of different sizes, we estimate that the cost associated with submitting drug cost data and enrollment data would on average be in the range of about 0.9 percent of the value of the retiree subsidy.

In addition to data reporting, employers that receive the subsidy will also be required to retain data and records for six years. For the purpose of this analysis, we assume that the time involved in record retention would vary by firm size, with the average time ranging from 4 hours for the smallest firms to 20 hours for the largest firms. Based on these assumptions and taking into account the varied time involved across firms of different sizes, we estimate that on average the record retention would be in the range of about 0.4 percent of the value of the subsidy.

c. Conclusion

Based on our analyses, we estimate that the administrative costs associated with obtaining the retiree subsidy will represent on average in the range of about 6.8 percent of the value of the subsidy in 2006 and are expected to decline significantly in subsequent years. After the first year, we believe these costs will decline as the initial work associated with identifying the eligible population will have been accomplished and as employers/unions and their agents gain more experience with the program.

J. Medigap Provisions

The MMA prohibits Medigap insurers from selling new Medigap policies that cover prescription drugs after December 31, 2005 and prohibits the renewal of existing Medigap policies with drug coverage for beneficiaries who enroll in Medicare Part D. Part D enrollees with current Medigap drug coverage have the choice of renewing their existing Medigap policy without drug coverage or buying certain other Medigap plans that do not have drug coverage if they enroll in a Part D plan in the initial enrollment period. We emphasize that the MMA itself directly restructures the role of Medigap insurance, and that it is not the result of this rulemaking.

We estimate that about 1.9 million beneficiaries would be enrolled in Medigap plans with drug coverage in 2006, absent the law change. As discussed elsewhere in this analysis, we estimate that the vast majority of these beneficiaries will enroll in Medicare Part D. However, we note that these estimates do not take into account the possibility that a small portion of beneficiaries with pre-standardized Medigap plans may have creditable drug coverage. To the extent that such situations exist and beneficiaries, who have had these policies for a long period of time (that is, prior to standardization in the early 1990s), choose to remain in them, our estimates of the number of beneficiaries shifting from Medigap drug coverage to Medicare Part D may be slightly overstated.

As a result of the statutory prohibition on the sale of Medigap policies with drug coverage to Part D enrollees, we expect these beneficiaries will move from Medigap policies that contain prescription drug coverage to Medigap policies that do not contain such coverage. We expect that the policies without drug coverage will have lower premiums. We estimate that the resulting reduction in Medigap insurers revenues associated with the MMA prohibition on the sale or renewal of policies with drug coverage would be approximately $2.4 billion in 2006, $2.5 billion in 2007, $2.7 billion in 2008, $2.9 billion in 2009, and $3.1 billion in 2010. We note, however, that some Medigap insurers may choose to enter the PDP or MA-PD market and offer those products. As discussed elsewhere in the impact analysis, the Medicare prescription drug benefit is subsidized and expected to attract substantial enrollment, which may provide new business opportunities for Medigap insurers. In addition, we believe that the movement of beneficiaries from Medigap drug coverage to Medicare Part D will generate substantial savings for these beneficiaries on prescription drug costs. The standard Medicare Part D benefit provides a 75 percent government-subsidized benefit, catastrophic coverage, and cost savings from discounts and other cost management activities. It also is not likely to suffer from the substantial adverse selection, and resulting increased premiums, that are seen in Medigap plans with drug coverage.

Our projections of Medigap enrollment in policies with drug coverage and the premiums associated with that drug coverage were developed using data from NAIC on standardized Medigap plans, and information gathered by a CMS contractor on pre-standardized Medigap plans and waiver State plans. Our current estimates of the revenue impact on Medigap insurers are slightly lower than those presented in the proposed rule because the analysis assumes a slightly lower rate of enrollment in Medicare Part D. While our estimates do not take into account standalone Medigap drug policies, these policies represent substantially less than 1 percent of the Medigap market and would not affect the estimates.

K. Small Business Analysis

The Regulatory Flexibility Act (RFA) requires agencies to determine whether a rule will have a ''significant economic impact on a substantial number of small entities.''

If a rule is expected to have a significant economic impact on a substantial number of small entities the RFA requires that a Regulatory Flexibility Analysis be performed. Under the RFA, a ''small entity'' is defined as a small business (as determined by the Small Business Administration (SBA)), a non-profit entity of any size that is not dominant in its field, or a small government jurisdiction. HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

With respect to the Medicare prescription drug benefit and retiree drug subsidy, there are four areas that we believe merit discussion related to small business impacts: (1) retail pharmacies, (2) long-term care pharmacies,(3) insurers and PBMs, and (4) employers. We anticipate that the retail pharmacy industry, which is comprised of both chains and a large number of independent pharmacies, will play a critical role in the Medicare drug benefit as it furnishes prescription medicines and pharmacy services to beneficiaries enrolled in Medicare Part D. While the Medicare prescription drug benefit is expected to have several effects on retail pharmacy revenues, both positive and negative, our estimate is that the impact on the overall retail pharmacy industry, including small pharmacies, generally will be positive.

In addition to retail pharmacies, long-term care pharmacies will play an important role in the Medicare Part D drug benefit. The long-term care (LTC) pharmacy industry is dominated by four large corporations. Because of significant data limitations related to the remainder of the market, we are unable to predict with certainty either the presence or absence of ''a significant economic impact on a substantial number'' of small LTC pharmacies. We believe that a more competitive market under Medicare Part D will reward LTC pharmacies offering the lowest prices and highest quality service; it may also open the door for new entrants into the market as LTC facilities restructure their existing contracts with LTC pharmacies. We anticipate that there may be changes in market share among the pharmacies that service LTC facilities. The competitive results we expect are likely to impact many small LTC pharmacies positively, while some will likely experience a negative effect. This changing market will be the result of the competitive situation under Medicare Part D.

Since PDPs and MA-PDs are the principal vehicles through which the Medicare prescription drug benefit is administered, we also examine whether there are any small business impacts on the types of businesses expected to apply to be prescription drug plans—that is, insurers and PBMs. The effects of the statute and regulation promulgating the Medicare Part D program would increase drug utilization and thus be favorable to many insurers and PBMs. Furthermore, in considering how the regulations could be made more flexible, we have analyzed the regulatory provisions of this rule over which we have discretion and concluded that they have little overall effect on the insurance and PBM industry, and certainly not a significant adverse impact.

In the case of the small employers who continue to provide qualified prescription drug coverage for their retirees, we estimate that savings obtained from the Medicare retiree drug subsidy will greatly exceed the employer's administrative costs associated with obtaining the subsidy, and thus the result of the retiree drug subsidy provision is a net positive impact. We would like to make participation in the retiree drug subsidy program as simple as possible for small entities. As discussed elsewhere in the preamble we have made the retiree drug subsidy as flexible as possible for employers by giving them the option to use either a calendar year or plan year cycle for purposes of obtaining the retiree subsidy, and to elect the payment frequency (that is, monthly, quarterly, or annually) that best meets their needs. For example, small employers may find receiving payment only on an annual basis as the least burdensome approach given the size of their retiree population and associated Medicare retiree prescription drug payments, and our final rule provides for this option.

While we believe that we could certify that this rule will not have a significant economic impact on a substantial number of small retail pharmacies, employers, or insurers/PBMs, we provide a Regulatory Flexibility Analysis for each. In addition, since we are unable to predict with certainty either the presence or absence of a significant economic impact on a substantial number of small long-term care pharmacies, we also provide an analysis for these entities.

In addition, in accordance with Section 1102(b) of the Social Security Act, we also address whether this rule will have an impact on the operations of small rural hospitals.

1. Retail pharmacies

The RFA requires us to determine whether this rule will have a significant economic impact on a substantial number of small retail pharmacies. SBA considers pharmacies with firm revenues of less than $6 million to be small businesses. The 1997 Economic Census (the latest available detailed data) indicates that there were about 21,000 firms operating about 41,000 retail pharmacies and drug store establishments (NAICS code 44661) continuously through 1997. Of these firms, about 20,000 had revenues under $5 million (which was the small business size standard in 1997) and operated a total of about 21,000 establishments. Since over 95 percent of retail pharmacy firms are small businesses (as defined by the SBA size standards), we do expect that the statutorily-created Medicare prescription drug benefit will have some effect on a substantial number of small retail pharmacies. However, we estimate that overall the revenue effect on the retail pharmacy industry, including small pharmacies, will generally be positive.

We anticipate that, although the Medicare prescription drug benefit will lead to both revenue increases and decreases for retail pharmacies, the increase in revenues is estimated to more than offset the decrease in revenues. First, we expect that the vast majority of beneficiaries currently without prescription drug coverage will choose to enroll in Medicare Part D. The extension of drug coverage to these individuals, and the resulting lower out-of-pocket costs they face when purchasing prescription drugs, is expected to lead to higher drug utilization and total expenditures, and consequently higher revenues for retail pharmacies. At the same time, some of these beneficiaries without prior drug coverage, as well as some beneficiaries with Medigap drug coverage, would be expected to realize new pharmacy discounts under Medicare Part D that they otherwise would not obtain. We note that the Medicare prescription drug benefit would not lead to any additional pharmacy discounts for the majority of beneficiaries who currently have drug coverage as they already obtain pharmacy discounts through their current insurers (for example, employer-sponsored health plans, Medicare Advantage plans, and State plans). In addition, we have examined the potential for increased use of mail order pharmacies among some beneficiaries, and its potential impact on retail pharmacies. As described in more detail in the subsequent methodological discussion, we estimate that the complex set of countervailing effects of increased utilization and new pharmacy discounts and possibly new use of mail order pharmacies among some beneficiaries would result in a net increase in retail pharmacy revenues ranging from a lower bound of 1.5 percent to an upper bound of 2.7 percent. This estimated increase in retail pharmacy revenues will be partially offset by a reduction in retail pharmacy revenues for dual eligibles as discussed subsequently.

Since State Medicaid programs typically pay higher reimbursement rates to retail pharmacies than private sector insurers, we expect that retail pharmacies would experience some

reduction in revenues due to the movement of full-benefit dual eligibles from Medicaid drug coverage to Medicare drug coverage (through PDPs and MA-PDs). As discussed in more detail subsequently, our upper bound estimate of the average reduction in retail pharmacy revenues that could result from full-benefit dual eligibles receiving drug coverage from Medicare is 1.0 percent. We believe this is an overestimate of the revenue reduction because it does not take into account the effect of the Federal Upper Payment Limit on reducing Medicaid reimbursement rates for many multi-source drugs. Also, to the extent that a State Medicaid program has adopted managed care arrangements to lower the cost of drugs for dual eligibles, our estimate of the revenue impact of pharmacy reimbursement changes for full-benefit dual eligibles would be overstated.

Considering together the effect of increased utilization, new pharmacy discounts and possibly new use of mail order pharmacies among some beneficiaries, and reimbursement changes for full-benefit dual eligibles, we estimate that retail pharmacy revenues would experience a net increase ranging from 0.5 percent to 1.6 percent, as a result of the Medicare prescription drug benefit. Furthermore, while we are not able to provide a quantitative estimate at this time, we expect that retail pharmacies may realize additional revenues from the MMA requirement that PDPs and MA-PDs offer medication therapy management programs to targeted enrollees, which may be furnished by retail pharmacists. Our estimates also do not take into account that increased use of prescription drugs resulting from the Medicare drug benefit may lead to increased foot traffic in retail pharmacies and increased sales for pharmacies' other goods in addition to prescription medicines.

We note that our estimate of the overall impact on small retail pharmacies represents the average effect. We recognize that the effect on any specific retail pharmacy will likely vary to some extent around the average. While we have estimated that the average effect on small retail pharmacies would range from 0.5 percent to 1.6 percent, it is possible that some individual retail pharmacies could experience smaller positive effects and even in some cases negative revenue effects. While it is possible that a specific retail pharmacy because of unique circumstances could experience a negative revenue impact, we believe that this will generally be uncommon. While we cannot predict with full certainty the dynamic effects of this new program for individual pharmacies, we will monitor program and plan performance related to beneficiary access and periodically solicit views on ways we can improve the program.

It is important to note that our estimates of the revenue effect of Medicare Part D on retail pharmacies differ slightly from those presented in the proposed rule. We have revised our analysis to reflect the slightly lower uptake assumption for Medicare Part D assumed throughout the final rule impact analysis. Because retail pharmacies are estimated to experience increased revenues due to the increased utilization of drugs among beneficiaries who gain drug coverage under Medicare Part D, our assumption of slightly lower enrollment in Medicare Part D results in our finding a slightly smaller positive revenue impact on retail pharmacies. In the proposed rule, we estimated that the average impact of Medicare Part D on retail pharmacies would be a revenue increase of 0.6 percent to 1.9 percent. Due to our revised Part D uptake assumptions, we now estimate that the average impact of Medicare Part D on retail pharmacies will be a revenue increase of 0.5 to 1.6 percent.

Comment: In the proposed rule, we sought comments on several issues related to small pharmacies, including comments on our conclusion that retail pharmacy revenues would be positively impacted by Medicare Part D, comments and data related to the distributional impact of Medicare Part D on small retail pharmacies, and comments on any aspect of the rule that may affect adversely affect pharmacies of any size.

We received several comments that questioned our conclusion that Medicare Part D would have a positive revenue impact on small retail pharmacies. One commenter asserted that the proposed rule's analysis overstated the degree of certainty about the revenue impact on retail pharmacies and failed to acknowledge that some retail pharmacies may lose revenue. The commenter also asserted that the impact on retail pharmacies would depend on the degree to which its business model is based on prescription drug sales, the proportion of its customer base that is made up of Medicare beneficiaries and dual eligibles, and whether the pharmacy is preferred or non-preferred. This commenter also took issue with the assertion that small retail pharmacies will share in the positive revenue effects of Medicare Part D because the commenter claimed that the any willing pharmacy provision was of limited effectiveness due to the preferred pharmacy provisions, the special provisions for MA-PD plans that own their own pharmacies to meet network adequacy standards, and the provisions for Part D plans to meet network adequacy standards through accreditation from a Medicare-approved accrediting organization.

We also received several comments that asserted that small retail pharmacies and in some cases regional chains would be hurt by the preferred pharmacy provision because they cannot collectively negotiate contracts with plans. The commenters asserted that plans could designate large retail pharmacy chains as preferred, and leave out small pharmacies. The commenters claimed that even if small retail pharmacies are allowed access to preferred pharmacy networks, if the fees negotiated by the large corporations are very low, smaller pharmacies can not afford to participate. Another commenter wanted us to mandate that plans solicit inner city and rural pharmacies that meet SBA small business standard for their pharmacy network and give them access to any terms that the plan offers to a subset of pharmacies.

A number of commenters asserted that small, independent, or rural pharmacies would be hurt unless steps were taken to avert plans from steering beneficiaries to mail order, implement TRICARE standards at a smaller geographic level (many urged implementation at the local level, some supported the State level), eliminate the preferred provider provisions, and provide guidelines for plans on dispensing fees. One commenter wanted dispensing fees for non-profit entities to reflect their preferred acquisition costs, arguing that without this Medicare would be assisting tax-exempt non-profit competitors of small business pharmacies.

Response: Our analysis estimated that on average retail pharmacy revenues will increase by 0.5 percent to 1.6 percent as a result of Medicare Part D. We believe these estimates are conservative because they do not take into account the effect of the Federal Upper Payment limit on current Medicaid reimbursement, the additional revenues that retail pharmacies are likely to receive from medication therapy management, and the additional revenues that retail pharmacies that sell non-prescription drug products will gain from additional foot traffic.

As noted in the proposed rule, we recognize that our estimates represent an average impact and that the effect on individual retail pharmacies will vary around this average. While we believe

that we have conservatively estimated an average revenue increase ranging from 0.5 percent to 1.6 percent, it is possible that some individual retail pharmacies could experience smaller positive effects and even in some cases negative revenue impacts, while others may experience larger positive effects. While a specific retail pharmacy because of its individual circumstances could experience a negative revenue impact we believe this will generally be uncommon for several reasons.

While we agree with the commenter that retail pharmacies with a disproportionate customer base made up of Medicare beneficiaries and dual eligibles will be more heavily impacted by Medicare Part D, we believe this is unlikely to translate into a negative impact for retail pharmacies. The effect of Medicare Part D on retail pharmacy revenues is largely driven by increased utilization of drugs among beneficiaries without prior drug coverage and reduced revenues for beneficiaries who are dual eligibles (as well as increased revenues from medication therapy management for targeted beneficiaries with chronic illnesses, which is not reflected in our estimates). If a retail pharmacy had an unrepresentative customer base, with substantially more dual eligibles and fewer uninsured beneficiaries than average, then it is possible that the pharmacy might experience a negative revenue impact from Medicare Part D. However, as mentioned in the proposed rule, we believe it is likely that retail pharmacies that serve large populations of dual eligibles will be located in low-income areas that also have a large population of beneficiaries without prior drug coverage, and consequently, larger revenue declines associated dual eligibles would be offset by larger revenue increases associated with beneficiaries that lacked prior drug coverage. We sought comment on this in the proposed rule and received no specific data or information on this issue.

We also agree that Medicare Part D will generally have a greater impact on those retail pharmacies that depend on prescription drug revenues for a larger portion of their sales. We note, however, that since the average impact on retail pharmacies' prescription drug revenues is estimated to be positive, the impact on retail pharmacies' overall revenues would also be expected to be positive regardless of the extent to which a pharmacy relies on prescription drug revenues.

A number of commenters voiced concern that the preferred pharmacy provision would disadvantage small retail pharmacies. As discussed in the preamble, the preferred pharmacy provision is stipulated by statute. This provision would allow plans the option of offering differential cost-sharing in preferred versus non-preferred pharmacies provided that this does not increase government costs. While we acknowledge that preferred pharmacies may have some competitive advantage over non-preferred pharmacies, we believe a number of factors mitigate this. Importantly, our policy decision in the final rule to strengthen the network adequacy requirements by implementing the TRICARE access standard at the State (rather than regional) level provides pharmacies with more leverage in negotiating with Part D plans. In addition, the final rule requirement that plans offer reasonable and relevant standard terms and conditions for network participation to all similarly situated pharmacies promotes retail pharmacy access to Part D networks. In addition, the estimated 11 million Part D low-income subsidy enrollees—which account for more than one-third of all Part D enrollees in 2006—would not face a difference in cost-sharing between preferred and non-preferred pharmacies because of the nominal cost-sharing levels guaranteed by the low-income subsidy. Also, as indicated in the preamble, plans cannot use the preferred pharmacy provision in a discriminatory manner, for example related to rural areas. Finally, the statutory requirement that any differential cost-sharing not effect the Government cost when combined with the final rule requirement that plans offer standard terms and conditions for participation to any willing pharmacy, we believe mitigates against large differentials in cost sharing between preferred and non-preferred pharmacies.

With respect to the commenter requesting that we require plans to offer preferred terms to small pharmacies in rural and inner city areas, we believe that we have used the available statutory authority to the fullest extent possible to promote the participation of small pharmacies. We have done this through our requirement that plans offer reasonable and relevant standard terms and conditions for network participation. We also modified our access standard to be measured on a State basis rather than a regional basis, which necessitates plans providing adequate access to rural areas and strengthens pharmacies bargaining power.

We disagree with the comment that allowing special network adequacy standards for MA-PD plans that provide retail prescription drugs through pharmacies owned by the plan would impact retail pharmacies negatively, as we do not think that these types of arrangements are very common. We also believe that the provision that Part D plans could meet the network adequacy standards through accreditation from a Medicare-approved accrediting body, would not in any way jeopardize network adequacy or retail pharmacies' ability to participate in networks. As discussed in the preamble, the accreditation standards used by the organizations would have to be determined by CMS to be no less stringent than our own requirements and we would retain the authority to initiate enforcement action against any Part D plan sponsor that we determine, on the basis of our own survey or the results of the accreditation survey, no longer meets the Medicare requirements with regard to network adequacy.

With respect to mail order, as discussed in the preamble, the statute allows plans to offer lower cost-sharing at preferred pharmacies, including mail order pharmacies. Consequently, we cannot, as some commenters urged, require plans to offer similar coinsurance in both retail and mail order settings. However, this is similar to what currently occurs in the commercial insurance market today. We have included in our impact estimates the effect of beneficiaries using mail order at the same rate as individuals in the commercial market. Even taking into account this possible increased use of mail order among beneficiaries, our analysis finds an overall positive impact of Medicare Part D on retail pharmacy revenues. In addition, there are some aspects of Medicare Part D, which are not as typical of the commercial market, which put retail pharmacies on a more level playing field with mail order. As noted in the proposed rule, the nearly 11 million beneficiaries who are estimated to enroll in the low-income subsidy face nominal cost-sharing, and consequently we believe there will be little, if any, difference in these beneficiaries' out-of-pocket costs between retail and mail order pharmacies. Our regulation also requires that plans allow retail pharmacies to dispense the same quantity of a prescription (for example, a 90-day supply) as mail order pharmacies, provided it is allowed by State pharmacy law. Also under Medicare Part D, plans are required to have medication therapy management programs which represent an additional service that pharmacists will be able to provide and receive reimbursement.

As noted previously, a number of commenters expressed concern that

dispensing fees to retail pharmacies may not be adequate and urged us to provide guidance to Part D plans to ensure adequate dispensing fees, including one commenter who requested that dispensing fees for non-profit pharmacies reflect their preferred acquisition costs so as to not to disadvantage for-profit pharmacies that compete with these entities. Given plans' need to secure a network of providers (especially in light of the final rule decision to strengthen the network adequacy standards by implementing the TRICARE standard at the State, rather than regional, level), we believe plans will have every incentive to adequately reimburse retail pharmacies for the costs involved with providing covered Part D drugs to plan enrollees.

Comment: One commenter stated that retail pharmacies will receive additional revenues from medication therapy management and fees paid by plans for providing drug utilization review and quality assurance. Another commenter wrote that the lack of detail in the proposed rule on medication therapy management makes it difficult to estimate its economic impact.

Response: While it is difficult to quantify the revenue impact on retail pharmacies of medication therapy management at this time, we believe, as one of the commenters indicates, that plan payments to pharmacies for medication therapy management will generate additional retail pharmacy revenues. As noted elsewhere, the positive revenue effect from these types of payments to retail pharmacies is not included in our impact estimates, making our estimate of a positive revenue impact on retail pharmacies conservative.

Comment: One commenter asserted that additional foot traffic in retail pharmacies would not offset what it claimed was an adverse impact of Medicare Part D on retail pharmacies because more than 90 percent of small retail pharmacy revenues are derived from prescription drugs.

Response: Our analysis in the proposed rule found that on average retail pharmacy revenues would increase as a result of Medicare Part D because the increased utilization of prescription drugs associated with Medicare beneficiaries acquiring drug coverage is estimated to more than offset decreased revenues from new pharmacy discounts and new use of mail order among some beneficiaries. We indicated in the proposed rule that our estimate of the revenue impact on retail pharmacies was conservative since it did not take into account several issues, including the possibility that pharmacy revenues may increase to some extent due to additional foot traffic generating increased sales of non-prescription drug products for pharmacies. We agree with the commenter that small retail pharmacies typically derive more of their revenues from prescription drugs than large pharmacies. Consequently, while small retail pharmacies would likely experience some increase in their non-drug revenues due to additional foot traffic, the increase would be less significant for small pharmacies than large pharmacies. However, since our revenue estimates conservatively assume no revenue increase resulting from additional foot traffic, our estimate of the average revenue impact on retail pharmacies is unaffected by this issue.

Comment: One pharmacy association commenter criticized our definition of significant economic impact as a revenue impact of 3 to 5 percent. The commenter claimed that this does not take into account pharmacy profit margins, which they assert have ranged in past decade from 2.9 percent to 3.8 percent (on a net, pre-tax basis).

Response: HHS uses revenues rather than profit margins to estimate the economic impact of a rule on small entities because in our experience reliable data on profit margins are very difficult to obtain, while reliable data on revenues are much more readily available and straightforward.

One example of the difficulties in obtaining reliable profit margin data and in how to interpret those data in the case of small businesses relates to how owners' salaries are treated. Profit margin estimates can vary substantially depending on how one considers the owner's salary relative to the profits of the business. For example, a 2002 study on the pharmacy industry conducted by Booz Allen Hamilton for us cites data from the National Community Pharmacist Association (NCPA), which indicate that independent retail pharmacies had average profit margins, in 2000, of nearly 8 percent when owners' salaries were included and about 3 percent when owners' salaries were excluded. Furthermore, when the Internal Revenue Service (IRS) determines income tax liability for sole proprietorships, it considers the businesses' incomes to be profits plus the owners' salaries. In the case of pharmacies and drug stores, IRS data on sole proprietorships show fairly similar profit margin levels with NCPA—about 7 percent including owners' salaries in the late 1990s. Thus, if profit margins were used to determine the economic impact of rules on small businesses, how the owners' salaries are treated could significantly alter findings. Furthermore, data are generally not available to separate the portion of an owner's salary that compensates for labor versus the portion that reflects profit taking in the form of salary, which makes developing an accurate estimate of small businesses' profit margins very difficult.

Even if these difficulties were not present, changes in sales levels do not translate directly into proportional changes in profits. One commenter, discussed later in this analysis, claims that higher sales levels can reduce profits. In fact, retailers have many possible responses to changes in their sales levels in terms of management, staffing, inventory levels, and other aspects of their business models, and which responses they choose are likely to determine whether, and to what extent, profits rise or fall. We have no way to predict these responses' precise effects on profits, but of course would expect decisions to be profit maximizing.

Regardless of whether the HHS standard for significant economic impact focuses on revenues rather than profit margins, as stated elsewhere in the preamble, we have taken a number of steps to mitigate the financial impact on small retail pharmacies and drug stores.

Comment: One commenter asserted that the regulatory impact analysis should estimate collectively the effect of both the implementation of Medicare Part D and changes in Medicare Part B on pharmacies.

Response: Changes to Medicare Part B are not the subject of this rule, and as such are not within the scope of this regulatory impact analysis.

a. Expansion of Drug Coverage and Increased Access to Pharmacy Discounts Among Beneficiaries Previously Lacking Such Coverage or Discounts

A substantial portion of beneficiaries (about 24 percent as of 2001) lack drug coverage. As discussed in Section E, we project that generally 95 percent of beneficiaries without drug coverage will enroll in the Medicare drug benefit (with somewhat lower uptake—71 percent—assumed among beneficiaries with drug spending in the lowest quintile). The expansion of drug coverage to these individuals is likely to have countervailing effects on pharmacy revenues. First, it is likely to lead to increased drug utilization and spending among beneficiaries without prior drug coverage, and thus increased pharmacy revenues. Second, it is likely to lead to increased access to pharmacy discounts for some beneficiaries who previously did not receive such discounts (specifically, many beneficiaries

without drug coverage and beneficiaries with Medigap drug coverage), and thus decreased revenues for pharmacies. Because many beneficiaries that currently have prescription drug coverage (for example, those in employer sponsored retiree health plans or Medicare Advantage plans) already receive pharmacy discounts through those insurers, we do not expect the Medicare prescription drug benefit to generate any new pharmacy discounts for these beneficiaries. In addition, it is possible that the Medicare drug benefit may lead to new use of mail order pharmacies among beneficiaries without prior drug coverage and beneficiaries with Medigap drug coverage, potentially having some effect on retail pharmacy revenues. Overall, we estimate that increased utilization for beneficiaries without prior drug coverage and new pharmacy discounts and possible new use of mail order pharmacies among some beneficiaries will result in a net positive revenue impact for retail pharmacies.

Medicare beneficiaries without prior drug coverage who enroll in the Medicare drug benefit will face a substantial reduction in out-of-pocket costs for prescription medicines, and consequently we expect that their drug utilization and expenditures will increase. Beneficiaries with drug coverage fill more prescriptions and have higher total drug spending than beneficiaries without drug coverage. Based on 2001 MCBS data, beneficiaries with drug coverage have average total drug spending that is 109 percent greater than beneficiaries without drug coverage. These spending differences hold true even among beneficiaries with similar numbers of chronic conditions. For example, average spending for beneficiaries with drug coverage was higher than for beneficiaries without drug coverage among beneficiaries with no chronic conditions (247 percent higher), 1–2 chronic conditions (107 percent higher), 3–4 chronic conditions (76 percent higher), and 5 or more chronic conditions (53 percent higher). Thus, we expect that the expansion of drug coverage to beneficiaries who previously did not have such coverage will lead to increased drug utilization and spending, and thus higher pharmacy revenues. For the purpose of this analysis, we assume that beneficiaries without prior drug coverage who enroll in the Medicare drug benefit will experience a 76 percent increase in total drug spending. We base this assumption on the fact that most beneficiaries without drug coverage fall into the category of having 1–2 chronic conditions or 3–4 chronic conditions, and we have chosen the more modest use difference seen in the 3–4 chronic condition group. Furthermore, we believe that this is a conservative assumption because the average difference across the population in drug spending for beneficiaries with and without coverage is 109 percent. Beneficiaries without drug coverage whom we project would enroll in Medicare Part D account for about 12 percent of all drug spending by Medicare beneficiaries (based on 2001 MCBS data). If we assume that these previously uninsured Part D enrollees experience a 76 percent increase in drug expenditures due to a use effect, this would represent about an 8.9 percent increase in total drug spending by Medicare beneficiaries.

At the same time, to the extent that beneficiaries without drug coverage did not receive pharmacy discounts prior to Medicare Part D, we would expect that pharmacy discounts negotiated by PDPs and MA-PDs could result in some reduction in pharmacy revenues. While the vast majority of beneficiaries who currently have drug coverage are likely to already be receiving pharmacy discounts, and thus the Medicare drug benefit would not result in any change in pharmacy discounts for these beneficiaries, this may not be the case for beneficiaries without drug coverage. As mentioned previously, the April 2000 HHS Report ''Prescription Drug Coverage, Spending, Utilization, and Prices'' found that on average individuals with drug coverage paid a 15 percent lower price for prescription drugs at the point of sale than individuals without drug coverage. The discount insured individuals receive at the point of sale reflects a combination of pharmacy and manufacturer discounts. However, to take a conservative approach, we assume that Medicare Part D enrollees without prior drug coverage realize 15 percent price discounts at the point of sale, all of which reflect pharmacy discounts. This assumption is conservative not only because it assumes that the entire 15 percent discount comes from pharmacies, but also because some of these beneficiaries are likely to have received pharmacy discounts previously through the Medicare drug discount card, which began offering discounts in June 2004 and which includes substantial discounts from drug manufacturers, and through senior pharmacy discounts previously offered by many pharmacies. Thus, our assumption that all Part D enrollees without prior drug coverage would receive new pharmacy discounts of 15 percent under Medicare Part D overstates the negative revenue impact on pharmacies. With these beneficiaries accounting for about 12 percent of all drug spending by Medicare beneficiaries, we estimate that extending a 15 percent discount to these beneficiaries would result in about a 1.8 percent decrease in total drug spending by Medicare beneficiaries.

Another group of beneficiaries who we believe may obtain new pharmacy discounts under Medicare Part D are beneficiaries with Medigap drug coverage. Few Medigap plans actively negotiate prescription drug discounts for enrollees. Consequently, we assume that all beneficiaries with previous Medigap drug coverage who are projected to enroll in Medicare Part D obtain new pharmacy discounts. With these enrollees accounting for about 4 percent of prescription drug spending by all beneficiaries, we estimate that extending pharmacy discounts to these beneficiaries could result in about a 0.6 percent decline in total Medicare drug spending by beneficiaries.

It is also possible that the Medicare prescription drug benefit may result in new use of mail order pharmacies by some beneficiaries. We believe that the new Medicare benefit is unlikely to affect the use of mail order pharmacies among beneficiaries currently with employer sponsored or Medicare Advantage drug coverage as mail order is an option currently available to these beneficiaries and the implementation of Medicare Part D makes no changes in this regard. We also believe that there is likely to be no effect on mail order use by beneficiaries who qualify for the low-income subsidy because nominal cost sharing exists regardless of where the beneficiary purchases the prescriptions (and as noted above, for those without prior drug coverage or less generous prior drug coverage, we expect that these beneficiaries will fill significantly more prescriptions). The two groups where it is possible that mail order usage may increase are beneficiaries without prior drug coverage and beneficiaries with Medigap drug coverage. The effect of Medicare Part D on mail order use by these beneficiaries, however, is uncertain. For example, Medicare Part D includes a provision that allows retail pharmacies (subject to State pharmacy laws) to provide a 90-day supply, putting them on equal footing with mail order pharmacies in this regard.

To estimate the potential effect of new mail order use among beneficiaries without prior drug coverage and beneficiaries with prior Medigap drug

coverage, we take the approach of making estimates based on two alternate assumptions. As a lower bound, we assume that there is no additional mail order use. As an upper bound, we assume that the percent of beneficiaries using mail order pharmacies among these two groups of beneficiaries increases to be similar to the rate of use among beneficiaries with private employer-based drug coverage. There is limited publicly available data related to mail order utilization. To supplement publicly available data we tried to obtain information from proprietary sources to help inform our upper bound estimates. For our upper bound assumptions, we use data from the Medical Expenditure Panel Survey (MEPS) to assign higher rates of mail order use (that is, the percentage of population that fills at least one prescription through mail order) to the population that gains drug coverage and to beneficiaries with prior Medigap drug coverage. We also tried to obtain data on the share of drug spending through mail order pharmacies that occurs among individuals who use these pharmacies. However, we were unable to obtain this type of information. We were able to obtain some proprietary information regarding the share of total plan spending occurring through mail order and retail pharmacies for a commercially insured over 65 population. Using this information in combination with the recognition that a number of prescriptions are unlikely to be filled through mail order (for example such as antibiotics and pain medication used to treat acute conditions, or newly prescribed medications), we developed an upper bound assumption that as much as 50 percent of drug spending among new users of mail order might occur through mail order pharmacies. We do not expect mail order use to approach this level; we use it simply for purposes of estimating the maximum potential impact. Under this upper bound assumption, we estimate that as a result of mail order effects, aggregate Medicare drug spending in retail pharmacies could decrease by as much as 2.0 percent. Thus, based on our lower bound and upper bound assumptions, we estimate that possible new use of mail order pharmacies among some beneficiaries could result in a decrease in retail pharmacy revenues of somewhere between 0 to 2.0 percent. If a shift in mail order use were to occur, our prior estimates of utilization and discount effects would be altered slightly since they are based on the assumption of no change in mail order use. We estimate that under our upper bound assumptions related to mail order, our previous estimates of the combined effect of utilization increases and new pharmacy discounts for some beneficiaries would need to be adjusted downward by as much as 1.1 percentage points. We note that even with these adjustments based on a very high upper bound assumption, the net effect for retail pharmacies remains positive. In the proposed rule, we requested additional data that could help inform our assumptions and analysis related to new mail order use by beneficiaries without prior drug coverage, but we did not receive any comments providing data on this issue.

Taken together, we estimate that the effect of expanding access to prescription drug coverage among beneficiaries without prior drug coverage and the effect of new pharmacy discounts and possibly new use of mail order pharmacies by some beneficiaries will result in a net increase in total prescription drug spending by Medicare beneficiaries at retail pharmacies of between 3.8 percent and 6.6 percent. We estimate that this would represent an average increase in retail pharmacy revenues of between 1.5 percent and 2.7 percent, as Medicare beneficiaries account for about 40.5 percent of outpatient prescription drug spending for the non-institutionalized population according to 1999 MEPS data (Stagnitti MN et al., AHRQ, ''Outpatient Prescription Drug Expenses, 1999'', 2003). Furthermore, while not quantifiable at this time, we expect that pharmacies may realize additional revenues from the MMA requirement that PDPs and MA-PDs offer medication therapy management programs to targeted enrollees, which may be furnished by pharmacists. In addition, it is likely that increased use of prescription drugs by Medicare beneficiaries will lead to increased foot traffic in pharmacies and increased pharmacy revenues from non-pharmaceutical products as well.

b. Medicare's Assumption of Drug Coverage for Full-Benefit Dual Eligibles

Because State Medicaid programs typically pay higher reimbursement rates to pharmacies than private sector insurers, the movement of full-benefit dual eligibles from Medicaid drug coverage to Medicare drug coverage (through PDPs and MA-PDs) has potential implications for pharmacy revenues. Our upper bound estimate of the average reduction in pharmacy revenues that could result from full-benefit dual eligibles receiving drug coverage from Medicare is 1.0 percent.[12] We believe that this is an overestimate because it does not take into account the effect the Federal Upper Payment Limit has in reducing Medicaid reimbursement rates for multi-source drugs with at least three generic equivalents. Also, to the extent that a State Medicaid program has adopted managed care arrangements to lower the cost of drugs for dual eligibles, our estimate of the revenue impact of pharmacy reimbursement changes for full-benefit dual eligibles would be overstated.

We conducted the following analysis to estimate how the transfer of dual-eligibles' drug coverage from Medicaid to Medicare would affect pharmacy revenues. First, we developed an estimate of the average Medicaid drug reimbursement rate across States. To begin, we considered how Medicaid reimburses pharmacies for drugs. Medicaid reimburses pharmacies for drugs based on the estimated acquisition costs (EAC) plus a dispensing fee. There is variation across States in how they define and the level at which they set EAC and the dispensing fee. The vast majority of States define EAC as the average wholesale price (AWP) less a certain percentage discount, while a small number define it as wholesale acquisition cost (WAC) plus a certain percentage or the lower of an AWP-based or WAC-based payment amount. Dispensing fees also vary by State and typically range from $3 to $5. Some States use the same reimbursement formula for brand and generic drugs, while others institute a greater discount off of AWP for generic drugs or a higher dispensing fee for generic drugs, and in some cases both. In addition, Medicaid reimbursement rates for multi-source drugs with 3 or more generic equivalents are generally capped by the Federal Upper Payment Limit.

Based on information on the Medicaid EAC and dispensing fee for each State for brand and generic drugs as of fourth quarter 2004, we estimated the overall drug reimbursement rate (EAC plus dispensing fee) as a percent of AWP separately for brand and generic drugs. We did this by estimating the dispensing fee as a percent of the average AWP, using unpublished

[12] This is slightly lower than our proposed rule estimate of a 1.1 percent revenue effect because we have updated our analysis to take into account the most recently available Medicaid pharmacy reimbursement rates. Because a few States have reduced their current Medicaid pharmacy reimbursement rates, the effect on pharmacy revenues of shifting dual eligibles' drug coverage from Medicaid to Medicare is slightly less.

Express Scripts data on the average AWP for brand drugs ($77.42) and generic drugs ($32.57) in 2002.[13] (It should be noted that under this methodology the total reimbursement rate for generic drugs (including the ingredient cost and the dispensing fee) as a percent of AWP is much greater than the reimbursement rate as a percent of AWP for the ingredient cost alone, because the dispensing fee represents a fairly high percentage of AWP for low cost generic drugs.) For States that set EAC based on WAC rather than AWP, we express their reimbursement formula in AWP terms by assuming that WAC is equivalent to roughly 20 percent of AWP, based on information about the typical relationship between WAC and AWP in the 2000 HHS Prescription Drug study. After estimating an overall Medicaid reimbursement amount for brand and generic drugs for each State, we estimate the weighted average reimbursement rate across States, using the number of full-benefit dual eligibles with drug coverage in each State for weights. Based on this method, we estimate that average Medicaid reimbursement to pharmacies (for ingredient cost and dispensing fee combined) is roughly equivalent to AWP minus 7 percent for brand drugs and AWP for generic drugs. It should be noted that this likely overstates current Medicaid reimbursement rates for generic drugs because it does not take into account that Medicaid reimbursement for multi-source drugs with 3 or more generic equivalents is generally capped by the Federal upper payment limit.

We then estimated an average Medicaid reimbursement rate across all drugs (brand and generic) by weighting the average reimbursement estimates for brand and generic drugs by the percent of Medicaid expenditures we assume they comprise. According to a survey of State Medicaid programs by the Kaiser Family Foundation, States estimate that 80 percent of State Medicaid drug expenditures are on brand drugs and 20 percent on generics. Using these figures for weights, we estimate an overall average Medicaid drug reimbursement rate (including dispensing fee) of roughly 5 percent off of AWP.

The revenue impact on pharmacies of transitioning dual eligibles from Medicaid to Medicare Part D is measured by taking pharmacies' current revenues for dual eligibles minus their expected revenues for this population under Medicare Part D. Consequently, by overstating current Medicaid pharmacy revenues, our analysis overstates (rather than understates) the adverse impact on pharmacies from transitioning dual eligibles to Medicare Part D.

Second, for the purpose of this analysis, we make assumptions about the average pharmacy reimbursement rate for brand and generic drugs under PDPs and MA-PDs. We base these assumptions on available literature about typical pharmacy reimbursement rates under private sector insured products. It must be noted that these assumptions are not meant to convey our expectation of the actual pharmacy reimbursement rates negotiated by PDPs and MA-PDs with pharmacies under the Medicare drug. Instead, they are assumptions made solely for this regulatory flexibility analysis. According to a survey sponsored by Takeda Lilly of employer sponsored insurance plans covering more than 17 million lives, the average reimbursement for ingredient cost for a brand drug in 2002 was about 14 percent off of AWP (Takeda, ''The Prescription Drug Benefit Cost and Plan Design Survey Report,'' 2003). In addition, according to a report by Express Scripts, there tends to be about a three times greater discount off of AWP for generic drug ingredient cost than for brand drug ingredient cost (Express Scripts, ''Drug Trends 2002 Report,'' June 2003). Based on these studies, we assume reimbursement for ingredient costs of 14 percent off of AWP for brand drugs and 42 percent off of AWP for generic drugs. In terms of dispensing fees, the Novartis Pharmacy Benefit Reports, which is a survey of HMO plans, finds an average dispensing fee of $1.79 for brand drugs and $2.08 for generic drugs as of 2002 (Novartis, ''Pharmacy Benefit Report: Facts and Figures,'' 2003). The Takeda Lilly survey of employer-sponsored plans indicates an average dispensing fee of $2.13 for brand and $2.22 for generic drugs. For the purpose of this analysis, we average the findings from the two studies and assume a dispensing fee of $1.96 for brand drugs and $2.15 for generic.[14] Similar to the Medicaid reimbursement analysis, we estimate these dispensing fees as a percent of average AWP for brand and generic drugs and then add them to our ingredient cost reimbursement assumptions to arrive at average reimbursement estimates—11 percent off of AWP for brand drugs and 35 percent off of AWP for generic drugs. We then weight the average reimbursement estimates for brand and generic drugs by the percent of expenditures they are assumed to comprise to arrive at an overall average reimbursement estimate (including dispensing fee) of 16 percent off AWP for all drugs.

Third, we estimated the share of national retail prescription drug spending accounted for by Medicaid drug expenditures on dual eligibles. According to a special analysis by the Kaiser Commission on Medicaid and the Uninsured, Medicaid prescription drug spending on dual eligibles was $9.5 billion in 2000, including fee-for-service and managed care and netting out manufacturer rebates (Kaiser Commission on Medicaid and the Uninsured, ''The Proposed Medicare Prescription Drug Benefit: A Detailed Review of Implications for Dual Eligibles and Other Low-Income Medicare Beneficiaries,'' September 2003). In addition, national retail prescription drug spending, net of manufacturer rebates, was $121.5 billion in 2000 according to National Health Expenditures projections by our Office of the Actuary. (*http://www.cms.hhs.gov/statistics/nhe/projections–2003/t11.asp*). Based on the above figures, we estimate Medicaid drug spending on dual eligibles comprised about 7.8 percent of total national retail prescription drug spending net of rebates in 2000. While this estimate is based on drug spending adjusted for rebates, drug spending without adjustments for rebates would be a better measure of the actual amount of revenues flowing through pharmacies. Manufacturer rebates typically occur on the back end between manufacturers and third party insurers and do not impact pharmacy revenues. Therefore, we adjust our estimate to pre-rebate levels of drug spending using the following method. We take national retail prescription drug spending net of rebates and inflate it based on our Office of the Actuary's estimate that national retail prescription drug spending in 2000 would be 6 percent higher without the adjustments for rebates. We also take our estimate of Medicaid prescription drug spending for dual eligibles and inflate it based on information from the Kaiser Study, which indicates that

[13] These unpublished Express Scripts estimates of average AWP for brand and generic drugs in 2002 reflect the average AWP for a 30-day equivalent weighted by the number of scripts, based on utilization data from a commercially insured population age 65 and older, with employer sponsored insurance and with an integrated benefit (network and mail prescription coverage).

[14] There was a typographical error in the text of the proposed rule describing our dispensing fee assumption for generic drugs. Our model and findings in the proposed rule were based on an assumed generic dispensing fee of $2.15. The proposed rule text should have read $2.15, not $2.11.

rebates reduced Medicaid fee-for-service drug spending in 2000 by an average of about 19 percent. Absent information on the percent of Medicaid drug spending for dual eligibles that is under fee-for-service versus managed care, we take an extremely conservative approach and inflate Medicaid drug spending to pre-rebate as though all spending had been fee-for-service. It should be noted that we strongly believe this overstates the amount of Medicaid drug spending on dual eligibles, and thus overstates any negative revenue impact on pharmacies. Based on the above, we estimate that Medicaid drug spending on dual eligibles is about 9.1 percent of total national retail prescription drug spending. Finally, we estimate the potential impact on pharmacy revenues of transferring responsibility for drug coverage of full benefit dual eligibles from Medicaid to Medicare.

Based on our previous estimates of average pharmacy drug reimbursement rates under Medicaid and private insurers, we estimate that prescription drug spending on dual eligibles would account for about 8.1 percent of national retail prescription drug spending if drugs were reimbursed at rates typical of private sector insurer rates rather than Medicaid.[15] Thus, our upper bound estimate of the average reduction in pharmacy revenues that could result from full-benefit dual eligibles receiving drug coverage from Medicare is about 1.0 percent. As mentioned previously, we believe that this is an overestimate of the impact on pharmacies because it does not take into account existing policies that reduce Medicaid reimbursement rates such as the Federal Upper Payment limit for multi-source drugs with at least three generic equivalents.

Comment: Another commenter asserted that if pharmacy revenues increase as predicted in the proposed rule then pharmacies will lose money because business expenses (more claims transmissions, more inventory, higher paychecks) will be more than 3 percent.

Response: Due to the expansion of prescription drug coverage among Medicare beneficiaries, prescription drug utilization is expected to increase moderately among beneficiaries, which will result in more scripts being dispensed by pharmacies. To accommodate a modest increase in the demand for prescription drugs, pharmacies will turn over more inventory to sell to beneficiaries and may also, depending on their current capacity, respond by increasing their staff hours. Similarly, pharmacies are likely to experience some increase in the number of claims transmissions they submit due to increased utilization of drugs among beneficiaries and due to the submission of claims transmissions for beneficiaries with Medicare Part D drug coverage who previously lacked any coverage. Part D plans will be paying pharmacies for the cost of dispensing these drugs through fees plans negotiate with pharmacies for ingredient cost and dispensing. In addition, some pharmacists may receive additional payments from plans for medication management services. We believe that the need for plans to maintain an adequate pharmacy network provides a strong incentive for plans to compensate pharmacies adequately for their costs.

In addition to the increased claims transmissions discussed above, pharmacies may also have additional claims transmissions for those Part D enrollees who have supplemental drug coverage (for example, from an employer or SPAP) that is coordinated with, but not integrated with, Medicare Part D. Since it is unknown how prevalent supplemental drug coverage will be, and whether it will more commonly take the form of enhanced coverage that is integrated with Part D or supplemental drug coverage that is coordinated with Part D, it is difficult to make an estimate of the additional claims transmission volume that may be generated. However, because of the efficiency of arranging for additional coverage through the PDP or MA-PD, we think the incentive is to arrange for or provide enhanced coverage rather than utilize claims based coordination of benefits. Furthermore, since claims transmissions costs are generally a very small fraction of the cost of dispensing a prescription to a beneficiary, and even smaller fraction of the average price of a prescription, we believe that these costs would not be substantial, especially in comparison to the additional pharmacies revenues generated by Medicare Part D. In addition, as discussed elsewhere, we will be arranging for a TrOOP facilitation process to minimize the level of effort involved for pharmacies in dealing with coverage that supplement Medicare Part D.

Comment: One commenter voiced concern about the private sector dispensing estimates used in the impact analysis, arguing that the generic fee was not sufficiently greater than the brand fee to provide incentives for use of generic drugs. In addition the commenter asserted that these fees were below a pharmacy's average cost for dispensing a prescription, which it claimed was $7.50 to $8.00 depending on the geographic location.

Response: We indicated in the proposed rule that the assumptions we made about the average pharmacy reimbursement rate, including dispensing fees, for brand and generic drugs under PDPs and MA-PDs were not meant to convey our expectation of the actual pharmacy reimbursement rates negotiated by PDPs and MA-PDs with pharmacies. Instead, they were assumptions made in order to estimate the potential impact of Medicare Part D on pharmacies for the purpose of a regulatory flexibility analysis. These assumptions were based on available literature about typical pharmacy reimbursement rates under private sector insured products.

Dispensing fees paid to pharmacies will depend on the outcome of the negotiations between pharmacies and plans. Given plans' need to secure a network of providers, we believe plans will have every incentive to adequately reimburse pharmacies for the costs involved with providing covered Part D drugs to plan enrollees. Furthermore, as discussed in the preamble plans have the flexibility to provide higher dispensing fees for generic drugs to encourage utilization if they wish to do so.

Comment: One commenter asserted that the analysis overstates the current Medicaid revenues to pharmacies because the commenter claims that 20 percent of all Medicaid prescriptions are paid at the pharmacy's usual and customary rate, not the estimated acquisition cost, and because there are higher costs of business in Medicaid that do not exist in private programs. They assert that this means that the transfer to Medicare Part D of the dual eligibles could have a greater effect on pharmacies than estimated.

Response: As discussed elsewhere, we believe that our analysis overstates the revenues pharmacies currently receive from Medicaid because it does not take into account the effect of the Federal Upper Payment Limit in capping Medicaid reimbursement for multi-source drugs with 3 or more generic equivalents. Due to data limitations, our analysis also overstates current pharmacy revenues from Medicaid because we inflate Medicaid drug spending for dual eligibles to pre-rebate levels as though all spending had been fee-for-service. In addition, to the extent

[15] The 8.1 percent figure is computed by multiplying our estimate of drug spending for dual eligibles as a percent of NHE (9.1 percent) by our estimate of pharmacy reimbursement rates typical of private sector insurers (AWP–16 percent, or 84 percent of AWP) and dividing by our estimate of average Medicaid pharmacy reimbursement (AWP-5 percent, or 95 percent of AWP).

that Medicaid reimbursement is further limited by pharmacies' usual and customary price, as the commenter asserts, our estimates of current pharmacy revenues from Medicaid would be further overstated.

c. Overall Effect

Considering together the effect of increased utilization, new pharmacy discounts and possibly new use of mail order pharmacies among some beneficiaries, and reimbursement changes for full-benefit dual eligibles, we estimate that retail pharmacy revenues would increase on average by between 0.5 percent and 1.6 percent as a result of the Medicare prescription drug benefit. This is the result of an increase in prescription drug revenues ranging from 1.5 percent to 2.7 percent due to the net effect of increased utilization, new pharmacy discounts, and possibly new use of mail order pharmacies among some beneficiaries, and a 1.0 percent decrease in pharmacy revenues (upper bound estimate) due to drug coverage for full-benefit dual eligibles shifting from Medicaid to Medicare.

In addition, we believe that these estimates understate the degree to which pharmacy revenues increase as a result of the Medicare prescription drug benefit for several reasons. Our estimate of the revenue reduction resulting from the transfer of drug coverage for full benefit dual eligibles from Medicaid to Medicare is likely to be overstated because it does not take into account the effect of the Medicaid upper payment limit on reducing Medicaid reimbursement rates for some multi-source drugs. In addition to revenue effects we have estimated, the Medicare prescription drug benefit is likely to provide other sources of revenue increases for pharmacies; for example, through targeted medication therapy management programs under Medicare Part D which may be furnished by pharmacists, or through increased foot traffic in pharmacies leading to increased pharmacy sales of other goods in addition to prescription medicines. For these reasons, we estimate that the Medicare prescription drug benefit will have a positive revenue impact on the pharmacy industry overall.

We believe that the program's effect on small pharmacies will also be positive. We expect that small pharmacies will participate in the networks of Medicare Part D plans and consequently will share in the positive revenue impacts. Given the current industry practice of broad pharmacy networks and given Medicare Part D's any willing pharmacy provision, which includes the requirement that plans offer reasonable and relevant standard terms and conditions for network participation to all similarly situated pharmacies, we anticipate that all pharmacies that wish to participate in Medicare Part D will be able do so. Furthermore, we believe that the strengthening of the network adequacy standard in the final rule to be implemented at the State level provides pharmacies more bargaining leverage with plans. For these reasons, we would expect the great majority of small business pharmacies to share in the increased business created by the Part D drug benefit.

d. Other Pharmacy Issues

Requirements related to reporting, recordkeeping, and other compliance activities for small pharmacies under this program are minimal. The statute requires that network pharmacies notify a Part D enrollee at the point of sale of the differential between the price of a drug and the lowest priced generic drug under the program that is therapeutically equivalent and bioequivalent and available at the pharmacy. While it is possible that this requirement could represent some burden, we anticipate that the burden would be at most marginal. The pharmacy community routinely indicates that it is common practice for pharmacies to promote the use of generic drugs. Thus, this requirement is unlikely to represent a change in current practice for most pharmacies. We anticipate that the costs of the systems infrastructure required to furnish this pricing information will be borne by the Part D plan. The only cost to pharmacies would be the time involved in conveying the information to the beneficiary, which we anticipated would be small.

2. Long-Term Care (LTC) Pharmacies

a. LTC Pharmacy Access

As discussed in subpart C of the preamble, the Act provides that, in establishing rules for convenient access to network pharmacies, we may include standards with respect to access to long-term care pharmacies for Part D enrollees who reside in long-term care facilities. As discussed previously in the preamble, we believe that the Medicare drug benefit can improve competition in the long-term care pharmacy market, while Medicare's requirements for participation preserve the relationships and levels of service that long-term care facilities now enjoy vis-à-vis their contracted long-term care pharmacies.

To that end, our final rule requires that Part D plans offer standard contracting terms and conditions for long-term care pharmacies. In other words, we are establishing a specific ''any willing pharmacy'' requirement for long-term care pharmacies. Part D plans would be expected to develop standard contracting terms and conditions for long-term care pharmacies, such that any pharmacy in a service area could become an eligible long-term care pharmacy by certifying that it meets certain performance and service criteria for providing pharmacy services to long-term care facilities, which will reflect widely used best practices and will be detailed through guidance. Plans in a region would be required to contract with any willing long-term care pharmacy in that region, provided those pharmacies were able to reach agreement with plans on all standard contract terms and conditions—including payment rates.

As discussed, we will require Part D plans to demonstrate that they have contracts with a sufficient number of LTC pharmacies to ensure ''convenient access'' to prescription drugs for institutionalized beneficiaries within the service area. As noted in the subpart C preamble, we do not think we have the statutory authority to establish access requirements related to the routine use of out-of-network pharmacies. Thus, in the context of beneficiaries residing in LTC facilities, Part D plans will therefore have to demonstrate that they have an adequate plan network for beneficiaries who may reside in LTC facilities. We would also expect that LTC facilities, in choosing LTC pharmacies, will want pharmacies who are participating in all Part D plans in which their residents are enrolled within their area. We will provide more detailed information in CMS guidance regarding what constitutes ''convenient access,'' but we expect that plans will demonstrate convenient access based in part on the number of enrollees in their service areas and the geographic distribution, capacity, and contracting relationships between long-term care facilities and long-term care pharmacies in those service areas. We note that these LTC pharmacy access requirements are in addition to the retail pharmacy access standards.

In formulating our policies for LTC pharmacy access, we have relied on information provided by all stakeholders through the proposed rule comment process. Through these comments and follow-up discussions, we have listened to specific concerns of pharmacies (chains and independents, including small pharmacies), trade associations representing for profit and non-profit nursing facilities, trade associations representing LTC pharmacies, LTC and independent pharmacists, State Medicaid pharmacy

directors, pharmacy benefit managers (PBMs) and plans, and beneficiary advocates. We considered a number of policy alternatives and have discussed those considerations fully in the preamble for subpart C and in Section M., Alternatives Considered, of this Impact Analysis. Taking into consideration the feedback we received from the various stakeholders, we believe our final regulations for the Part D benefit will ensure LTC facility residents' access to prescription drugs in a way that balances greater competition in the LTC pharmacy market with the preservation of relationships and levels of service that LTC facilities currently receive from their contracted LTC pharmacies. We also believe that the policy approach we are taking provides new opportunities for small LTC pharmacies.

b. Impacts on the Current LTC Pharmacy Market

We estimate from the National Health Expenditures data previously mentioned that prescription drug spending in the LTC sector of nursing homes and nursing home providers was about $12.5 billion in 2003. Clearly, the implementation of Part D will influence the LTC pharmacy market. We have actively sought information on the LTC pharmacy market and the role of small pharmacies in that market. From our stakeholder outreach and research, we have determined that four large national corporations claim a majority of the market's revenue (about 60 percent). None of these four corporations is a small business; their revenues range from hundreds of millions of dollars to billions of dollars. As a group these four corporations do business in all but 4 States, and in the aggregate operate hundreds of pharmacies.

There are very limited data sources related to the rest of the LTC pharmacy industry. Consequently, we present the information we are able to obtain and provide a qualitative discussion of our assessment of impacts on the LTC pharmacy market. We obtained through the Economics Department of the National Association of Chain Drug Stores (NACDS) information indicating that in the aggregate there are approximately 1,760 LTC pharmacies, of which approximately 1,360 do not appear to be establishments of the four large corporations. Based on information from a financial analyst report, some of these pharmacies may be part of smaller regional chains. Information from financial analysts indicate that the remaining approximately 40 percent of the LTC pharmacy market is handled by smaller regional or individual market LTC pharmacies. We were not able to locate publicly available data which would inform us of the revenues for all LTC pharmacies. We were able to obtain one financial analyst report indicating that some of the smaller regional or individual entities have revenues greater than the $6 million small business threshold established by the Small Business Administration for pharmacies. In addition, industry sources indicate that some of the entities in the LTC pharmacy market are also in the retail pharmacy market.

We were also able to learn from NACDS that there are differences in the geographic distribution of LTC pharmacies between the larger corporate LTC pharmacies and other LTC pharmacies. For example, 85 percent of corporate pharmacy facilities are in urban areas (MSAs), whereas approximately 77 percent of the regional or individual LTC pharmacies are in urban areas. Conversely, the regional and individual pharmacies appear to have a relatively larger physical presence in rural (non-MSA) areas. For example, the smaller regional and individual LTC pharmacies outnumber the national corporate pharmacies 5–1 in rural (non-MSA) areas, whereas in urban areas this ratio is lower.

Some stakeholders believe that the size of the independently-owned pharmacies may make it more difficult for them to compete in certain geographic locations. We believe the data on market presence in rural versus urban locations supports this. From financial analysts, we learned that the chains that own LTC pharmacies typically view the density of LTC facilities (that is, number of facilities within a geographic area) and Medicaid pharmacy reimbursement rates as some of the key factors in determining interest in ownership and geographic market entry.

As discussed in greater detail subsequently, we believe that the changed competitive market under Part D will likely make it possible for new players to enter the LTC pharmacy market, and will likely also create better incentives for price competition for the provision of drugs and pharmacy services to LTC facility residents. The National Community Pharmacists Association (NCPA) has indicated that LTC pharmacy is the fastest growing segment of the independent pharmacy business. NCPA has stated that if competition is injected into this marketplace, independent pharmacies will compete on price and win on service. We have received similar information from independent and chain pharmacies, as well as pharmacy wholesalers who are currently in or contemplating entry into the LTC pharmacy market.

Part D plans will be required to offer a standard contract to ''any willing'' LTC pharmacy. Once a pharmacy has negotiated its agreement with a plan and becomes a network provider, the LTC pharmacy is eligible for selection by a LTC facility to serve the pharmacy needs of the residents of that facility that are members of that plan. We expect that each long-term care facility will select one or more eligible network pharmacies to provide a plan's long-term care drug benefits to its residents. In order to minimize the number of pharmacy suppliers and maintain patient safety, long-term care facilities will likely select long-term care pharmacies that meet Part D standards and participate in the largest number of plans' long-term care networks.

The competitive design of Medicare Part D provides several benefits. First, Part D plans, depending on the level of competition, may be able to negotiate more favorable market rates due to the incentive pharmacies have to be in as many networks as possible. This potentially means that LTC facility residents may receive better pricing on their prescription drugs. Second, if a LTC pharmacy is participating in as many plans as possible, it is likely that a LTC facility will be able to select only one pharmacy to serve all of its residents. This would help to preserve the ''one pharmacy—one nursing home relationship'' priority cited in comments by LTC facility and LTC pharmacy representatives.

Another impact of this competitive model may be a change in who receives and manages manufacturer rebates. Currently, large LTC pharmacy chains maintain their own formularies and have contracts with pharmaceutical manufacturers for performance payments or rebates (that is, price concessions based on volume, formulary and market share movement). Under Part D, with the LTC pharmacy subject to the formulary of the Part D plan, it is unlikely that manufacturers would continue to pay LTC pharmacies for the same rebates they will likely be paying Part D plans. In this more competitive system, the Part D plan would have to pass on the rebate in the form of lower beneficiary premiums and better benefits, in contrast to all of these rebate dollars generally accruing to LTC pharmacies under the current system. As discussed subsequently, this movement of management of formulary and related rebates from LTC pharmacies in the less competitive current environment through Part D

plans and on to beneficiaries and the Medicare program in the more competitive Part D environment may mean that the competitive pricing advantage that the large LTC pharmacy corporations had over smaller LTC pharmacies is lessened.

While LTC facilities may use a particular pharmacy for all of their residents and payers (including Medicaid prescription drug and LTC benefits, Medicare Part A drugs and services, and private pay pharmacy services), some contracts may need to be revised because payments from Medicare Part D plans will replace Medicaid payments on behalf of beneficiaries dually eligible for both programs. Currently, for LTC pharmacies, Medicaid is the largest single payer for prescription drugs and associated dispensing fees, providing for approximately 60 to 65 percent of their revenue. Dually eligible beneficiaries are a large portion of the Medicaid nursing home population. Thus, we would expect that a shift from Medicaid to Part D plan payment could have an impact on LTC pharmacies. Over time, we anticipate that the drug payments negotiated by Part D plans may be lower than Medicaid rates in some geographic areas, as a result of market competition. In support of this view, our analysis of data supplied by IMS Health for commonly used drugs provided through LTC pharmacies suggests an existing payment differential between Medicaid and third party payers, on the order of approximately 7 percent on average.

We expect over time in some geographic areas where there is healthy competition among Part D plans and among LTC pharmacies (including large corporations, regional and independent entities) to supply LTC facilities that payment rates may become more similar to those currently achieved by third party payers. In other markets where there is less competition (that is, independent entities but few or no large national corporate or regional chains), Part D plans may be less able to negotiate lower rates.

In the current market, some LTC pharmacies bundle a range of additional services along with the cost of the drugs and related dispensing fees that are offered to LTC facilities. Payment for these added services is often not segregated by service offering. Part D allowable costs do not include some of the non-dispensing services currently bundled into LTC pharmacy (for example, the Part D dispensing fee may not include costs associated with drug administration or other professional fees). With the implementation of Part D there will be a need to price these services separately, creating more transparency for the costs and charges paid by LTC facilities.

We recognize that some LTC pharmacies in more competitive markets may face both demand for a lower cost structure from Part D plans and simultaneous pressure from LTC facilities for value-added services that were previously bundled. As indicated by one commenter (not a small business), the demands of the market can produce stress on the participants; the commenter strongly suggested that without adequate reimbursement, LTC pharmacies will either reduce service levels or cease doing business. We believe that market competition in combination with our access requirements should result in effective negotiations between Part D plans and LTC pharmacies. Furthermore, the greater transparency in pricing and competition for value-added LTC pharmacy services to be provided to LTC facilities should result in more competitive pricing for these services. This transparency and competition may also provide more opportunities for small LTC pharmacies to compete on the basis of quality and service against larger players for LTC facility business. In addition, Part D plan payments under medication therapy management programs, described in further detail elsewhere in this preamble, may represent an additional revenue stream to long-term care pharmacies for some of the special services provided by these pharmacies but not reimbursed through dispensing fees.

While there is uncertainty related to the market behavior of the various players, we believe that under Part D, greater competition in the LTC pharmacy market may result over time in lower average Part D drug prices for beneficiaries and the Medicare program, and that it also may have the potential to reduce drug prices for non-Part D enrollees (private pay residents, as well as those covered under the Part A skilled nursing facility benefit). These changes would come as a result of competitive market forces.

Under Part D, small LTC pharmacies in rural areas are more likely to have a greater ability in their local markets to compete effectively compared to the larger LTC pharmacy chains. In non-rural areas, smaller regional and individual LTC pharmacies will benefit from the shift of manufacturer rebates and the leveling of the field upon which price is decided. However, structural efficiencies may be a key determinant of long-term success in areas in which there are more LTC pharmacies competing for business.

A more competitive market will reward pharmacies offering the lowest prices and highest quality service; it may also open the door for new entrants into the market as LTC facilities restructure their existing contracts. Because of the competition there may also be changes in the LTC facilities' negotiation of rates and services with LTC pharmacies. We anticipate that there may be changes in market share among the pharmacies that service LTC facilities. This changing market will be the result of the competitive situation afforded LTC facilities in choosing LTC pharmacies.

Although these changes may adversely affect some LTC pharmacies, large or small, we would note that as a result of the growth in the aged population, with the aging of the large cohort of the ''boomer'' generation, financial analysts predict significant growth in the LTC facility and pharmacy sector, and the changes associated with Part D implementation would not be expected to deter that growth.

As shown by our analysis, we are unable to predict with certainty either the presence or absence of ''a significant economic impact on a substantial number'' of small LTC pharmacies. In accordance with longstanding HHS policy, we therefore treat our regulatory provisions as having such an effect. Under the Regulatory Flexibility Act, we must present the following information. The need for and objectives of our final rule provisions on long term care pharmacy are described earlier in the preamble under subpart C. As indicated there and in this analysis, we have gone to great lengths (including an Open Door Forum and other types of outreach) to consult with the LTC pharmacy community, to identify alternatives, and to assess issues in reaching our final decision. Unfortunately, we have been unable to find authoritative data on the number of ''small'' LTC pharmacies affected in this fast-evolving field of business. Based on the previously mentioned data from NACDS and from a proprietary source serving this market, we believe there may be at least several hundred but probably less than 1,000 ''small'' LTC pharmacies, but we do not have specific data on either overall counts or on the number of small pharmacies that will have new access to serving LTC facilities as a result of the competitive changes outlined here. We are not imposing any new reporting or recordkeeping requirements, other than the statutory requirement related to providing beneficiaries with information on generic alternatives. We

have tried to reduce the burden for LTC pharmacies associated with this requirement and recognizing the unique situation for beneficiaries in LTC facilities, by modifying the timing of the requirement from a point of service basis. Long term care pharmacies will have to provide information about differential price information to Part D plans, which will in turn, provide that information to their institutionalized beneficiaries through an explanation of benefits statement. In addition, the performance and service criteria that we expect will be included in the standard contracts between Part D plans and LTC pharmacies will be those that simply reflect existing community practices with respect to LTC pharmacy service delivery. It is important to note that we have taken a significant step in terms of assuring business opportunity for small pharmacies by requiring that plan sponsors contract on equal terms with ''any willing'' pharmacy to assure broad access to nursing home residents. In practice, we believe that this means that many existing LTC pharmacies as well as new market entrants in certain areas will have a substantial competitive opportunity, in most instances broader than at present. As discussed under subpart C of this preamble and in the analysis above, the factual, legal, and policy reasons for this decision are compelling. Nonetheless there is inherent uncertainty related to the specific impact on any single entity. The competitive results we expect are likely to impact many small LTC pharmacies positively, while some will likely experience a negative effect.

3. Insurers and Pharmacy Benefit Managers (PBMs)

This rule sets forth the terms and conditions that must be met by firms to be approved to offer the Medicare prescription drug benefit. Organizations sponsoring the Medicare prescription drug benefit can be either stand alone Prescription Drug Plans (PDPs) or Medicare Advantage Prescription Drug Plans (MA-PDs). The requirements for Medicare Advantage are discussed in our separate rule. That rule includes a regulatory flexibility analysis specific to the Medicare Advantage program. Consequently the discussion here will focus on PDP sponsors. As discussed previously in the preamble, in order to be approved to offer the Medicare prescription drug benefit as a PDP an entity must be organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan, or have secured a time-limited Federal waiver. The SBA size standard for ''small entity'' health insurance firms is annual revenue of $6 million or less.

Our regulatory flexibility analysis for the Medicare Advantage rule includes an extensive discussion related to insurance firms that might potentially be eligible to be MA plans. That analysis is also applicable to insurance firms that might be interested in being a PDP. As noted for the MA market and equally applicable to the PDP market, essentially all of the insurance firms affected by the statute and our rule exceed size standards for ''small entities'' within the meaning of the RFA and implementing SBA guidelines, which State that an insurance firm is ''small'' only if its revenues are below $6 million annually. Stand-alone drug insurance policies are not a typical product in the insurance market today. Thus, the range of insurance companies that may choose to enter this market is uncertain. However, a portion of the insurance firms that might be interested in being a PDP and thus affected by these rules are ''small entities'' by virtue of their non-profit status.

PDP eligibility provisions in the MMA rely on the Medicare Advantage enrollment provision (unchanged from prior law) that no health insurance plan is normally eligible to participate unless it already serves at least 5,000 enrollees. Section 1860D–12(b)(3) of the Act provides that this minimum shall be waived during the first contract year in a region, since PDPs in the context of Part D are new entities. While there is also a 1,500 minimum standard enrollment for plans that predominantly serve rural populations, in the context of PDP services areas designed on a regional basis, we do not believe a predominantly rural situation would occur. In the proposed rule we sought comment on this question and received no response. Consequently, we have not considered this level of enrollment in our analysis. At the 5,000–enrollee level, no insurance plan would fall below the SBA revenue cutoff assuming estimated average per enrollee revenue of approximately $1,675 in 2006, a revenue level similar to that of prescription drug plans under the standard Medicare Part D benefit. Therefore, the statutory limits generally prevent any insurance firm defined as ''small'' pursuant to the RFA's size standards from participating in the program. It is also important to note that PDPs will only operate on a regional basis. We have established 34 PDP regions, not including territories, and the average population in these exceeds one million Medicare beneficiaries.

In our RFA for the Medicare Advantage program, we include a detailed analysis on regional Medicare Advantage markets and small entities. That discussion is applicable to the PDP market, and therefore we are not repeating that discussion here. That analysis also reviews the local Medicare Advantage market. As is noted in that analysis the option to be a local MA-PD plan provides opportunity for health insurance entities of all types and sizes (but probably not below the ''small'' insurance entity cutoff level defined by the SBA, which is lower than appears viable for a Part D risk-bearing insurance plan) to participate in offering the Medicare prescription drug benefit, albeit as part of a comprehensive benefit offered on a local basis. We point out that many HMOs are non-profit entities, as are several dozen Blue Cross and Blue Shield plans, and conclude that on balance Medicare Advantage provide favorable opportunities for them. We note that a number of HMOs and other insurers including a number of Blue Cross plans are sponsoring Medicare-endorsed drug discount cards under that new program, which suggests their future ability to participate as PDP or MA-PD participants, regardless of profit status. While this rule extends certain requirements related to the provision of Part D benefits to Medicare Advantage plans (for example, network adequacy standards and any willing pharmacy provisions), we believe that these requirements will not result in consequential additional costs for MA-PD plans. We believe that any well-designed plan would already meet or readily be able to accommodate these standards. For example, we believe that competition among plans for enrollees will necessitate that they have a pharmacy network that is at least as broad as those stipulated by our network adequacy standards.

The other organizations that we think potentially may be interested in being PDP sponsors, or most certainly working closely with PDP and MA-PD sponsors to administer all or part of their drug programs, are pharmacy benefit managers (PBMs). PBMs are a relatively new player in the health care market. A major limitation on PBMs being PDP sponsors, however, is the statutory requirement for State licensure as a risk bearing entity, a status PBMs have not historically achieved. As discussed in section C (Federalism) of this Regulatory Impact Analysis, the MMA provides for a time-limited waiver to obtain State licensure, during which an organization can be approved by CMS to be a PDP sponsor. Since the Part D benefit is new, we sought information in the proposed rule on whether PBMs are considering

becoming PDP sponsors. While we received no specific comments indicating PBMs' intentions with regard to Medicare Part D, we note that we did receive comments on the proposed rule from several PBMs.

There are basically two types of PBMs in the market today. Some are subsidiaries of health plans (that is, managed care organizations or insurance companies), and others are independent PBMs. PBMs have evolved over time in the nature of services they provide. In the late 1970s and early 1980s they offered claims processing services. In the late 1980s and early 1990s their services evolved to include pharmacy network design and management, formulary design and manufacturer rebate negotiations, mail order pharmacy services, drug utilization review, and enrollee services (for example, call centers). During the 1990s, PBMs generally expanded to become managers of a wide array of pharmacy services as plan sponsors sought to control drug costs. For example, some PBMs now also provide clinical services such as disease management, and physician and patient education.

Under the ''carve-out'' trend by which pharmacy benefits are administered separately from medical benefits in employer-sponsored insurance, PBMs are now believed to administer roughly half of all pharmacy benefits for employer health plans, and this share is rising rapidly. The primary reasons are analyzed in a 2003 General Accounting Office report (''Federal Employees Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies'' available at *www.gao.gov*; see also the CMS study on PBMs cited above). These reports and others conclude that PBMs help insurance plans achieve significant savings in their drug coverage, for example, through use of discounts and rebates to lower prices, through drug utilization review, and through shifting sales from name brands to generics. Obviously, insurance plans can do these things for themselves, but most find that PBMs substantially improve their ability to achieve savings.

Because PBMs rely heavily on computerized systems to manage pharmacy records, they also provide safeguards against many kinds of medication errors through drug utilization review. Which services a PBM provides to a particular plan sponsor is negotiated between the PBM and the sponsor. Selection of a PBM (usually one, but sometimes two, one for mail order and one for retail) by plan sponsors is strongly influenced by the expected cost of drug benefits, with PBMs gaining a competitive advantage in contractual negotiations by offering lower average costs per prescription.

There are believed to be about one hundred PBM firms. Some are stand-alone companies, but most are subsidiaries of health insurance firms (for example, Wellpoint and Anthem) or owned by drug store chains (for example, Walgreens). Although a handful of particularly large firms account for most of the ''covered lives'' and industry revenue, the industry is regarded by analysts as highly competitive. We have no information on the size of the smaller firms in the industry, but it is likely that none of them, or at most a very small number, would fall below the $6 million annual revenue threshold used by the SBA for defining ''small entities'' in the insurance industry. (The smallest companies are in any event most likely to be subsidiaries or components of health insurance companies and other large firms.) This is an industry in which there appear to be marked advantages to larger size, through both economies of scale and bargaining power. Nor do we believe that a substantial number, if any, are non-profit entities. In the proposed rule we requested additional information on the characteristics of this industry and its firms, but we did not receive comments on this issue.

The MMA will expand PBM business in two ways. First, assuming that all or most PDPs and many MA-PDs will use PBMs, and that nearly all beneficiaries without drug coverage will enroll in a plan providing drug coverage, we anticipate that millions of beneficiaries will start purchasing their drugs using PBM-managed benefits. Second, all or most of those currently enrolled in plans that cover drug purchases on an indemnity basis (rather than through PBMs), and who sign up for PDP or MA-PD plans, will start using PBM services. This latter group includes most of the 1.9 million persons we estimate are currently enrolled in Medigap plans that offer drug coverage. Thus, drug insurance plans using PBMs are likely to enroll millions of new covered lives. Because these enrollees are on average much higher utilizers of drugs than most covered lives in the private sector, this will create positive and significant economic impact on the future volume of business for these firms.

Obviously, the scope, timing, and nature of additional PBM business will depend on the future decisions of PDP and MA-PD sponsors, and the PBMs themselves, and ultimately on the decisions of Medicare beneficiaries as they make choices among their various insurance options. Nothing in this rule directly regulates PBMs, positively or negatively, or directly encourages or discourages their use over alternative methods of managing drug benefits. Furthermore, there are many other influences on the role of PBMs and on the amount of drug spending that they manage. Chief among these is the continuing growth in spending on prescription drugs and the incentives this creates to control costs.

It is possible that the regional boundaries could affect the ability of some PBM firms to compete for PDP contracts. However, we believe that the regional boundaries are unlikely to be an issue for PBMs or PDP sponsors more generally due to our decision announced on December 6, 2004 to designate 34 PDP regions—25 regions made up of a single State, 6 regions made up of two States, with the remaining 3 regions made up of 3 States, 4 States and 7 States respectively. We believe that most if not all PBMs are not plan-specific, and thus would be able to compete in single State regions, multi-State regions, or nationally. In addition, in developing the regional boundaries, we were cognizant that the regions need to have a large enough Medicare population to assure PDP viability, while not being so large as to cause plans to have difficulty enrolling and providing services to beneficiaries especially in the start-up year. The 34 regions were designed to strike that balance.

For all the reasons given above, we conclude that while the statutorily-created Part D and Medicare Advantage programs will be largely favorable to PBMs, this rule as such will not significantly adversely effect a substantial number of small entity PBMs. In the proposed rule we sought comment on this conclusion and on any provisions that might adversely affect small firms; however, we received no comments on this issue.

4. Small Employers

In the case of the small employers, public and private, who provide qualified prescription drug coverage for their retirees, we estimate that savings obtained from the Medicare retiree drug subsidy will exceed the employer's administrative costs associated with obtaining the subsidy, and thus the result of the retiree drug subsidy provision is a net positive impact. We would like to make participation in the retiree drug subsidy program as simple as possible for small entities.

In the proposed rule we requested comments on any provisions of this proposed rule that may be particularly

difficult for small entities, and on any alternatives that might lessen such burdens. One of the particular areas of concern was the burden related to the payment timing, that is, monthly, quarterly, or annually. As noted previously, we want to make the retiree drug subsidy process as flexible as possible to encourage employers, including small employers, to participate. In particular, we think our provision allowing plan sponsors to voluntarily elect to use an annual or quarterly payment process, rather than requiring a monthly process, will significantly reduce the burden for small employers that wish to apply for the retiree drug subsidy.

In addition, as discussed in greater detail in subpart R of the preamble, given statutory provisions, we think our alternative approach for dealing with sponsors of insured plans helps to address concerns that were raised in the comments we received related to such retiree plan products. As discussed in the subpart R preamble and in the final regulation, the quarterly or monthly interim subsidy payments can be based on a determination by the insurer—using reasonable actuarial principles—that allocates a portion of the premium costs to the gross covered prescription drug costs incurred for a sponsor's qualifying covered retirees between the cost threshold and the cost limit. If the insurer determines premiums based on the pooling of employer/union experience in a given policy, the insurer will be permitted to make such determination based on the aggregate experience incurred under such policy for all employers'/unions' qualifying covered retirees. Thus, we think our decisions to provide the options for quarterly or annual payments, in addition to a monthly process, and to provide a simplified method for dealing with premium allocation for fully-insured retiree benefit arrangements, recognizing statutory payment provisions for the retiree drug subsidy, facilitates the participation of small employers in the retiree drug subsidy program.

Another area of concern for small employers was actuarial attestation. We received several comments from small employers stating that we should accept attestations of actuaries with the insurance carriers or with third party administrators who can attest on behalf of the sponsor that the sponsor's retiree drug coverage is actuarially equivalent to Part D. As indicated in the subpart R preamble, sponsors can submit attestations of actuaries employed by insurance carriers or the third party administrators of their retiree drug plans.

One health care plan administrator raised concerns about the burden of actuarial equivalence on small employers and requested streamlined processes. The commenter asserted that small self-insured retiree plans operated by third party administrators are unlikely to have an actuary on staff, and that even if a group of plans is operated through the same PBM they would still need separate actuarial studies. The commenter requested that due to the cost of an annual attestation, we allow small employers to submit an application, their eligibility list and plan benefit descriptions and provide CMS with two years of experience or premium data and have CMS actuaries perform the attestation on behalf of their plan.

As we noted previously, the statute does not permit us to perform the attestation on behalf of a plan sponsor. However, as discussed elsewhere, since many small employers are likely to purchase retiree coverage through insurance companies who offer similar policies to many employers, we expect that the costs of the actuarial attestation would be spread across these employers. In addition, we would expect that, in order to offer health insurance and develop a benefits package, a self-insured plan sponsored by a small employer would have access to actuarial information through a third party administrator or through the entity that assisted the employer in designing the insurance offering, and that the simplified computation methods that we are developing would lessen the complexity and time involved in the actuarial valuation.

At the same time, we acknowledge that there are administrative costs associated with obtaining the retiree drug subsidy. We believe that the revenues from the subsidy would outweigh the costs. As noted earlier, we estimate that the administrative costs associated with obtaining the Medicare retiree drug subsidy will represent on average about 6.8 percent of the Medicare retiree drug subsidy payments in 2006 (declining in subsequent years after initial start-up costs), and that the bulk of these costs will be associated with preparing the actuarial valuation, retiree drug subsidy application, related enrollment information, and reporting data on prescription drug costs for the purpose of receiving subsidy payments. It is important to note that this estimate reflects an average across all plan sponsors. While administrative costs for small employers as a percent of retiree subsidy dollars are likely to be higher than the average, we believe that subsidy payments are likely to exceed the administrative costs of obtaining the subsidy for many small employers. Although smaller employers will spread their administrative costs across fewer qualifying retirees for whom they will be receiving Medicare retiree drug subsidy payments than larger employers, they are expected to have lower costs associated with identifying their Medicare retirees and related enrollment information than large employers. Additionally, we expect that among small employers that purchase retiree coverage from insurance companies, much of the costs associated with the actuarial valuation and data reporting would generally be spread across many employers that are purchasing the same or similar insurance products.

However, it is important to note that under Medicare Part D, employers have several options for providing prescription drug assistance to their retirees at a lower cost. For example, employers that purchase enhanced benefits or provide supplemental wraparound coverage for their retirees who are enrolled in Part D plans will also achieve savings because the Federal government provides a significant subsidy for the cost of standard Medicare Part D. We recognize that the relative benefits to employers of one option versus another will depend on an employer's individual circumstances. In developing all of the employer/union options described in this final rule, we have sought to provide employers and unions with maximum flexibility while minimizing employer/union burden as much as possible.

We believe that affected small businesses are unlikely to experience increased revenues of the magnitude that would approach 3 to 5 percent of revenues due to the Medicare retiree drug subsidy payments. We arrive at this conclusion as follows. First, we estimate the number of covered lives per firm offering retiree coverage. To make this estimate, we use 2001 data from the Medical Expenditure Panel Survey (MEPS) on the number of establishments (by firm size), with retiree coverage for the over 65 population, and the number of retirees covered by these establishments. As a conservative approach, we assume two covered lives per retiree to estimate the number of covered lives in these establishments. This assumption overstates the number of covered lives as not all Medicare beneficiaries are married, or are married to an individual who is also a Medicare beneficiary. Second, we convert the number of

establishments offering age 65 and over retiree coverage to a firm based count using the ratio of the number of establishments to the number of firms, based on the U.S. Census Bureau's Statistics on U.S. Businesses for 2001 (see *http://www.census.gov/epcd/www/smallbus.htm#EmpSize*). Using this firm based count we then estimate the average number of age 65 and over covered lives per firm. For firms with fewer than 100 employees our estimated average number of 65 and older covered lives was 6.15; the corresponding figure for firms with a firm size of 100 to 999 employees was 44.7. Data for 2001 on the overall number of establishments, the overall estimated number of firms, the number of estimated firms with retiree coverage for retirees aged 65 and over, the number of covered retirees, and the estimated number of retirees and covered lives per firm, are shown in Table IV–5.

As an extreme example, we assume the absolute maximum subsidy per person that an employer/union can receive in 2006 is $1,330 (that is, 28 percent of the difference between $250 and $5,000, and assuming no further adjustment related to netting out discounts, chargebacks or rebates). As discussed earlier, we estimated an average per capita Medicare retiree drug subsidy amount at $668 in 2006 (which, for example, would be equivalent to about $891 of taxable income for employers with a marginal tax rate of 25 percent and about $1,028 of taxable income for employers with a marginal tax rate of 35 percent). Using the $1,330 value, the retiree drug subsidy payments would be about $8,178 per firm with less than 100 employees and $59,456 for firms with 100 to 999 employees. These amounts almost certainly are overstated because they assume that every qualifying covered retiree would have annual allowable prescription drug costs of at least $5,000 in 2006, and that each firm would thus receive the maximum retiree drug subsidy payment for every covered individual, which is unlikely.

We compare these estimates with revenues for firms of these respective sizes. We trend forward 1997 revenue data by firm size, from the U.S. Census, to 2001 based on the annual change in the average Consumer Price Index (CPI). While revenues would likely grow at a faster rate than the CPI due to increases in the quantity of items and/or services sold, we take a conservative approach by only accounting for increases in prices from 1997 to 2001 via the annual changes in the average CPI. The most recent year that data on revenues are available is for 1997. We used U.S. Census Bureau data for 2001 for estimating the number of firms. The estimated per firm average revenues for 2001 are about $1.2 million for firms with a firm size of less than 100 employees and $28 million for firms with a firm size of 100 to 499 employees.

The Medicare retiree drug subsidy payments, therefore, represent only 0.7 percent of total revenues for firms with a firm size of less than 100 employees, and 0.2 percent for firms with a firm size of 100 to 999 employees. Because revenue data are not available for firms with 100 to 999 employees, we conservatively use the per-firm revenues for firms with a firm size of 100 to 499 employees to represent the per-firm revenues for firms with a firm size of 100 to 999 employees. For further illustrative purposes, Table IV–6 shows by different firm sizes the revenue impacts using the maximum assumption on retiree drug subsidy payments. Even for the smallest firms, the revenue impacts of the subsidy would be less than 2 percent. The table shows that, as the firm size increases, the percentage of the revenues accounted for by the subsidy decreases. We therefore conclude that this rule will not have a significant economic impact on a substantial number of small employers. This conclusion applies equally to non-profit employers and small local government employers, though we do not have detailed data on these groups (had we the data, the comparison would have been on a cost rather than revenue basis, but the relationships of retirees to active employees would have been similar.) Because of the likely interest in the Medicare retiree drug subsidy program, however, we present some additional background information related to the number of small entities that might potentially be eligible to receive the Medicare retiree drug subsidy payments.

To estimate the number of potentially eligible small businesses for RFA purposes, we need to determine the appropriate standards for identifying a small business. In general, the SBA has size standards that define small businesses within a given industry based on either the average annual receipts (millions of dollars) or average employment (number of employees) of a firm (''Table of Size Standards Matched To North American Industry Classification System Codes, January 28, 2004,'' U.S. Small Business Administration, available at *www.sba.gov*). However, we did not have data available on retiree coverage among either establishments or firms by annual revenues, but these data are available by employee size. We used an alternative size standard for RFA purposes based on our consultation with the Office of Advocacy at the SBA. The alternative size standards are based on the number of the firm's employees, rather than the firm's annual revenues.

Because our data from the Medical Expenditure Panel Survey (MEPS) on the number of establishments providing retiree drug coverage are at the 2-digit North American Industry Classification System (NAICS) code level and the MEPS industry group level (which is based on rolling-up 2-digit NAICS codes), while the SBA size standards are at the 6-digit NAICS code level, we developed an approach for rolling up the size standards to the 2-digit NAICS code level. For the purpose of our analysis, we classified a business within a 2-digit NAICS code as a small business based on the largest SBA employment size standard among all the six-digit NAICS codes that comprised that two-digit NAICS code. It is likely that this methodology overstates the number of small businesses because some large businesses are likely counted as small businesses. Our employee firm size standards ranged from 150 to 1,500 employees.[16]

We estimate the number of small businesses who offer retiree drug coverage based on an analysis of 2001 MEPS data. We mapped the 19 two-digit NAICS codes to nine MEPS industry groups. Where the MEPS industry group consisted of two or more two-digit NAICS codes, we defined a small business using the largest employee size standard among the two-digit NAICS codes that cross-walked to the MEPS industry code. However, for each of nine MEPS industry groups, the MEPS data do have the number of establishments offering retiree health insurance coverage by the number of employees in the firm. We estimate that in 2001, there were 399,751 establishments offering retiree coverage to their retirees age 65 and older. Of this total, 65,208 (not shown in Table IV–5) were small businesses, based on the small business size standards (that is, 150 to 1,500 as noted earlier). These businesses represented 1.3 percent of all small establishments. These businesses also accounted for 16 percent of all establishments offering retiree coverage to their retirees that were age 65 and over.

[16] We used the following alternative size standards for the purpose of this RFA: less than 150 employees (NAICS codes 42 and 44), less than 500 employees (NAICS codes 11, 23, 56, 71, 72, and 81), and less than 1,500 employees (NAICS codes 21, 22, 31, 48, 51, 52, 53, 54, 55, 61, and 62).

While in the case of small businesses the number of establishments is very similar to our estimate of number of firms, this relationship is not the case for the largest firms; that is, those firms with more than 1,000 employees. As a result, from a firm perspective, we estimate that firms with less than 1,000 employees account for 93 percent of all private sector firms offering coverage to retirees age 65 and over, but account for only 10 percent of all retirees with employer-sponsored coverage.

While we have data on the number of small employers who offer retiree coverage, by industry sector, we do not have data on the number of retirees covered by small employers by industry sector. The only analysis we are able to do is the distribution of age 65 and over retirees between large firms with 1,000 or more employees and firms with less than 1,000 employees that offer retiree health coverage to this population. Most covered retirees receive their drug coverage from large employers and unions, both because these large employers/unions are more likely to provide coverage, and large employers/unions have a large number of retirees. According to data from MEPS, in 2001 the largest private sector firms (1,000 or more employees) covered 90 percent of all the retirees who had employer-sponsored retiree coverage, with only 10 percent of retirees being covered in firms of less than 1,000 employees.

As discussed previously, we expect that Medicare Part D will also positively impact those small employers that had provided retiree drug coverage prior to implementation of the Medicare prescription drug benefit but choose not to obtain the Medicare retiree drug subsidy payments. For example, some of these employers may choose to provide alternate forms of prescription drug coverage by either offering enhanced Medicare Part D benefits for their retirees or providing wraparound coverage. These employers would see reductions in their spending on retiree drug coverage, as the Medicare prescription drug benefit would partially offset their spending on drug coverage.

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Table IV-5
Estimated Number of Covered Retirees in Private Sector Establishments and Firms, 2001

Firm Size	Number of Private Sector Establishments, 2001*	Number of Private Sector Firms, 2001*	Ratio of Number of Establishments to Number of Firms	Number of Private Sector Establishments that Offer Coverage to Retirees Age 65 and Over, 2001**	Estimated Number of Private Sector Firms that Offer Coverage to Retirees Age 65 and Over, 2001	Number of Covered Retirees Age 65 and Over**, 2001	Estimated Average Number of Retirees per Private Sector Firm	Estimated Number of Covered Lives, per Private Sector Firm (assuming 2 covered lives per retiree)
Less than 100 employees	5,058,525	4,851,266	1.04	39,308	37,697	115,899	3.1	6.15
100 to 999 employees	418,085	93,876	4.45	29,438	6,610	147,745	22.4	44.70
1,000 or more employees	913,080	8,795	103.82	331,006	3,188	2,432,542	763.0	1,525.91
Total	6,389,690	4,953,937	n/a	399,751	47,496	2,696,186	56.8	113.53

Sources: *U.S. Census Bureau, Statistics of U.S. Businesses, 2001, http://www.census.gov/epcd/www/smallbus.htm#EmpSize
** Medical Expenditure Panel Survey (MEPS), 2001

Table IV-6
Analysis of Medicare Retiree Drug Subsidy Impacts for Different Private Sector Firm Sizes

Firm Size	Number of Private Sector Firms, 2001	Total Revenues, 2001 (in 000s)	Estimated Per Firm Revenues, 2001	Estimated Number of Covered Lives per Firm	Maximum Per Person Subsidy	Total Estimated Retiree Drug Subsidy Amount	Estimated Subsidy as Percent of Revenues
1 to 9 employees	3,716,934	$1,815,857,996	$488,535	6.15	$1,330	$8,178	1.7%
10 to 19 employees	616,064	$1,049,691,336	$1,703,867	6.15	$1,330	$8,178	0.5%
20 to 99 employees	518,258	$2,781,101,533	$5,366,249	6.15	$1,330	$8,178	0.2%
100 to 499 employees	85,304	$2,385,814,720	$27,968,380	44.70	$1,330	$59,456	0.1%

Sources: Number of Firms, Revenues: U.S. Census Bureau, Statistics of U.S. Businesses, http://www.census.gov/epcd/www/smallbus.htm#EmpSize

5. Rural Hospitals

Section 1102(b) of the Social Security Act requires us to prepare a regulatory flexibility impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. This rule will not affect small rural hospitals since the program will be directed at outpatient prescription drugs, not drugs provided during a hospital stay. As required by law, prescription drugs provided during hospital stays are covered under a separate Medicare payment system. Therefore, we are not providing an analysis.

6. Other Requirements in the Regulatory Flexibility Act

The RFA requires that a Final Regulatory Flexibility Analysis (FRFA) meet certain requirements, including responsiveness to public comments, estimates of small entities affected, a description of compliance requirements, a description of steps to minimize impact on small entities, and a statement of the factual, legal, and policy reasons for selecting the adopted alternatives. This impact analysis, taken together with the preamble as a whole, meets all of these requirements. Since the overall effects of the final rule are generally positive on small entities (with the exception of small long-term care pharmacies for which the effect is uncertain), and since we have consistently chosen the least burdensome compliance options legally available to us, we believe we have met or exceeded all expectations.

L. Accounting Statement

In accordance with the OMB A–4 circular on regulatory impact analyses, we have included an accounting statement in Table IV–7. The Medicare prescription drug benefit and retiree drug subsidy represent a transfer of revenues from taxpayers to Medicare beneficiaries, States, and retiree plans sponsored by employers and unions. The table provides an estimate of the annualized amount of transfers from taxpayers to these entities over the five-year period from CY 2006–2010. For the purpose of the accounting statement, these estimates are shown separately with a 3 percent and 7 percent discount rate in 2001 dollars.

The table also indicates that there will be some administrative costs associated with the Medicare prescription drug benefit, specifically the costs associated with disclosure notices, coordination of benefits, and the Medicare retiree drug subsidy. Costs associated with these activities are discussed in the respective sections of this impact analysis.

The accounting statement also provides a summary of the effects of the rule on State and local governments and small businesses, as discussed in the relevant sections of the analysis.

Table IV-7
Accounting Statement
Annualized Estimates for Medicare Prescription Drug Benefit and Retiree Drug Subsidy, CY 2006-2010
(2001 dollars in billions)

	3 percent discount rate	7 percent discount rate
Monetized Transfers		
From Taxpayers to Beneficiaries, States, and Employers/Unions	$51.2*	$51.0*
Administrative Costs		
Notice Requirement	$0.02**	$0.02**
Coordination of Benefits	Not fully quantifiable at this time	Not fully quantifiable at this time
Administrative Costs Incurred by Employers and Unions to Obtain the Medicare Retiree Drug Subsidy	6.8 percent of subsidy in 2006 and declining in subsequent years	6.8 percent of subsidy in 2006 and declining in subsequent years
Category	Effects	
Effect on State and Local Governments	Estimated net positive revenue impact for the period CY 2006-2010 in current dollars: State governments ($7.9 billion); Local governments ($4.3 billion)	
Effect on small business	**Small Retail Pharmacies:** Positive impact. Estimated economic impact is not expected to reach the threshold for significant (3 to 5 percent of revenues). **Small Long-Term Care Pharmacies:** Impact uncertain. Not able to predict with certainty either the presence or absence of a significant economic impact on a substantial number of small long-term care pharmacies. **Small PBMs:** Impact favorable for PBM industry, and no significant adverse impact on a substantial number of small entities. **Small Insurers:** Impact favorable on insurance industry, and no significant adverse impact on a substantial number of small entities as defined by SBA. **Small Employers:** Positive impact. Estimated economic impact is not expected to reach the threshold for significant (3 to 5 percent of revenues).	

* This estimate differs from the one presented in the proposed rule due to use of a corrected method for calculating annualized cost.

** Estimate covers CY 2005-2010.

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M. Alternatives Considered

1. Designation of Regions

The MMA requires that we establish between 10 to 50 PDP regions within the 50 States and the District of Columbia, and at least one PDP region covering the territories. These regions will define PDP service areas. PDPs that provide service in a particular region must cover that region entirely. PDPs can submit bids to provide services in anywhere from one to all regions.

The MMA stipulates that, to the extent practicable, PDP regions must be consistent with MA regions. However, if we determine that access to Part D benefits would be improved by establishing PDP regions that are different than MA regions, we may do so. In developing the PDP and MA-PD regions, we relied on a market survey (conducted for us by Research Triangle Incorporated), obtained input from a series of public meetings and calls, and reviewed hundreds of written comments.

On December 6, 2004, we announced the 34 PDP regions and 26 Medicare Advantage PPO regions. The decision on the regional configuration for PDPs, per se, is not a subject of this rule, although our authority from the Act to designate different regions is included in the final rule. Therefore, as part of alternatives considered we are including background related to our decision to designate PDP regions that differ somewhat from the MA regions. In designating PDP regions, our primary objective is to ensure that all beneficiaries have reliable access to PDP plans at the lowest possible cost. The law requires that beneficiaries have a choice of enrolling in at least two qualifying plans, at least one of which is a PDP. If it is not possible to achieve that with PDP plans undertaking the standard level of risk, the law makes provision for limited risk PDPs, and in cases where that does not occur a fallback plan that is paid based on cost.

For several reasons, we believe it is beneficial to have several PDP plans operating in a region. Most importantly, more plans means greater beneficiary ability to obtain coverage that meets their needs and greater competitive pressure to provide high quality and low costs. We also believe that PDPs that assume some financial risk, as opposed to a fallback plan that is paid based on cost, are likely to negotiate larger price concessions for beneficiaries. In addition, more competition for enrollees between PDPs, as well as MA-PDs, is likely to generate higher quality service for beneficiaries.

Given the goal of providing beneficiary access to risk-bearing PDP plans in as many areas as possible, we considered the need to configure the PDP regions that are different from MA regions, and whether a different configuration would contribute to this goal. One of the principal questions we needed to consider is whether regions should be comprised of the largest possible number (the 50 States, or a close approximation), or a smaller number of regions covering larger geographic areas. Designating a smaller number of regions that cover large geographic areas might be desirable in the sense that areas that might be less likely to attract market interest could be grouped with other more sought after areas. Large regions might also offer PDPs a larger potential enrollee market that would provide more leverage in negotiating rebates and discounts with manufacturers. On the other hand, regions of too large a size could deter participation if there are concerns by PDPs about providing uniform benefits and bearing financial risk across large and possibly diverse health care markets. Furthermore, an important consideration, which we received comment on, is the administrative capacity of PDPs to handle a large volume of initial enrollees in the start-up year, including distribution of plan information, enrollment cards, and answering beneficiaries' inquiries through call centers. Because of the differences in enrollment expectations between regional PPOs and PDPs, from an administrative capacity standpoint it is possible to design somewhat larger geographic areas covering larger populations for PPO regions than for PDP regions. At the same time, to the extent possible, having consistent or at least very similar regions for the MA-PDs and the PDPs will facilitate beneficiary choice and Medicare program administration. As was announced on December 6, 2004, we have established in the vast majority of areas identical PDP and PPO regions. In a limited set of situations, (that is, for 8 PPO multi-state regions), the regions have been further subdivided to contain a smaller number of States, and consequently population sized PDP regions. We have used our authority to create PDP regions that are different from the MA regions in those circumstances where we believed it was necessary to create a reasonably sized potential population enrollment in order to attract sufficient PDPs into the region. While there are PDP regions with larger populations, those regions are typically a single State region.

2. Bid Level Negotiations

As mentioned previously, the FEHBP standard in 5 USC 8902(i) requires us to ascertain that a PDP's or MA-PD's bid ''reasonably and equitably reflects the costs of benefits provided.'' In addition, we note that section 1860D–11(e)(2)(c) of the Act requires that the portion of the bid attributable to basic prescription drug coverage must ''reasonably and equitably'' reflect revenue requirements . . . for benefits provided under that plan, less the sum . . . of the actuarial value of reinsurance payments.'' Analogous to the manner in which the Office of Personnel Management views its FEHBP management responsibilities, we see this requirement as imposing the fiduciary responsibility to evaluate the appropriateness of the overall bid amount.

In general, we expect to evaluate the reasonableness of bids submitted by at-risk plans by means of the actuarial valuation analysis. This would require evaluating the plan's assumptions regarding the expected distribution of costs, including average utilization and cost by drug coverage tier, for example, in the case of standard coverage—(1) those with no claims; (2) those with claims up to deductible; (3) those with claims between the deductible and the initial coverage limit; (4) those with claims between the initial coverage limit and the catastrophic limit; and (5) those with claims in excess of the catastrophic limit. We could test these assumptions for reasonableness through actuarial analysis and comparison to industry standards and other comparable bids. Bid negotiation could take the form of negotiating changes upward or downward in the utilization and cost per script assumptions underlying the bid's actuarial basis.

As discussed in greater detail in the preamble, we considered the circumstances and manner under which we would need to use our authority to carry out bid level negotiations. We anticipate that market forces will generally lead to efficient and appropriate bid prices. In areas where there is competition for enrollees among a number of PDPs and MA-PDs that are at-risk for the provision of Part D drug coverage to beneficiaries, our strong expectation is that we will be able to rely on the incentives provided by competitive bidding, and we would use our authority for bid level negotiations only on the rare occasion we find that a plan's data differs significantly from its peers without any indication as to the factors accounting for this result. If there are any regions with minimal competition (for example, just two Part D plans) or less financial risk (for

example, just limited risk PDPs), we anticipate that it is possible that bid-level negotiations might be slightly more common.

A second issue we considered is to what extent we could negotiate aggregate bid prices with fallback plans. As mentioned elsewhere in the preamble, similar to at-risk and limited-risk plans, we will evaluate whether a fallback plan bid is reasonably justified, and if the price reference points appear too high or low, we may request an explanation of the bidder's pricing structure and the nature of their arrangements with manufacturers. We would also ensure that there is no conflict of interest leading to higher bids.

In addition, since fallback plans are paid on a cost basis, there is significantly less incentive for them to negotiate lower drug prices and take other steps to reduce drug expenditures. Consequently, we also considered options through the contracting process to provide fallback plans with some incentives to control cost. We expect to tie fallback plan performance payments to the plan's ability to keep drug costs below a certain level. We believe that this carries out the Congress' requirement under 1860D–11(g)(5)(B)(i) of the Act that payments to fallback plans take into account the plan's ability to contain costs through mechanisms such as generic substitution or price discounts. Under this approach, we might include performance incentives similar to those used in many pharmacy benefit management contracts today, such as the plan achieving certain targets such as an average discount (including manufacturer discounts) off of AWP (or other pricing reference points chosen by CMS), average cost per script, average generic substitution rate, average dispensing fee per script, or average administrative fee per script. However, because these incentives would apply only to fallback plan performance fees, they would not provide as strong incentives for drug cost control as the incentives faced by risk-bearing plans to keep overall costs down.

3. HSAs, FSAs, MSAs, and HRAs and TrOOP

As discussed in the preamble of subpart C, we considered how health savings accounts (HSAs), flexible savings arrangements (FSAs), health reimbursement arrangements (HRAs), and Archer MSAs should be treated relative to beneficiary spending against the annual out-of-pocket limit. Costs that are paid by a Part D enrollee will count as incurred, or true out-of-pocket (TrOOP) costs, while costs that are paid by a ''group health plan,'' ''insurance or otherwise,'' or ''third party payment arrangements'' through which Part D enrollees may be reimbursed will not count as TrOOP expenditures. The issue we considered was whether expenditures from an HSA, FSA, Archer MSA, or HRA are to be exempted from the definition of ''group health plan'' and treated as expenditures that are incurred by a beneficiary.

The statute provides that the Secretary may establish procedures ''for determining whether costs for Part D eligible individuals are being reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement..'' We believe the statute thus grants us discretion to decide whether personal savings vehicles are equivalent to such plans for the purpose of applying the incurred costs rule.

As noted previously, we agree with the majority of commenters that HSAs, FSAs, and Archer MSAs are similar to beneficiaries' bank accounts in the sense that such accounts consist of funds set aside by a beneficiary for his or her personal use, as opposed to group health plan contributions which are essentially pooled for the benefit of numerous enrollees in a structured benefit plan.

We do not think, as previously summarized, that allowing HSA, FSA, and Archer MSA expenditures to count toward the TrOOP would create a double taxpayer subsidy. Because a beneficiary's own savings, when not in the context of an HSA, FSA, or Archer MSA, will be counted as incurred costs for the purpose of meeting the true-out-of-pocket threshold, there will be no differential treatment of funds on the expenditure side. In contrast, we believe that to not except HSAs, FSAs, and Archer MSAs from our definition of ''group health coverage'' would create an unjustifiable penalty on beneficiaries for the use of personal health savings vehicles. We have determined that the action most consistent with the intent to count an individual eligible's contributions toward incurred costs is to exempt personal savings vehicles (HSAs, FSAs, and Archer MSAs) from our definition of ''group health plan.≥

However, we think that health reimbursement arrangements (HRAs) differ from HSAs, FSAs, and Archer MSAs because HRAs are solely employer-funded; therefore, we considered them separately. HRAs are fundamentally different from HSAs, FSAs, and Archer MSAs, which are funded at least in part by the individual. Due to this distinction, we have determined that HRA contributions should not count toward the true-out-of-pocket threshold. To reflect this distinction, we have added a definition to the regulation that defines ''personal savings vehicles'' to include HSAs, FSAs, and Archer MSAs; the definition does not include HRAs.

4. Actuarial Equivalence of Retiree Drug Subsidy and Interactions with Other Means of Enhancing Retiree Drug Coverage

As discussed previously, the MMA requires that plans qualifying for the retiree drug subsidy must offer retiree drug benefits that are at least actuarially equivalent to those available under the standard Part D benefit. The MMA also provides the Secretary with the authority to determine the standards and methods for specific actuarial equivalence requirements associated with qualifying for the retiree drug subsidy.

In considering the issues related to actuarial equivalence, we have been very cognizant that the Congress has clearly and repeatedly articulated four key policy objectives for the Medicare retiree drug subsidy program created by Section 1860D–22 of the Act and for securing and enhancing retiree drug coverage more generally through the other means of assuring high quality retiree drug coverage that are provided by the Act (including, as described above, employer/union wraparound coverage and employer/union support for enhanced Part D plans). As discussed previously, our consideration of the various alternatives for determining actuarial equivalence in the context of the retiree drug subsidy reflects these four policy objectives: 1) maximizing the number of Medicare-eligible retirees with high quality employment-based retiree drug coverage, and maximizing the generosity of their coverage; 2) avoiding financial windfalls in the retiree drug subsidy program by ensuring that plan sponsors contribute at least as much to retiree drug coverage as Medicare pays them as a subsidy; 3) minimizing administrative burden while maximizing flexibility for employers and unions; and 4) fulfilling our fiduciary responsibility by limiting overall budgetary costs.

As discussed elsewhere in this document, for more than a decade prior to enactment of the MMA, employers have been systematically reducing the availability and generosity of the level of retiree drug coverage offered, particularly for future retirees. The MMA provisions creating Part D provide multiple options for assisting plan sponsors in continuing to provide high

quality retiree drug benefits. Sponsor options range from participating in the retiree drug subsidy program to taking advantage of various mechanisms for complementing the drug coverage that their retirees receive through Part D plans by providing additional coverage over and above the standard Part D benefit that, in combination with standard Part D coverage, maintains or exceeds the generosity of their current benefit designs. As discussed earlier in this impact analysis, there is considerable uncertainty about how plan sponsors will respond to the various options that are available to them under Medicare Part D. In the proposed rule, we sought comments on how best to use the Secretary's statutory authority in setting the specific actuarial equivalence requirements related to qualifying for the retiree drug subsidy, while balancing the various tradeoffs and interactions among our key policy objectives. Our ultimate goal in implementing these MMA provisions is not only to protect but also to enhance the availability of high quality drug benefits for retirees.

a. Options for Determining Actuarial Equivalence

In the proposed rule, we discussed various possible options for determining actuarial equivalence, and sought comments on desirability and legal bases for the different options, as well as on plan sponsors' likely responses to the different approaches for determining actuarial equivalence. We received a substantial number of comments encouraging flexibility in the methodology for determining actuarial equivalence. The preamble considers the issues that were raised in the various comments that we received, and describes the policy decisions that we made relating to these issues. A discussion of the options that we considered relating to the actuarial equivalence standard and plan definition that will be used in determining actuarial equivalence for the purpose of qualifying for the retiree drug subsidy program follows.

i. Actuarial Equivalence Standard

One important factor that will affect how employers and unions respond to the retiree drug subsidy relates to the actuarial equivalence standard. As discussed earlier in this impact analysis, while we believe that most of the employment-based retiree drug coverage that is currently available in the marketplace is at least as generous as the standard Part D benefit on a gross value basis, there is considerable variation in employers' and unions' contributions to the cost of retiree coverage (for example, approximately 30 percent of the large private sector firms with 1,000 or more employees that currently offer retiree health coverage to new Medicare-age retirees require those retirees to pay 61 to 100 percent of the cost of their retiree health premiums, according to the 2004 Kaiser/Hewitt Survey on Retiree Health Benefits). Thus, the actuarial equivalence standard that is selected will affect the number of employers and unions that are able to qualify for the substantial assistance that is available through the retiree subsidy. As noted previously, however, the retiree drug subsidy is one of several options available to employers and unions for continuing to provide assistance with drug costs.

As discussed in the preamble, our proposed rule described three potential standards for determining actuarial equivalence in the context of the retiree drug subsidy: 1) a single prong ''gross value'' test in which the value of the sponsor's retiree drug plan design is compared with the value of the standard Part D plan design, without taking the financing of the coverage into account (the same test as for ''creditable coverage,'' which would generally require that the expected amount of paid claims under the sponsor's retiree drug coverage be at least equal to the expected amount of paid claims under the standard Part D benefit); 2) a gross value test as in the first option, with an additional stipulation restricting the subsidy payment that a plan sponsor receives to no more than what the sponsor contributed to the cost of the retiree drug coverage on behalf of its retirees; and 3) a two-prong test in which the first prong is the ''gross value'' test as in the first option, and the second prong is a ''net value'' test which takes into account the sponsor's contribution toward the financing of the retiree prescription drug coverage. We also discussed several variants for determining the threshold value of the second prong in the third option, the ''net value'' test, including: a) the average per capita amount that Medicare will expect to pay for the retiree drug subsidy (the lowest variant); b) the after-tax value of the retiree drug subsidy (since the retiree subsidy payments are not subject to Federal income tax); and c) the expected value of paid claims under standard Part D coverage minus the retiree's expected monthly beneficiary premiums for such coverage (the highest variant).

In the proposed rule, we stated that the first option (single-prong gross value test) could not by itself preclude the existence of windfalls because unless financing is considered, an employer or union could theoretically impose as much as the full cost of the retiree drug coverage on the retiree through retiree premiums, and still be eligible for a subsidy payment if the value of the drug benefit that the employee was paying for was at least equal to the value of the standard Part D benefit. We also noted that the second option (single-prong gross value test with a requirement that the retiree drug subsidy payment amount could not exceed the amount paid by a plan sponsor on behalf of its retirees) would preclude windfalls and be relatively easy to operationalize, but stated that we had questions about the adequacy of the legal basis underpinning this option. Similarly, we stated that the third option (two-prong test of the gross value and net value of the sponsor's retiree drug coverage) would preclude windfalls, and that each of the three potential variants of the second prong of the two-prong test (that is, the net value test) would also preclude windfalls. However, we noted that each of these variants provides a different balance between the potentially competing objectives of maximizing the number of plan sponsors that participate in the retiree drug subsidy and providing greater protection to beneficiaries.

The vast majority of comments that we received from both business groups and beneficiary advocacy groups supported the two-prong test (the third option) as best serving our stated goals of maximizing the number of retirees that retain their employer or union-sponsored retiree drug coverage while not creating windfalls to plan sponsors. However, we did receive several comments that supported the gross value test (the first option) because they felt there was no legislative authority to require any other test, or because they were concerned that they would not be able to qualify for the retiree drug subsidy based on a net value test (due to relatively high retiree premium contribution levels in their plans).

We received a variety of comments relating to the threshold value for the second prong of the two-prong test, with beneficiary advocacy and union groups generally supporting the highest variant that was identified in the proposed rule (that is, the expected value of paid claims under standard Part D coverage minus the retiree's expected monthly beneficiary premiums for such coverage) due to concerns about the potential for cost-shifting, and employer groups supporting the lowest variant that was identified in the proposed rule (that is, the average per capita amount that Medicare expects to pay for the retiree drug subsidy in a given year) due to concerns about maximizing employer

and union eligibility for the retiree drug subsidy. Additionally, several employer groups proposed that we consider an additional variant for the net value test, which would involve either: 1) determining the expected value of claims paid under Part D by adjusting for the impact that the true-out-of-pocket (TrOOP) provision would have on the value of the reinsurance subsidy portion of the standard Part D benefit if an employer or union chose to provide their retirees with additional coverage that supplemented the standard Part D benefit; or 2) allowing plan sponsors to use the expected per capita value of the retiree drug subsidy that they would receive (based on their own claims experience) as a proxy for this test since, by their calculation, both of these approaches would result in approximately the same value. These employer groups asserted that their proposed alternative variant would provide a more appropriate comparison because the relative value of the standard Part D benefit would be lower for their retirees since catastrophic coverage is only available when an individual's TrOOP expenses exceed a specified threshold, and employers/unions' contributions for supplemental drug coverage would not count toward the beneficiary's true out-of-pocket spending for purposes of TrOOP.

As discussed in the preamble, the approach that we have taken in the final rule with regard to the actuarial equivalence standard seeks to balance our various policy goals within the context of our statutory authority. We agree with the majority of commenters that the two-prong test best accomplishes our goals of maximizing the number of beneficiaries retaining employment-based retiree drug coverage while not creating windfalls to sponsors. We also believe that the MMA statutory provisions impose some constraints on the methods that can be used in determining actuarial values for the purpose of qualifying for the retiree drug subsidy.

For these reasons, we have decided to require the use of a two-prong test for determining actuarial equivalence in the contest of the retiree drug subsidy, with the first prong of the test (the gross value test) generally requiring that the expected amount of paid claims under the sponsor's retiree drug coverage be at least equal to the expected amount of paid claims under the standard Part D benefit. We have also decided to establish that employment-based retiree drug coverage satisfies the net value portion of the actuarial equivalence test if its actuarial value (as determined after reducing the gross value of the benefit by expected retiree premiums) is at least equal to the net value of defined standard prescription drug coverage under Part D (as determined after reducing the gross value of the benefit by the expected monthly beneficiary premiums), with the net value of the defined standard prescription drug coverage reflecting the impact of having an employer's or union's coverage supplement a retiree's Part D coverage and thus increase the point at which the retiree would receive catastrophic Part D benefits. We will require sponsors to calculate the value of the drug coverage provided under the sponsor's plan and the defined standard prescription drug coverage under Part D based upon their own claims experience for plan participants (or their spouses or dependents) who are Part D eligible individuals because we believe that the plan sponsors' claims experience for these individuals best reflects the true value of the prescription drug coverage under the plan. However, we will allow plan sponsors that do not have sufficient claims data to support a reasonable calculation based on actual claims data to utilize alternative normative databases in accordance with our guidance. Our guidelines on the appropriate methodology for applying this two-prong actuarial equivalence test will also include simplified actuarial methods that could be used by plan sponsors that may have difficulty measuring the TrOOP impact associated with their benefit design.

We believe that this approach effectively balances our policy objectives of maximizing the number of beneficiaries who receive high quality retiree drug coverage while avoiding the creation of windfalls. We agree that employers and unions are likely to consider the effects that TrOOP will have on the value of the Part D benefit for their retirees (that is, reducing the value of the reinsurance subsidy for catastrophic coverage) as one of the factors in their decision making. In this context, we agree with the commenters who stated that employers and unions will be deciding among several options, including continuing to sponsor a plan for retiree drug coverage by electing the retiree drug subsidy, sponsoring or becoming a PDP, or providing wraparound coverage that supplements Part D. While we understand the concerns of some commenters relating to the potential for cost-shifting to occur if a lower threshold value is used for the net value test, we note that the ongoing erosion that has occurred in the generosity of retiree health coverage in recent years, through increases in retirees' premium contributions and cost-sharing arrangements, indicates that many plan sponsors already had an incentive to restructure the costs of their retiree health benefits prior to the enactment of the MMA. We do not believe that the Medicare retiree drug subsidy program, in and of itself, creates any additional incentives for plan sponsors to shift costs than what already exists; indeed, as discussed elsewhere in this impact analysis and in the proposed rule, employer survey results suggest that prior to the MMA many plan sponsors were already planning on making additional increases in retirees' premiums and cost-sharing within the next few years in an effort to manage the cost of retiree health coverage. Rather, we believe that the presence of the additional resources that are available through the retiree drug subsidy program, as well as the use of the two-prong actuarial equivalence test, will provide an incentive for more employers and unions to retain the generosity of their existing retiree drug coverage than would have occurred absent the law change. Thus, we believe that accounting for the effect of TrOOP in the net value portion of the two-prong actuarial equivalence test will assist in maximizing the number of employers and unions that will qualify for and choose to apply for the retiree drug subsidy, thereby helping to maximize the number of Medicare beneficiaries that will be able to retain their employment-based retiree drug coverage.

ii. Plan Definition

Another important factor that will affect employers' and unions' responses to the retiree drug subsidy program relates to plan definition that will be used for the purpose of determining actuarial equivalence in the context of the retiree drug subsidy. In this case, the primary issue relates to whether employers and unions that offer multiple benefit designs within a given retiree health plan (for example, with differing retiree contribution levels and/or cost-sharing arrangements) will be required to apply the actuarial equivalence test across all of the beneficiaries in the plan, or if these employers and unions should be allowed to apply the actuarial equivalence test to subgroups of beneficiaries and/or benefit designs within a given plan, if they choose to do so.

As discussed in the preamble, in the proposed rule, we proposed to adopt the rules in COBRA regulations for determining the number of group health plans an employer or union sponsor provides. Under those rules, all benefits

offered by a plan sponsor would be treated as one group health plan unless the sponsor treats them as separate plans through its plan documents and operations. The proposed rule also stated that plan sponsors would be required to determine actuarial equivalence for each plan ''as a whole.'' That is, a given plan would be determined to be actuarially equivalent if, on average, the actuarial value of the retiree drug coverage under the plan is at least equal to the actuarial standards described above.

While several employer groups agreed with our use of the COBRA plan definition, they also indicated that plan sponsors need additional flexibility to distinguish among retirees with differing arrangements within a single plan when establishing actuarial equivalence (such as groups of retirees with different benefit arrangements characterized by contribution or benefit levels based on years of service, date of retirement, collectively bargained status, status as a member of a ''grandfathered'' group of retirees, or other factors). These commenters stated that many plan sponsors may use a single administrative system to administer multiple benefit designs, and it is not uncommon that a given retiree health plan would include both a grandfathered group of retirees for whom the employer makes a substantial contribution and a non-grandfathered group with limited or no employer contributions. These commenters also expressed concern that it is possible that such a plan might not be able to qualify for the retiree drug subsidy based on its average actuarial value due to the averaging of the generous benefits of the grandfathered retirees with the less generous benefits of the non-grandfathered retirees that are in the same plan. For this reason, they recommended that sponsors should be given the discretion to aggregate all retirees in a single plan as a whole or to apply the actuarial equivalence test to each individual ''benefit option'' within a plan in order to maximize the number of employers and unions that are able to qualify to receive retiree drug subsidy payments. However, a few commenters expressed concern that the plan definition that is used for the purpose of the retiree drug subsidy should minimize the extent to which some classes of retirees are offered, and employers/unions receive subsidy payments for, retiree drug coverage that is inferior to the standard Part D benefit.

We believe the MMA provisions give CMS the authority to provide for the actuarial attestation to be submitted for the plan as a whole or to require that separate actuarial attestations be provided for each benefit option within a single plan. We also believe that by providing increased flexibility in the requirements for qualifying for the retiree drug subsidy, we can increase the incentive to plan sponsors to maintain their retiree drug coverage, and thereby maximize the number of Medicare retirees that retain their employment-based retiree drug coverage. However, we also believe that the MMA requires us to insure that all beneficiaries in plans that are receiving the retiree drug subsidy have creditable drug coverage that is at least equal in value to the standard Part D benefit.

In an effort to balance these concerns, we have added provisions in the final rule to allow plan sponsors the flexibility of choosing whether to apply the net prong of the actuarial equivalence test to their plan as a whole, or to apply the net prong of the actuarial equivalence test to each individual benefit option within a plan. In this context, a sponsor will only be allowed to apply the net prong of the actuarial equivalence test to a given retiree drug plan on an aggregate basis if each benefit option in that plan qualifies as creditable coverage (that is, each benefit design under the plan must meet the gross value test, which is the first prong of the two-prong actuarial equivalence test). A plan sponsor that fails to meet that standard for a given plan will be required to apply the net prong of the actuarial equivalence test to each individual benefit option within that plan for the purpose of qualifying for the retiree drug subsidy. However, sponsors may aggregate together the benefit options within the plan that meet the creditable coverage standard (that is, the gross value test) for purposes of the net prong of the actuarial equivalence test. We believe that these requirements will maximize plan sponsors' flexibility, protect beneficiaries, and reduce the chance of windfalls being created.

b. Interaction With Other Means of Enhancing Retiree Drug Coverage

We recognize that employers' and unions' decisions about choosing between obtaining the retiree drug subsidy versus using other means to provide additional retiree drug coverage that complements the standard Part D benefit (for example, by offering supplemental drug coverage that wraps around a Part D plan, or providing enhanced coverage through a PDP or MA-PD) will depend on the relative attractiveness of each of these options, given their particular circumstances. We believe that the flexibility that we have provided in this final rule with regard to the actuarial equivalence requirements related to qualifying for the Medicare retiree drug subsidy will help to make the retiree drug subsidy an attractive and feasible option for many employers and unions.

Additionally, as discussed earlier, we note that in addition to the retiree drug subsidy, Medicare Part D also gives employers and unions a variety of other options for continuing to provide prescription drug assistance to their Medicare-eligible retirees. We believe that these additional approaches to providing generous retiree coverage will be attractive to employers and unions who may not make sufficient contributions or provide sufficiently generous coverage on their own to qualify for the retiree drug subsidy. Ultimately, we believe that this combination of approaches will maximize the number of beneficiaries who continue to receive employment-based assistance with their drug coverage as a result of combining the additional resources for supporting retiree health coverage that are available through Medicare Part D with contributions from employers and unions.

5. Retiree Subsidy—Payment Methodology and Data Reporting

a. Method and Frequency of Medicare Retiree Drug Subsidy Payments

We believe that the statute gives us broad discretion to determine the methodology and timing for distributing the Medicare retiree drug subsidy payments. The proposed rule covered in detail the various options for calculating and making these payments. Specifically, we presented several alternatives for the method and frequency of subsidy payments and rebates, and included a discussion of whether payments should be based on an employer or union's plan year or calendar year.

Regarding the method and frequency of payments, we described four options in the proposed rule: (1) monthly payments based on actual experience with monthly adjustments for price concessions; (2) a single end-of-year payment based on plan sponsors' submission of actual cost data including rebate data at the close of the plan year; (3) multiple payments at interims throughout the year based on estimates of claims, rebates, chargebacks, and discounts, with an end-of-year reconciliation; or (4) periodic lagged payments throughout the year based on actual claims experience and estimates of discounts, chargebacks, and rebates, with an end-of-year reconciliation. A detailed discussion of these four options can be found in the proposed rule. In

short, annual retroactive payments would have the greatest administrative simplicity compared to interim or monthly payments; however, more frequent payments would provide a more even cash flow for sponsors. In addition, making payments based on estimates rather than actual costs would allow for faster payments to sponsors, but would require additional work to produce actuarially sound estimates and later to reconcile estimates with actual experience, and would potentially have a greater risk that substantial overpayments or underpayments could occur.

In the proposed rule, we stated that option one was our preferred approach. Under this option, the plan sponsor would submit the amount of beneficiary spending eligible for the retiree subsidy by the 15th of the month following each monthly payment period. Sponsors would also submit the amount of any rebates, discounts, other price concessions received, and any adjustments to actual expenditures from prior months. By the 30th of each month, Medicare would make a subsidy payment based on the certified amount for the preceding month and adjusted for price concessions recognized for prior months. At the end of the calendar year, there would be a final reconciliation of actual costs except for any outstanding price concessions, which would be accounted for when they are received or recognized, and reconciled as an offset of a future monthly payment.

The responses to our proposed alternatives were mixed. While recognizing that plan sponsors may prefer different methods and frequency of payments based on their unique situations, we proposed option one as our preferred approach because we wanted to balance employers' and unions' perceived preference for frequent payments with a desire to avoid overly complex administrative procedures. Although we felt that this solution reasonably balanced various concerns, the comments we received indicated that flexibility is needed to reflect different circumstances of individual sponsors.

Thus, our final decision was to create a flexible payment system in which employers and unions could choose among multiple methods of receiving payment. We will allow a sponsor to receive payments on a monthly, quarterly, or annual basis. Under the monthly or quarterly option a sponsor will provide the aggregated actual gross covered retiree plan-related prescription drug costs incurred for all of its qualifying covered retirees during the payment period for which it is claiming a subsidy payment, an estimate of the difference between these gross costs and allowable costs (based on expected rebates and other price concessions), and any other data CMS may require. Sponsors choosing the monthly or quarterly payment options would then be required to provide within 15 months after the end of the plan year the total gross covered retiree plan-related prescription drug costs for the plan year segregated by each qualifying covered retiree; actual rebate/discount/other price concession data for the plan year in question; and any other data CMS may require.

Under the annual payment approach, we will offer two payment options: (1) a one-time final annual payment, in which a sponsor will submit actual cost and rebate/discount/other price concession data per retiree within 15 months after the end of the plan year; or (2) an interim annual payment, in which a sponsor after the end of the plan year will submit the aggregated actual gross drug costs incurred for all of its qualifying covered retirees for which it is claiming a subsidy payment; an estimate of the difference between these gross costs and allowable costs (based on expected rebates and other price concessions); and any other data CMS may require after the end of the plan year. Sponsors choosing the interim annual payment option would then be required to provide within 15 months after the end of the plan year the total gross covered retiree plan-related prescription drug costs for the plan year segregated by each qualifying covered retiree; actual rebate/discount/other price concession data for the plan year in question; and any other data CMS may require. In cases where manufacturer rebates, discounts, and other price concessions are not specifically allocated to the drug spending of a particular qualifying covered retiree, we will permit the plan sponsor (or its agent) to assign these rebates/discounts/other price concessions to their qualifying covered retirees based on reasonable actuarial principles.

b. Plan Year Versus Calendar Year

The proposed rule included a discussion of whether to use a plan year or calendar year in determining the retiree drug subsidy amount. As with the method and frequency of payments, commenters' preferences were mixed with respect to this issue. We had originally proposed the calendar year approach because it would be the least burdensome method for us to administer. This approach is most straightforward since the cost threshold and cost limit levels are determined on a calendar year basis. However, we recognize that using a plan year approach would be more consistent with the administrative practices of plan sponsors whose plan operations are based on a non-calendar year. In response to numerous comments requesting flexibility in this area, we have determined that a plan-year approach should be used. Using a plan-year approach, we will be able to accommodate employer or union-sponsored plans that are structured around either a calendar-based plan year or a non-calendar plan year.

A non-calendar year approach to retiree subsidy payments requires the creation of rules for: (1) determining whether a sponsor's plan is actuarially equivalent to Part D for purposes of qualifying for the retiree subsidy; (2) applying the cost threshold and cost limit, which function on a calendar-year basis, to the plan year; and (3) determining retiree subsidy payments for employers/unions with a plan year that straddles 2005 and 2006 when the Medicare retiree drug subsidy begins. In subpart R of the preamble we present the options for calculating subsidy payments using a plan year approach with respect to each of these factors. In summary, we determined that the cost threshold and cost limit for the calendar year in which the plan year ends will be used for determining subsidy payments. For the purpose of determining actuarial equivalence, a plan sponsor may use the elements of the defined standard prescription drug coverage from the calendar year before the year in which the plan year ends, provided that the attestation of actuarial equivalence is submitted no later than 60 days after the publication of the new coverage limits for the upcoming calendar year. During the transition to the retiree subsidy program for employers/unions with a plan year beginning in 2005 but ending in 2006, subsidy amounts will be determined on a monthly basis for the entire plan year (2005–2006), but will only be paid for claims incurred in 2006.

c. Retiree Subsidy Data Collection

Another issue we considered related to the retiree drug subsidy is what type of data should be collected from plan sponsors. Our objectives in making this decision were to minimize the burden on plan sponsors while ensuring that we receive adequate data to correctly determine subsidy payments to plan sponsors. Regardless of the method that is used to make the retiree subsidy payments, we will need data from plan sponsors to calculate the appropriate payment levels. The question is whether

actual cost data should be submitted by plan sponsors on an individual retiree basis or in an aggregated format.

We considered several alternatives in this area. CMS could require that plan sponsors submit: (1) aggregate allowable costs of all eligible retirees in the plan for the relevant time period; (2) costs aggregated over the relevant time period for each individual in the plan; (3) a combination of individual and aggregate data; or (4) actual claims data for each individual retiree in the plan.

Many commenters favored option one, aggregated reporting of allowable retiree costs, because employers and unions may not currently keep records of individual costs for some of the elements that must be submitted to CMS. However, it is important that the data submissions are sufficiently detailed to ensure that we can make accurate payments to plan sponsors. We ultimately determined that data aggregated across all plan enrollees would not be sufficient to fulfill this purpose.

As described in the proposed rule, we previously ruled out the fourth option because we believe requiring submissions of enrollee level claims data would be overly burdensome for plan sponsors taking the subsidy and raise privacy concerns. Option two—aggregate per enrollee data—would create some administrative burdens and privacy concerns, but to a lesser and more reasonable degree than a claims level data requirement.

A combination approach to data collection would diminish the negative effects of individual level data submissions while providing for sufficient assurance of payment accuracy. For instance, we could require the type of submission described in option two for the first two years of the subsidy, and require the type of submission described in option one thereafter. Alternatively, the format of data we require might vary depending on the timing of the plan sponsor's submission within a plan year.

We determined that the latter of these two combinations is better aligned with the various payment methodologies that will be used under the retiree subsidy program. If a sponsor elects to receive monthly or quarterly retiree subsidy payments or an interim annual retiree subsidy payment, the plan sponsor will be required to submit aggregated gross cost data, an estimate of the difference between these gross costs and allowable costs (based on expected rebates and other price concessions), and any other data CMS may require upon submission of data for payment at each of the time intervals elected by the sponsor, with a final reconciliation within 15 months after the end of the plan year. Using aggregated data for interim monthly, quarterly or annual payments will allow plan sponsors to receive more frequent payments without a disproportionate administrative burden.

Regardless of the payment method chosen, for final reconciliation purposes all sponsors will be required to submit total gross cost data segregated per qualifying covered retiree; actual rebates, discounts, or other price concessions received for such costs; and any other data CMS may require, within 15 months after the end of the plan year. This requirement will provide assurance that subsidy payments are appropriate for the actual costs incurred. If rebates and other price concessions for a plan are not specifically allocated by a manufacturer to the drug spending of a particular qualifying covered retiree, a sponsor will be permitted to assign such price concessions to qualifying covered retirees using reasonable actuarial principles. For sponsors who choose the monthly, quarterly, or interim annual payment option, the final data submission will serve as the basis for the reconciliation process, in which we will adjust the payments made for the plan year in question in a manner that we will specify in separate guidance. For sponsors who choose the one-time final annual payment method, this will be the primary submission of cost data required for payment. However, as discussed in the preamble, plan sponsors who choose either of the annual payment options will still be required to provide us with updates of their enrollment information on a monthly basis.

6. Beneficiary Access to Drugs in Long-Term Care Facilities

Section 1860D–4(b)(1)(C)(iv) of the Act provides that, in establishing rules for convenient access to network pharmacies, we may include standards with respect to access to long-term care pharmacies for Part D enrollees who reside in skilled nursing facilities and nursing facilities (hereinafter referred to as ''long-term care facilities''). While we do not directly regulate long-term care pharmacies, this rule will indirectly influence their operations. Long-term care facilities generally contract with one long-term care pharmacy to supply the prescription drugs needed by the residents. With the implementation of Part D, in order to serve Medicare Part D enrollees as a network pharmacy, these long-term care pharmacies will have to contract with both the facility and the Part D plans serving the region. In the proposed rule, we stated our goal of balancing convenient access to long-term care pharmacies with appropriate payment to long-term care pharmacies under the provisions of the MMA. We proposed two potential options to meet this goal and requested public comment.

Under one option, we would use the authority provided under section 1860D–4(b)(1)(C)(iv) of the Act to require prescription drug plans and MA-PD plans to approach some or all long-term care pharmacies in their service areas with at least the same terms available under their plans' standard pharmacy contracts. Alternatively, we would not require that plans contract with long-term care pharmacies and would, instead, strongly encourage PDP sponsors and MA organizations offering MA-PD plans to negotiate with and include long-term care pharmacies in their plans' pharmacy networks.

To the extent that we require Part D plans to solicit long-term care pharmacies in their service areas to join their networks, plans may be forced to negotiate preferential contracting terms and conditions (relative to the terms they would offer any other pharmacy willing to participate in its network) for long-term care pharmacy-specific packaging and services with a number of long-term care pharmacies in order to meet our requirement. If we require Part D plans to contract with any long-term care pharmacy in a service area, we cannot compel long-term care pharmacies to accept the plans' terms and conditions. Yet, given the additional risk associated with institutionalized beneficiaries, it may not be sufficient to rely on the market alone to ensure that Part D plans include a sufficient number of long-term care pharmacies in their networks. Absent a contracting mandate, Part D plans may view contracting with long-term care pharmacies—given the risk associated with institutionalized beneficiaries—as too risky.

If we do not require Part D Plans to contract with long term care pharmacies, some Part D enrollees in long-term care facilities may be served by plans whose networks do not include the long-term care pharmacy under contract with their long-term care facility. As a result, long-term care facilities could face an additional administrative burden-managing covered Part D drugs supplied by multiple sources (such as other long-term care pharmacies, and mail-order pharmacies). This scenario differs from current industry practices of most long-term care facilities. In the absence of direct collaboration between a plan and a Part D enrollee's long-term care pharmacy, it would be difficult for long-

term care facilities to meet Federal pharmacy management standards.

The second option (that is, do not require but encourage Part D plans to negotiate with and include long-term care pharmacies in their networks) would allow for the long-term care pharmacies to maintain their existing one-on-one relationships with long term care facilities. However, for beneficiaries whose Part D plan networks do not include the long-term care pharmacy under contract with their long-term care facility, accessing out-of-network pharmacies could remain a problem. However, it is important to note that the Final Rule provides a special enrollment period for PDP enrollment and disenrollment for beneficiaries entering in, living in, or leaving an institution. In addition, individuals enrolled in MA-PD plans have an unlimited open enrollment period for institutionalized individuals. In addition, we believe that relying on the pharmacy access standards in § 423.120(a) of our final rule will not assure sufficient access to long-term care pharmacies, since many of these pharmacies are not retail pharmacies and therefore would not count toward those requirements.

We believe it is essential to inject competition into the long-term care pharmacy market while preserving the relationships and levels of service that long-term care facilities now enjoy vis-à-vis their contracted long-term care pharmacies. As discussed in greater detail in the preamble for subpart C, our Final Rule will require that Part D plans offer standard contracting terms and conditions, including product performance and delivery and packaging requirements to all long-term care pharmacies in their service areas. We will also require Part D plans to demonstrate that they have contracts with a sufficient number of long-term care pharmacies to ensure ''convenient access'' to prescription drugs for institutionalized beneficiaries within the region.

To further assure ''convenient access'' to a pharmacy for long-term care residents, we will allow each long-term care facility to select one or more eligible network pharmacies to provide a plan's long-term care drug benefits to its Medicare residents. In order to minimize the number of pharmacy suppliers and maintain patient safety, long-term care facilities will likely select long-term care pharmacies meeting Part D standards that participate in the largest number of plan networks. To maintain convenient access and minimize out-of-pocket expenditures, plan beneficiaries would obtain Part D benefits from the eligible long-term care pharmacy selected by the facility. As noted previously, beneficiaries in long-term care facilities are eligible for special enrollment periods. In order to preserve their existing relationships with long-term care facilities, all long-term care pharmacies will likely have to accept the terms and conditions (and network pricing) offered by the Part D plan or lose the plan's entire book of business to another long-term care pharmacy. We believe that our long-term care pharmacy access rules will align incentives for competition while maintaining beneficiary access to the necessary services.

7. Coordination of Benefits and TrOOP

We also considered options regarding implementing provisions in the statute related to coordination of benefits between PDP and MA-PDs and SPAPs and other insurance coverage. Under Option 1, the PDPs and MA-PD plans would be solely responsible for tracking TrOOP costs. Under Option 2, we would be involved, hiring a TrOOP facilitation contractor to establish a single point of contact between primary and secondary payers.

The overwhelming majority of commenters supported the second option, with us having a role in ensuring coordination of benefits and facilitating accurate TrOOP tracking. Given this preference, we are prepared to assume a role in ensuring these important functions occur, and that they occur in as real-time as possible. While plans ultimately are responsible for tracking TrOOP consistent with the statute as discussed elsewhere in the preamble, we will facilitate the coordination of benefits and participate in other processes to help ensure that the plan are in a position to do so. We continue to fully develop the specifications of such assistance, and the operational details involved in bringing it about. In accordance with the statute, we will establish procedures before July 1, 2005 to ensure the effective coordination of benefits.

N. Conclusion

We estimate that about 39 million Medicare beneficiaries will receive drug coverage either through a Medicare Part D plan (that is, by enrolling in a PDP or a MA-PD) or through an employer or union sponsored retiree plan that is eligible for the Medicare retiree drug subsidy in CY 2006. By CY 2010, due to growth in the overall Medicare population, we estimate that about 42 million Medicare beneficiaries will be receiving drug coverage through a Medicare Part D plan or through an employer or union sponsored retiree plan that is eligible for the Medicare retiree drug subsidy. The net Federal budgetary effect of the Medicare prescription drug benefit and retiree drug subsidy is estimated to be about $293 billion during CY 2006–2010. Medicare Part D is estimated to generate about $7.9 billion in net savings for States over the five-year period from CY 2006–2010.

All Medicare beneficiaries will have access to a benefit that protects against catastrophic drug costs. On average, for non-low-income beneficiaries the benefit will cover half their costs, and for beneficiaries with very high drug costs it will cover substantially more. For low-income beneficiaries coverage is comprehensive, covering on average about 96 percent of their prescription drug costs.

Medicare beneficiaries who have no drug coverage today will now be able to obtain an affordable benefit that provides substantial assistance with prescription drug costs. Those beneficiaries with existing private coverage through retirement benefits and Medicare Advantage plans will receive the benefits of new Medicare subsidies to maintain and enhance their coverage. Beneficiaries with public coverage through Medicaid and State programs will have more secure (and potentially more generous) benefits because of the comprehensive low-income Medicare benefit. Beneficiaries who pay the full costs for limited Medigap drug coverage will now be able to obtain highly-subsidized, more generous coverage.

Overall, we anticipate that by giving beneficiaries access to affordable insurance coverage that helps them to pay for their outpatient prescription drugs—which have become a critical component in the delivery of comprehensive, quality health care services—the Medicare prescription drug benefit will help beneficiaries to lead healthier, more productive lives.

List of Subjects

42 CFR Part 400

Grant programs-health, Health facilities, Health maintenance organizations (HMO), Medicaid, Medicare Reporting and recordkeeping requirements

42 CFR Part 403

Grant programs-health, Health insurance, Hospitals

42 CFR Part 411

Kidney diseases, Medicare, Reporting and recordkeeping requirements

42 CFR Part 417

Administrative practice and procedure, Grant programs-health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs-health, Medicare, Reporting and recordkeeping requirements

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping

■ For reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amend 42 CFR chapter IV as follows:

PART–400 INTRODUCTION; DEFINITIONS

■ 1. The authority citation for part 400 continues to read as follows:

Authority: (Secs. 1102 and 1971 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and 44 U.S.C. Chapter 35.

Subpart B—Definitions

■ 2. Section 400.202 is amended by—

A. Adding in alphabetical order the definition of Medicare Part C.

B. Adding in alphabetical order the definition of Medicare Part D.

■ The additions read as follows:

§ 400.202 Definitions specific to Medicare.

* * * * *

Medicare Part C means the choice of Medicare benefits through Medicare Advantage plans authorized under Part C of the title XVIII of the Act.

Medicare Part D means the voluntary prescription drug benefit program authorized under Part D of title XVIII of the Act.

* * * * *

PART 403—SPECIAL PROGRAMS AND PROJECTS

■ 3. The authority citation for part 403 continues to read as follows:

Authority: 42 U.S.C. 1359b–3 and secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395 hh).

Subpart B—Medicare Supplemental Policies

■ 4. Section 403.205 is revised to read as follows:

§ 403.205 Medicare supplemental policy.

(a) Except as specified in paragraph (e) of this section, Medicare supplemental (or Medigap) policy means a health insurance policy or other health benefit plan that—

(1) A private entity offers to a Medicare beneficiary; and

(2) Is primarily designed, or is advertised, marketed, or otherwise purported to provide payment for expenses incurred for services and items that are not reimbursed under the Medicare program because of deductibles, coinsurance, or other limitations under Medicare.

(b) The term policy includes both policy form and policy as specified in paragraphs (b)(1) and (b)(2) of this section.

(1) *Policy form*. Policy form is the form of health insurance contract that is approved by and on file with the State agency for the regulation of insurance.

(2) *Policy*. Policy is the contract—

(i) Issued under the policy form; and

(ii) Held by the policy holder.

(c) If the policy otherwise meets the definition in this section, a Medicare supplemental policy includes-

(1) An individual policy;

(2) A group policy;

(3) A rider attached to an individual or group policy; or

(4) As of January 1, 2006, a stand-alone limited health benefit plan or policy that supplements Medicare benefits and is sold primarily to Medicare beneficiaries.

(d) Any rider attached to a Medicare supplemental policy becomes an integral part of the basic policy.

(e) Medicare supplemental policy does not include a Medicare Advantage plan, a Prescription Drug Plan under Part D, or any of the other types of health insurance policies or health benefit plans that are excluded from the definition of a Medicare supplemental policy in section 1882(g)(1) of the Act.

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 5. The authority citation for part 411 is revised to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395 w–101 through 1395w–152, and 1395hh).

Subpart J—Financial Relationships Between Physicians and Entities Furnishing Designated Health Services

■ 6. In § 411.351, the definition of ''Outpatient prescription drugs'' is revised to read as follows:

§ 411.351 Definitions.

* * * * *

Outpatient prescription drugs mean all drugs covered by Medicare Part B or Part D.

* * * * *

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLAN

■ 7. The authority citation for part 417 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e–5, and 300e–9), and 31 U.S.C. 9701.

■ 8. In § 417.440, revise paragraph (b)(2) to read as follows:

§ 417.440 Entitlement to health care services from an HMO or CMP.

* * * * *

(b) * * *

(2) *Supplemental services elected by an enrollee.* (i) Except as provided under paragraph (b)(2)(ii) of this section, a Medicare enrollee of an HMO or CMP may elect to pay for optional services that are offered by the HMO or CMP in addition to the covered Part A and Part B services.

(ii) An HMO or CMP may elect to provide qualified prescription drug coverage (as defined at § 423.104 of this chapter) as an optional supplemental service in accordance with the applicable requirements under part 423 of this chapter, including § 423.104(f)(4) of this chapter.

(iii) The HMO or CMP may not set health status standards for those enrollees whom it accepts for these optional supplemental services.

* * * * *

■ 9. In § 417.534, add paragraph (c) to read as follows:

§ 417.534 Allowable costs.

* * * * *

(c) *Medicare Part D program costs.* To the extent that an HMO or CMP provides qualified prescription drug coverage to enrollees under Part D, no costs related to the offering or provision of Part D benefits are reimbursed under this part. These costs are reimbursed solely under the applicable provisions of part 423 of this chapter.

■ 10. Part 423 is added as set forth below:

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

Subpart A—General Provisions

423.1 Basis and scope.
423.4 Definitions.
423.6 Cost-Sharing in beneficiary education and enrollment-related costs.

Subpart B—Eligibility and Enrollment

423.30 Eligibility and enrollment.
423.32 Enrollment process.
423.34 Enrollment of full-benefit dual eligibles
423.36 Disenrollment process

423.38 Enrollment periods.
423.40 Effective dates.
423.44 Involuntary disenrollment by PDP.
423.46 Late enrollment penalty.
423.48 Information about Part D.
423.50 Approval of marketing materials and enrollment forms.
423.56 Procedures to determine and document creditable status of prescription drug coverage.

Subpart C—Benefits and Beneficiary Protections

423.100 Definitions.
423.104 Requirements related to qualified prescription drug coverage.
423.112 Establishment of prescription drug plan service areas.
423.120 Access to covered Part D drugs.
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423.128 Dissemination of Part D plan information.
423.132 Public disclosure of pharmaceutical prices for equivalent drugs.
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Subpart D—Cost Control and Quality Improvement Requirements for Part D Plans

423.150 Scope.
423.153 Drug utilization management, quality assurance, and medication therapy management programs (MTMPs).
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Subpart E—[Reserved]

Subpart F—Submission of Bids and Monthly Beneficiary Premiums; Plan Approval

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Subpart H—[Reserved]

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423.415 Temporary waivers for entities seeking to offer a prescription drug plan in more than one State in a region
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423.440 Prohibition of State imposition of premium taxes; relation to State laws.

Subpart J—Coordination under Part D Plans with Other Prescription Drug Coverage

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Subpart K—Application Procedures and Contracts with PDP Sponsors

423.500 Scope and basis.
423.501 Definitions.
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423.503 Evaluation and determination procedures for applications to be determined qualified to act as a sponsor.
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423.505 Contract provisions.
423.506 Effective date and term of contract.
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Subpart L—Effect of Change of Ownership or Leasing of Facilities during Term of Contract

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Subpart N—Medicare Contract Determinations and Appeals

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423.904 Eligibility determinations for low-income subsidies.
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423.908 Phased-down State contribution to drug benefit costs assumed by Medicare.
423.910 Requirements.

Authority: Secs 1102, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh).

Subpart A—General Provisions

§ 423.1 Basis and scope.

(a) Basis. (1) This part is based on the indicated provisions of the following sections of the Social Security Act:

1860D–1. Eligibility, enrollment, and information.

1860D–2. Prescription drug benefits.

1860D–3. Access to a choice of qualified prescription drug coverage.

1860D–4. Beneficiary protections for qualified prescription drug coverage.

1860D–11. PDP regions; submission of bids; plan approval.

1860D–12. Requirements for and contracts with prescription drug plan (PDP) sponsors.

1860D–13. Premiums; late enrollment penalty.

1860D–14. Premium and cost-sharing subsidies for low-income individuals.

1860D–15. Subsidies for Part D eligible individuals for qualified prescription drug coverage.

1860D–16. Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

1860D–21. Application to Medicare Advantage program and related managed care programs.

1860D–22. Special rules for Employer-Sponsored Programs

1860D–23. State pharmaceutical assistance programs.

1860D–24. Coordination requirements for plans providing prescription drug coverage.

1860D–31. Medicare prescription drug discount card and transitional assistance program.

1860D–41. Definitions; treatment of references to provisions in Part C.

1860D–42. Miscellaneous provisions.

(2) The following specific sections of the Medicare Modernization Act also address the prescription drug benefit program:

Sec. 102 Medicare Advantage conforming amendments.

Sec. 103 Medicaid amendments.

Sec. 104 Medigap.

Sec. 109 Expanding the work of Medicare Quality Improvement Organizations to include Parts C and D.

(b) *Scope.* This part establishes standards for beneficiary eligibility, access, benefits, protections, and low-income subsidies in Part D, as well as establishes standards and sets forth requirements, limitations, procedures and payments for organizations participating in the Voluntary Medicare Prescription Drug Program.

§ 423.4 Definitions.

The following definitions apply to this part, unless the context indicates otherwise:

Actuarial equivalence means a state of equivalent value demonstrated through the use of generally accepted actuarial principles and in accordance with section 1860D–11(c) of the Act and with CMS actuarial guidelines.

Brand name drug means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(c)), including an application referred to in section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 USC 355(b)(2)).

Cost plan means a plan operated by a Health Maintenance Organization (HMO) or Competitive Medical Plan (CMP) in accordance with a cost-reimbursement contract under section 1876(h) of the Act.

Eligible fallback entity or fallback entity is defined at § 423.855.

Fallback prescription drug plan is defined at § 423.855.

Formulary means the entire list of Part D drugs covered by a Part D plan.

Full-benefit dual eligible individual has the meaning given the term at § 423.772, except where otherwise provided.

Generic drug means a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(j)) is approved.

Group health plan is defined at § 423.882.

Insurance risk means, for a participating pharmacy, risk of the type commonly assumed only by insurers licensed by a State and does not include payment variations designed to reflect performance-based measures of activities within the control of the pharmacy, such as formulary compliance and generic drug substitutions, nor does it include elements potentially in the control of the pharmacy (for example, labor costs or productivity).

MA stands for Medicare Advantage, which refers to the program authorized under Part C of title XVIII of the Act.

MA plan has the meaning given the term in § 422.2 of this chapter.

MA-PD plan means an MA plan that provides qualified prescription drug coverage.

Medicare prescription drug account means the account created within the Federal Supplementary Medical Insurance Trust Fund for purposes of Medicare Part D.

Monthly beneficiary premium means the amount calculated under § 423.286 for Part D plans other than fallback prescription drug plans, and § 423.867(a) for fallback prescription drug plans.

PACE Plan means a plan offered by a PACE organization.

PACE organization is defined in § 460.6 of this chapter.

Part D eligible individual means an individual who meets the requirements at § 423.30(a).

Part D plan (or Medicare Part D plan) means a prescription drug plan, an MA-PD plan, a PACE Plan offering qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage.

Part D plan sponsor or Part D sponsor refers to a PDP sponsor, MA

organization offering a MA-PD plan, a PACE organization offering a PACE plan including qualified prescription drug coverage, and a cost plan offering qualified prescription drug coverage.

PDP region means a prescription drug plan region as determined by CMS under § 423.112.

PDP sponsor means a nongovernmental entity that is certified under this part as meeting the requirements and standards of this part that apply to entities that offer prescription drug plans. This includes fallback entities.

Prescription drug plan or PDP means prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in § 423.272 and that is offered by a PDP sponsor that has a contract with CMS that meets the contract requirements under subpart K of this part. This includes fallback prescription drug plans.

Service area (Service area does not include facilities in which individuals are incarcerated.) means for —

(1) A prescription drug plan, an area established in § 423.112(a) within which access standards under § 423.120(a) are met;

(2) An MA-PD plan, an area that meets the definition of MA service area as described in § 422.2 of this chapter, and within which access standards under § 423.120(a) are met;

(3) A fallback prescription drug plan, the service area described in § 423.859(b);

(4) A PACE plan offering qualified prescription drug coverage, the service area described in § 460.22 of this chapter; and

(5) A cost plan offering qualified prescription drug coverage, the service area defined in § 417.1 of this chapter.

Subsidy-eligible individual means a full subsidy eligible individual (as defined at § 423.772) or other subsidy eligible individual (as defined at § 423.772).

Tiered cost-sharing means a process of grouping Part D drugs into different cost sharing levels within a Part D sponsor's formulary.

§ 423.6 Cost-sharing in beneficiary education and enrollment-related costs.

The requirements of section 1857(e)(2) of the Act and § 422.6 of this chapter with regard to the payment of fees established by CMS for cost sharing of enrollment related costs apply to PDP sponsors under Part D.

Subpart B—Eligibility and Enrollment.

§ 423.30 Eligibility and enrollment.

(a) *General rule.* (1) An individual is eligible for Part D if he or she:

(i) Is entitled to Medicare benefits under Part A or enrolled in Medicare Part B; and

(ii) Lives in the service area of a Part D plan, as defined under § 423.4.

(2) Except as provided in paragraphs (b), (c), and (d) of this section, an individual is eligible to enroll in a PDP if:

(i) The individual is eligible for Part D in accordance with paragraph (a)(1) of this section;

(ii) The individual resides in the PDP's service area; and

(iii) The individual is not enrolled in another Part D plan.

(3) Retroactive Part A or Part B determinations. Individuals who become entitled to Medicare Part A or enrolled in Medicare Part B for a retroactive effective date are Part D eligible as of the month in which a notice of entitlement Part A or enrollment in Part B is provided.

(b) *Coordination with MA plans.* A Part D eligible individual enrolled in a MA-PD plan must obtain qualified prescription drug coverage through that plan. MA enrollees are not eligible to enroll in a PDP, except as follows:

(1) A Part D eligible individual is eligible to enroll in a PDP if the individual is enrolled in a MA private fee-for-service plan (as defined in section 1859(b)(2) of the Act) that does not provide qualified prescription drug coverage; and

(2) A Part D eligible individual is eligible to enroll in a PDP if the individual is enrolled in a MSA plan (as defined in section 1859(b)(3) of the Act).

(c) *Enrollment in a PACE plan.* A Part D eligible individual enrolled in a PACE plan that offers qualified prescription drug coverage under this Part must obtain such coverage through that plan.

(d) *Enrollment in a cost-based HMO or CMP.* A Part D eligible individual enrolled in a cost-based HMO or CMP (as defined under part 417 of this chapter) that elects to receive qualified prescription drug coverage under such plan is ineligible to enroll in another Part D plan. A Part D eligible individual enrolled in a cost-based HMO or CMP offering qualified prescription drug coverage is eligible to enroll in a PDP if the individual does not elect to receive qualified prescription drug coverage under the cost-based HMO or CMP and otherwise meets the requirements of paragraph (a)(2) of this section.

§ 423.32 Enrollment process.

(a) *General rule.* A Part D eligible individual who wishes to enroll in a PDP may enroll during the enrollment periods specified in § 423.38, by filing the appropriate enrollment form with the PDP or through other mechanisms CMS determines are appropriate.

(b) *Enrollment form or CMS-approved enrollment mechanism.* The enrollment form or CMS-approved enrollment mechanism must comply with CMS instructions regarding content and format and must have been approved by CMS as described in § 423.50.

(i) The enrollment must be completed by the individual and include an acknowledgement by the beneficiary for disclosure and exchange of necessary information between the U.S. Department of Health and Human Services (or its designees) and the PDP sponsor. Individuals who assist beneficiaries in completing the enrollment, including authorized representatives, must indicate they have provided assistance and their relationship to the beneficiary.

(ii) Part D eligible individuals enrolling or enrolled in a Part D plan must provide information regarding reimbursement for Part D costs through other insurance, group health plan or other third-party payment arrangement, and consent to the release of the information provided by the individual on other insurance, group health plan or other third-party payment arrangements, as well as any other information on reimbursement of Part D costs collected or obtained from other sources, in a form and manner approved by CMS.

(c) *Timely process an individual's enrollment request.* A PDP sponsor must timely process an individual's enrollment request in accordance with CMS enrollment guidelines and enroll Part D eligible individuals who are eligible to enroll in its plan under § 423.30(a) and who elect to enroll or are enrolled in the plan during the periods specified in § 423.38.

(d) *Notice requirement.* The PDP sponsor must provide the individual with prompt notice of acceptance or denial of the individual's enrollment request, in a format and manner specified by CMS.

(e) *Maintenance of enrollment.* An individual who is

enrolled in a PDP remains enrolled in that PDP until one of the following occurs:

(i) The individual successfully enrolls in another PDP or MA-PD plan;

(ii) The individual voluntarily disenrolls from the PDP;

(iii) The individual is involuntary disenrolled from the PDP in accordance with § 423.44(b)(2);

(iv) The PDP is discontinued within the area in which the individual resides; or

(iv) The individual is enrolled after the initial enrollment, in accordance with § 423.34(c).

(f) *Enrollees of cost-based HMOs or CMPs and PACE.* Individuals enrolled in a cost-based HMO or CMP plan (as defined in part 417 of this chapter) or PACE (as defined in § 460.6 of this chapter) that offers prescription drug coverage under this part as of December 31, 2005, remain enrolled in that plan as of January 1, 2006, and receive Part D benefits offered by that plan until one of the conditions in § 423.32(e) are met.

§ 423.34 Enrollment of full-benefit dual eligible individuals.

(a) *General rule.* CMS must ensure the enrollment into Part D plans full-benefit dual eligible individuals who fail to enroll in a Part D plan.

(b) *Definition of full-benefit dual eligible individual.* For purposes of this section, a full-benefit dual eligible individual means an individual who is:

(1) Determined eligible by the State for—

(i) Medical assistance for full-benefits under title XIX of the Act for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act. ; or

(ii) Medical assistance under section 1902(a)(10)(C) of the Act (medically needy) or section 1902(f) of the Act (States that use more restrictive eligibility criteria than are used by the SSI program) for any month if the individual was eligible for medical assistance in any part of the month.

(2) Eligible for Part D in accordance with § 423.30(a).

(c) *Enrolling a full-benefit duel eligible individual.* Notwithstanding § 423.32(e), during the annual coordinated election period, CMS may enroll a full-benefit dual eligible individual in another PDP if CMS determines that the further enrollment is warranted.

(d) *Automatic enrollment rules.* (1) *General rule.* CMS must automatically enroll full-benefit dual eligible individuals who fail to enroll in a Part D plan into a PDP offering basic prescription drug coverage in the area where the individual resides that has a monthly beneficiary premium that does not exceed the low-income premium subsidy amount (as defined in § 423.780(b)). In the event that there is more than one PDP in an area with a monthly beneficiary premium at or below the low-income premium subsidy amount, individuals must be enrolled in such PDPs on a random basis.

(2) Individuals enrolled in an MSA plan or one of the following that does not offer a Part D benefit. Full-benefit dual eligible individuals enrolled in an MA Private Fee For Service (PFFS) plan or cost-based HMO or CMP that does not offer qualified prescription drug coverage or an MSA plan and who fail to enroll in a Part D plan must be automatically enrolled into a PDP plan as described in paragraph (d)(1) of this section.

(e) *Declining enrollment and disenrollment.* Nothing in this section prevents a full-benefit dual eligible individual from—

(1) Affirmatively declining enrollment in Part D; or

(2) Disenrolling from the Part D plan in which the individual is enrolled and electing to enroll in another Part D plan during the special enrollment period provided under § 423.38.

(f) *Effective date of enrollment.* Enrollment of full-benefit dual eligible individuals under this section must be effective as follows:

(1) January 1, 2006 for individuals who are full-benefit dual eligible individuals as of December 31, 2005;

(2) The first day of the month the individual is eligible for Part D under § 423.30(a)(1) for individuals who are Medicaid eligible and subsequently become newly eligible for Part D under § 423.30(a)(1) on or after January 1, 2006; and

(3) For individuals who are eligible for Part D under § 423.30(a)(1) and subsequently become newly eligible for Medicaid on or after January 1, 2006, enrollment is effective as soon as practicable after being identified as a newly full-benefit dual eligible individual, in a process to be determined by CMS.

§ 423.36 Disenrollment process.

(a) *General rule.* An individual may disenroll from a PDP during the periods specified in § 423.38 by enrolling in a different PDP plan, submitting a disenrollment request to the PDP in the form and manner prescribed by CMS, or filing the appropriate disenrollment request through other mechanisms as determined by CMS.

(b) *Responsibilities of the PDP sponsor.* The PDP sponsor must—

(1) Submit a disenrollment notice to CMS within timeframes CMS specifies;

(2) Provide the enrollee with a notice of disenrollment as CMS determines and approves; and

(3) File and retain disenrollment requests for the period specified in CMS instructions.

(c) *Retroactive disenrollment.* CMS may grant retroactive disenrollment in the following cases:

(1) There never was a legally valid enrollment; or

(2) A valid request for disenrollment was properly made but not processed or acted upon.

§ 423.38 Enrollment periods.

(a) *Initial enrollment period for Part D—Basic rule.* The initial enrollment period is the period during which an individual is first eligible to enroll in a Part D plan.

(1) *In 2005.* An individual who is first eligible to enroll in a Part D plan on or prior to January 31, 2006, has an initial enrollment period from November 15, 2005 through May 15, 2006.

(2) *February 2006.* An individual who is first eligible to enroll in a Part D plan in February 2006 has an initial enrollment period from November 15, 2005 through May 31, 2006.

(3) *March 2006 and subsequent months.* (i) Except as provided in paragraph (a)(3)(ii) and (a)(3)(iii) of this section, the initial enrollment period for an individual who is first eligible to enroll in a Part D plan on or after March 2006 is the same as the initial enrollment period for Medicare Part B under § 407.14 of this chapter.

(ii) Exception. For those individuals who are not eligible to enroll in a Part D plan at any time during their initial enrollment period for Medicare Part B, their initial enrollment period under this Part is the 3 months before becoming eligible for Part D, the month of eligibility, and the three months following eligibility to Part D.

(iii) An individual who becomes entitled to Medicare Part A or enrolled in Part B for a retroactive effective date has an initial enrollment period under this Part beginning with the month in which notification of the Medicare determination is received and ending on the last day of the third month following the month in which the notification was received.

(b) *Annual coordinated election period.* (1) *For 2006.* This period begins on November 15, 2005 and ends on May 15, 2006.

(2) *For 2007 and subsequent years.* For coverage beginning 2007 or any subsequent year, the annual coordinated election period is November 15th through December 31st for coverage beginning the following calendar year.

(c) *Special enrollment periods.* A Part D eligible individual may enroll in a PDP or disenroll from a PDP and enroll

in another PDP or MA-PD plan (as provided at § 422.62(b) of this chapter), as applicable, at any time under any of the following circumstances:

(1) The individual involuntarily loses creditable prescription drug coverage or such coverage is involuntarily reduced so that it is no longer creditable coverage as defined under § 423.56(a). Loss of credible prescription drug coverage due to failure to pay any required premium is not considered involuntary loss of the coverage.

(2) The individual was not adequately informed, as required by standards established by CMS under § 423.56, that he or she has lost his or her creditable prescription drug coverage, that he or she never had credible prescription drug coverage, or the coverage is involuntarily reduced so that it is no longer creditable prescription drug coverage.

(3) The individual's enrollment or non-enrollment in a Part D plan is unintentional, inadvertent, or erroneous because of the error, misrepresentation, or inaction of a Federal employee, or any person authorized by the Federal government to act on its behalf.

(4) The individual is a full-benefit dual eligible individual as defined under section 1935(c)(6) of the Act.

(5) The individual elects to disenroll from a MA-PD plan and elects coverage under Medicare Part A and Part B in accordance with § 422.62(c) of this chapter.

(6) The PDP sponsor's contract is terminated by the PDP sponsor or by CMS, as provided under § 423.507 through § 423.510, or the PDP plan is no longer offered in the area when the individual resides.

(7) The individual is no longer eligible for the PDP because of a change in his or her place of residence to a location outside of the PDP region(s) in which the PDP is offered.

(8) The individual demonstrates to CMS, in accordance with guidelines issued by CMS, that—

(i) The PDP sponsor offering the PDP substantially violated a material provision of its contract under this part in relation to the individual, including, but not limited to the following—

(A) Failure to provide the individual on a timely basis benefits available under the plan;

(B) Failure to provide benefits in accordance with applicable quality standards; or

(C) The PDP (or its agent, representative, or plan provider) materially misrepresented the plan's provisions in marketing the plan to the individual.

(ii) The individual meets other exceptional circumstances as CMS may provide.

§ 423.40 Effective dates.

(a) *Initial enrollment period.* (1) An enrollment made prior to the month of entitlement to Part A or enrollment in Part B is effective the first day of the month the individual is entitled to or enrolled in Part A or enrolled in Part B.

(2) Except as otherwise provided under § 423.34(f), an enrollment made during or after the month of entitlement to Part A or enrollment in Part B is effective the first day of the calendar month following the month in which the enrollment in Part D is made.

(3) If the individual is not eligible to enroll in Part D on the first day of the calendar month following the month in which the election to enroll in Part D is made, the enrollment in Part D is effective the first day of the month the individual is eligible for Part D.

(4) In no case is an enrollment in Part D effective before January 1, 2006 or before entitlement to Part A or enrollment Part B.

(b) *Annual coordinated election periods.* (1) *General rule.* Except as provided under paragraph (b)(2) of this section, for an enrollment or change of enrollment in Part D made during an annual coordinated election period as described in § 423.38(b), the coverage or change in coverage is effective as of the first day of the following calendar year.

(2) *Exception for January 1, 2006 through May 15, 2006.* Enrollment elections made during the annual coordinated election period between January 1, 2006 and May 15, 2006 are effective the first day of the calendar month following the month in which the enrollment in Part D is made.

(c) *Special enrollment periods.* For an enrollment or change of enrollment in Part D made during a special enrollment period specified in § 423.38(c), the effective date is determined by CMS, which, to the extent practicable, is determined in a manner consistent with protecting the continuity of health benefits coverage.

§ 423.44 Involuntary disenrollment by the PDP.

(a) *General rule.* Except as provided in paragraphs (b) through (d) of this section, a PDP sponsor may not—

(1) Involuntarily disenroll an individual from any PDP it offers; or

(2) Orally or in writing, or by any action or inaction, request or encourage an individual to disenroll.

(b) *Basis for disenrollment.* (1) *Optional involuntary disenrollment.* A PDP sponsor may disenroll an individual from a PDP it offers in any of the following circumstances:

(i) Any monthly premium is not paid on a timely basis, as specified under paragraph (d)(1) of this section; or

(ii) The individual has engaged in disruptive behavior, as specified under paragraph (d)(2) of this section.

(2) *Required involuntary disenrollment.* A PDP sponsor must disenroll an individual from a PDP it offers in any of the following circumstances:

(i) The individual no longer resides in the PDP's service area.

(ii) The individual loses eligibility for Part D.

(iii) Death of the individual.

(iv) The PDP sponsor's contract is terminated by CMS

or by a PDP or through mutual consent. The PDP sponsor must disenroll affected enrollees in accordance with the procedures for disenrollment set forth at § 423.507 through § 423.510.

(v) The individual materially misrepresents

information, as determined by CMS, to the PDP sponsor that the individual has or expects to receive reimbursement for third-party coverage.

(c) *Notice requirement.* (1) If the disenrollment is for any of the reasons specified in paragraphs (b)(1), (b)(2)(i), or (b)(2)(iv) of this section (that is, other than death or loss of Part D eligibility, the PDP sponsor must give the individual timely notice of the disenrollment with an explanation of why the PDP is planning to disenroll the individual.

(2) Notices for reasons specified in paragraphs (b)(1) through (b)(2)(i) and (b)(2)(iii) of this section must—

(i) Be provided to the individual before submission of the disenrollment notice to CMS; and

(ii) Include an explanation of the individual's right to file a grievance under the PDP's grievance procedures.

(d) *Process for disenrollment.* (1) *Monthly PDP premiums that are not paid timely.* A PDP sponsor may disenroll an individual from the PDP for failure to pay any monthly premium under the following circumstances:

(i) The PDP sponsor can demonstrate to CMS that it made reasonable efforts to collect the unpaid premium amount.

(ii) The PDP sponsor gives the enrollee notice of

disenrollment that meets the requirements set forth in paragraph (c) of this section.

(iii) Reenrollment in the PDP. If an individual is

disenrolled from the PDP for failure to pay monthly PDP premiums, the PDP

sponsor has the option to decline future enrollment by the individual in any of its PDPs until the individual has paid any past premiums due to the PDP sponsor.

(2) *Disruptive behavior.* (i) *Definition.* A PDP enrollee is disruptive if his or her behavior substantially impairs the plans ability to arrange or provide for services to the individual or other plan members. An individual cannot be considered disruptive if the behavior is related to the use of medical services or compliance (or noncompliance) with medical advice or treatment.

(ii) *Basis of disenrollment for disruptive behavior.* A PDP may disenroll an individual whose behavior is disruptive as defined in § 423.44(d)(2)(i) only after the PDP sponsor meets the requirements described in this section and after CMS has reviewed and approved the request.

(iii) *Effort to resolve the problem.* The PDP sponsor must make a serious effort to resolve the problems presented by the individual, including providing reasonable accommodations, as determined by CMS, for individuals with mental or cognitive conditions, including mental illness, Alzheimers disease, and developmental disabilities. In addition, the PDP sponsor must inform the individual of the right to use the PDP's grievance procedures. The individual has a right to submit any information or explanation that he or she may wish to the PDP.

(iv) *Documentation.* The PDP sponsor must document the enrollee's behavior, its own efforts to resolve any problems, as described in paragraph (d)(2)(iii) of this section, and any extenuating circumstances. The PDP sponsor may request from CMS the ability to decline future enrollment by the individual. The PDP sponsor must submit this information and any documentation received by the individual to CMS.

(v) *CMS review of the proposed disenrollment.* CMS reviews the information submitted by the PDP sponsor and any information submitted by the individual (which the PDP sponsor has submitted to CMS) to determine if the PDP sponsor has fulfilled the requirements to request disenrollment for disruptive behavior. If the PDP sponsor has fulfilled the necessary requirements, CMS reviews the information and make a decision to approve or deny the request for disenrollment, including conditions on future enrollment, within 20 working days. During the review, CMS ensures that staff with appropriate clinical or medical expertise reviews the case before making a final decision. The PDP sponsor is required to provide a reasonable accommodation, as determined by CMS, for the individual in exceptional circumstances that CMS deems necessary. CMS notifies the PDP sponsor within 5 working days after making its decision.

(vi) *Exception for fallback prescription drug plans.* CMS reserves the right to deny a request from a fallback prescription drug plan as defined in § 423.855 to disenroll an individual for disruptive behavior.

(vii) *Effective date of disenrollment.* If CMS permits a PDP to disenroll an individual for disruptive behavior, the termination is effective the first day of the calendar month after the month in which the PDP gives the individual written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(3) *Loss of Part D eligiblity.* If an individual is no longer eligible for Part D, CMS notifies the PDP that the disenrollment is effective the first day of the calendar month following the last month of Part D eligibility.

(4) *Death of the individual.* If the individual dies,

disenrollment is effective the first day of the calendar month following the month of death.

(5) *Individual no longer resides in the PDP service area—Basis for disenrollment.* The PDP must disenroll an individual if the individual notifies the PDP that he or she has permanently moved out of the PDP service area.

(6) *Plan termination.* (i) When a PDP contract terminates as provided in § 423.507 through § 423.510, the PDP sponsor must give each affected PDP enrollee notice of the effective date of the plan termination and a description of alternatives for obtaining prescription drug coverage under Part D, as specified by CMS.

(ii) The notice must be sent before the effective date of the plan termination or area reduction, and in the timeframes specified by CMS.

(7) *Misrepresentation of third-party reimbursement.*

(i) If CMS determines an individual has materially misrepresented information to the PDP sponsor as described under § 423.44(b)(2)(v), the termination is effective the first day of the calendar month after the month in which the PDP sponsor gives the individual written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(ii) *Reenrollment in the PDP.* Once an individual is disenrolled from the PDP for misrepresentation of third party reimbursement, the PDP sponsor has the option to decline future enrollment by the individual in any of its PDPs for a period of time CMS specifies.

§ 423.46 Late enrollment penalty.

(a) *General.* A Part D eligible individual must pay the late penalty described under § 423.286(d)(3) if there is a continuous period of 63 days or longer at any time after the end of the individual's initial enrollment period during which the individual meets all of the following conditions:

(1) The individual was eligible to enroll in a Part D plan;

(2) The individual was not covered under any

creditable prescription drug coverage; and

(3) The individual was not enrolled in a Part D plan.

(b) [Reserved]

§ 423.48 Information about Part D.

Each Part D plan must provide, on an annual basis, and in a format and using standard terminology that CMS may specify in guidance, the information necessary to enable CMS to provide to current and potential Part D eligible individuals the information they need to make informed decisions among the available choices for Part D coverage.

§ 423.50 Approval of marketing materials and enrollment forms.

(a) *CMS review of marketing materials.* (1) Except as provided in paragraph (a)(2) and (a)(3) of this section, a Part D plan may not distribute any marketing materials (as defined in paragraph (b) of this section), or enrollment forms, or make such materials or forms available to Part D eligible individuals, unless—

(i) At least 45 days (or 10 days if using certain types of marketing materials that use, without modification, proposed model language as specified by CMS) before the date of distribution, the Part D sponsor submits the material or form to CMS for review under the guidelines in paragraph (c) of this section; and

(ii) CMS does not disapprove the distribution of the material or form.

(2) If the Part D sponsor is deemed by CMS to meet certain performance requirements established by CMS, the Part D sponsor may distribute designated marketing materials 5 days following their submission to CMS.

(3) Prior to distribution, the Part D sponsor submits and certifies that for certain types of marketing materials it followed all applicable marketing guidelines, or for certain other marketing materials that it used, without modification, proposed model language as specified by CMS.

(b) *Definition of marketing materials.* Marketing materials include any

informational materials targeted to Medicare beneficiaries which—

(1) Promote the Part D plan.

(2) Inform Medicare beneficiaries that they may enroll, or remain enrolled in a Part D plan.

(3) Explain the benefits of enrollment in a Part D plan, or rules that apply to enrollees.

(4) Explain how Medicare services are covered under a Part D plan, including conditions that apply to such coverage.

(c) *Examples of marketing materials.* Examples of marketing materials include, but are not limited to—

(1) General audience materials such as general circulation brochures, newspapers, magazines, television, radio, billboards, yellow pages, or the Internet.

(2) Marketing representative materials such as scripts or outlines for telemarketing or other presentations.

(3) Presentation materials such as slides and charts.

(4) Promotional materials such as brochures or leaflets, including materials for circulation by third parties (for example, physicians or other providers).

(5) Membership communication materials such as membership rules, subscriber agreements, member handbooks and wallet card instructions to enrollees.

(6) Letters to members about contractual changes; changes in providers, premiums, benefits, plan procedures etc.

(7) Membership or claims processing activities.

(d) *Guidelines for CMS review.* In reviewing marketing material or enrollment forms under paragraph (a) of this section, CMS determines (unless otherwise specified in additional guidance) that the marketing materials—

(1) Provide, in a format (and, where appropriate, print size), and using standard terminology that may be specified by CMS, the following information to Medicare beneficiaries interested in enrolling—

(i) Adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges.

(ii) Adequate written explanation of the grievance and appeals process, including differences between the two, and when it is appropriate to use each.

(iii) Any other information necessary to enable beneficiaries to make an informed decision about enrollment.

(2) Notify the general public of its enrollment period in an appropriate manner, through appropriate media, throughout its service area.

(3) Include in the written materials notice that the Part D plan is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non-renewal may result in termination of the beneficiary's enrollment in the Part D plan. In addition, the Part D plan may reduce its service area and no longer be offered in the area where a beneficiary resides.

(4) Are not materially inaccurate or misleading or otherwise make material misrepresentations.

(5) For markets with a significant non-English speaking population, provide materials in the language of these individuals.

(e) *Deemed approval.* If CMS has not disapproved the distribution of a marketing materials or form submitted by a Part D sponsor for a Part D plan in a Part D region, CMS is deemed to not have disapproved the distribution of the marketing material or form in all other Part D regions covered by the Part D plan, with the exception of any portion of the material or form that is specific to the Part D region.

(f) *Standards for Part D marketing.* (1) In conducting

marketing activities, a Part D plan may not—

(i) Provide for cash or other remuneration as an inducement for enrollment or otherwise. This does not prohibit explanation of any legitimate benefits the beneficiary might obtain as an enrollee of the Part D plan.

(ii) Engage in any discriminatory activity such as, including targeted marketing to Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas.

(iii) Solicit Medicare beneficiaries door-to-door.

(iv) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the Part D sponsor or its Part D plan. The Part D organization may not claim that it is recommended or endorsed by CMS or Medicare or the Department of Health and Human Services or that CMS or Medicare or the Department of Health and Human Services recommends that the beneficiary enroll in the Part D plan. The Part D organization may explain that the organization is approved for participation in Medicare.

(v) Use providers, provider groups, or pharmacies to distribute printed information comparing the benefits of different Part D plans unless providers, provider groups or pharmacies accept and display materials from all Part D plan sponsors.

(vi) Accept Part D plan enrollment forms in provider offices, pharmacies or other places where health care is delivered.

(vii) Employ Part D plan names that suggest that a plan is not available to all Medicare beneficiaries.

(viii) Engage in any other marketing activity prohibited by CMS in its marketing guidance.

(2) In its marketing, the Part D organization must—

(i) Demonstrate to CMS's satisfaction that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over.

(ii) Establish and maintain a system for confirming that enrolled beneficiaries have in fact enrolled in the PDP and understand the rules applicable under the plan.

§ 423.56 Procedures to determine and document creditable status of prescription drug coverage.

(a) *Definition.* Creditable prescription drug coverage means any of the following types of coverage listed in paragraph (b) of this section only if the actuarial value of the coverage equals or exceeds the actuarial value of defined standard prescription drug coverage as demonstrated through the use of generally accepted actuarial principles and in accordance with CMS actuarial guidelines.

(b) *Types of coverage.* The following coverage is considered creditable if it meets the definition provided in paragraph (a) of this section:

(1) Prescription drug coverage under a PDP or MA-PD plan.

(2) Medicaid coverage under title XIX of the Act or under a waiver under section 1115 of the Act.

(3) Coverage under a group health plan, including the Federal employees health benefits program, and qualified retiree prescription drug plans as defined in section 1860D–22(a)(2) of the Act.

(4) Coverage under State Pharmaceutical

Assistance Programs (SPAP) as defined at § 423.454.

(5) Coverage of prescription drugs for veterans, survivors and dependents under chapter 17 of title 38, U.S.C.

(6) Coverage under a Medicare supplemental policy (Medigap policy) as defined at § 423.205.

(7) Military coverage under chapter 55 of title 10,

U.S.C., including TRICARE.

(8) Individual health insurance coverage (as defined in section 2791(b)(5) of the Public Health Service Act) that includes coverage for

outpatient prescription drugs and that does not meet the definition of an excepted benefit (as defined in section 2791(c) of the Public Health Service Act).

(9) Coverage provided by the medical care program of the Indian Health Service, Tribe or Tribal organization, or Urban Indian organization (I/T/U).

(10) Coverage provided by a PACE organization.

(11) Coverage provided by a cost-based HMO or CMP under part 417 of this chapter.

(12) Coverage provided through a State High-Risk Pool as defined under 42 CFR 146.113(a)(1)(vii).

(13) Other coverage as the Secretary may determine appropriate.

(c) *General disclosure requirements.* With the exception of PDPs and MA-PD plans under § 423.56(b)(1) and PACE or cost-based HMO or CMP that provide qualified prescription drug coverage under this Part, each entity that offers prescription drug coverage under any of the types described in § 423.56(b), must disclose to all Part D eligible individuals enrolled in or seeking to enroll in the coverage whether the coverage is creditable prescription drug coverage.

(d) *Disclosure of non-creditable coverage.* In the case that the coverage of the type described in § 423.56(b) is not creditable prescription drug, the disclosure described in paragraph (c) of this section to Part D eligible individuals must also include:

(1) The fact that the coverage is not creditable prescription drug coverage, as provided by CMS;

(2) That there are limitations on the periods in a year in which the individual may enroll in Part D plans; and

(3) That the individual may be subject to a late enrollment penalty, as described under § 423.46.

(e) *Disclosure to CMS.* With the exception of PDPs and MA-PD plans under § 423.56(b)(1) and PACE or cost-based HMO or CMP that provide qualified prescription drug coverage under this Part, all other entities listed under paragraph (b) of this section must disclose whether the coverage they provide is creditable prescription drug coverage to CMS in a form and manner described by CMS.

(f) *Notification content and timing requirements.* The disclosure notification to Part-D eligible individuals required in § 423.56(c) and (d) must be provided in a form and manner prescribed by CMS. Notices must be provided, at minimum, at the following times:

(1) Prior to an individual's initial enrollment period for Part D, as described under § 423.38(a);

(2) Prior to the effective date of enrollment in the prescription drug coverage and upon any change that affects whether the coverage is creditable prescription drug coverage;

(3) Prior to the commencement of the Annual Coordinated Election Period that begins on November 15 of each year, as defined in § 423.38(b); and

(4) Upon request by the individual.

(g) *When an individual is not adequately informed of coverage.* If an individual establishes to CMS that he or she was not adequately informed that his or her prescription drug coverage was not creditable prescription drug coverage, the individual may apply to CMS to have the coverage treated as creditable prescription drug coverage for purposes of applying the late penalty described in § 423.46.

Subpart C—Benefits and Beneficiary Protections.

§ 423.100 Definitions.

As used in this part, unless otherwise specified-

Actual cost means the negotiated price for a covered Part D drug when the drug is purchased at a network pharmacy, and the usual and customary price when a beneficiary purchases the drug at an out-of-network pharmacy consistent with § 423.124(a).

Affected enrollee means a Part D enrollee who is currently taking a covered Part D drug that is either being removed from a Part D plan's formulary, or whose preferred or tiered cost-sharing status is changing.

Alternative prescription drug coverage means coverage of Part D drugs, other than standard prescription drug coverage that meets the requirements of § 423.104(e). The term alternative prescription drug coverage must be either—

(1) *Basic alternative coverage* (alternative coverage that is actuarially equivalent to defined standard coverage, as determined through processes and methods established under § 423.265(d)(2)); or

(2) *Enhanced alternative coverage* (alternative coverage that meets the requirements of § 423.104(f)(1)).

Basic prescription drug coverage means coverage of Part D drugs that is either standard prescription drug coverage or basic alternative coverage.

Bioequivalent has the meaning given such term in section 505(j)(8) of the Food, Drug, and Cosmetic Act.

Contracted pharmacy network means pharmacies, including retail, mail-order, and institutional pharmacies, under contract with a Part D sponsor to provide covered Part D drugs at negotiated prices to Part D enrollees.

Covered Part D drug means a Part D drug that is included in a Part D plan's formulary, or treated as being included in a Part D plan's formulary as a result of a coverage determination or appeal under § 423.566, § 423.580, and § 423.600, § 423.610, § 423,620, and § 423.630, and obtained at a network pharmacy or an out-of-network pharmacy in accordance with § 423.124.

Dispensing fees means costs that-

(1) Are incurred at the point of sale and pay for costs in excess of the ingredient cost of a covered Part D drug each time a covered Part D drug is dispensed;

(2) Include only pharmacy costs associated with ensuring that possession of the appropriate covered Part D drug is transferred to a Part D enrollee. Pharmacy costs include, but are not limited to, any reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing quality assurance activities consistent with § 423.153(c)(2), measurement or mixing of the covered Part D drug, filling the container, physically providing the completed prescription to the Part D enrollee, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy. In the case of pharmacies owned and operated by a Part D plan itself, notwithstanding number (3) of this definition, dispensing fees are understood to be the equivalent of all reasonable costs discussed in the previous sentence, including the salaries of pharmacists and other pharmacy workers as well as the costs associated with maintaining the pharmacy facility and equipment necessary to operate the pharmacy; and

(3) Do not include administrative costs incurred by the Part D plan in the operation of the Part D benefit, including systems costs for interfacing with pharmacies.

Government-funded health program means any program established, maintained, or funded, in whole or in part, by the Government of the United States, by the government of any State or political subdivision of a State, or by any agency or instrumentality of any of the foregoing, which uses public funds, in whole or in part, to provide to, or pay on behalf of, an individual the cost of Part D drugs, including any of the following:

(1) An approved State child health plan under title XXI of the Act

providing benefits for child health assistance that meets the requirements of section 2103 of the Act;

(2) The Medicaid program under title XIX of the Act or a waiver under section 1115 of the Act;

(3) The veterans' health care program under Chapter 17 of title 38 of the United States Code;

(4) The Indian Health Service program under the Indian Health Care Improvement Act under Chapter 18 of title 25 of the United States Code; and

(5) Any other government-funded program whose principal activity is the direct provision of health care to persons.

Group health plan, for purposes of applying the definition of incurred costs in § 423.100, has the meaning given such term in 29 U.S.C. 1167(1), but specifically excludes a personal health savings vehicle, as used in this subpart.

Incurred costs means costs incurred by a Part D enrollee for covered Part D drugs —

(1) That are not paid for under the Part D plan as a result of application of any annual deductible or other cost-sharing rules for covered Part D drugs prior to the Part D enrollee satisfying the out-of-pocket threshold under § 423.104(d)(5)(iii), including any price differential for which the Part D enrollee is responsible under § 423.124(b); and

(2) That are paid for—

(i) By the Part D enrollee or on behalf of the Part D enrollee by another person, and the Part D enrollee (or person paying on behalf of the Part D enrollee) is not reimbursed through insurance or otherwise, a group health plan, or other third party payment arrangement, or the person paying on behalf of the Part D enrollee is not paying under insurance or otherwise, a group health plan, or third party payment arrangement;

(ii) Under a State Pharmaceutical Assistance Program (as defined in § 423.454); or

(iii) Under § 423.782.

Insurance means a health plan that provides, or pays the cost of Part D drugs, including, but not limited to, any of the following:

(1) Health insurance coverage (as defined in 42 U.S.C. 300gg–91(b)(1));

(2) A Medicare Advantage plan (as described under section 1851(a)(2) of the Act); and

(3) A PACE organization (as defined under sections 1894(a)(3) and 1934(a)(13) of the Act)

but specifically excluding a personal health savings vehicle.

I/T/U pharmacy means a pharmacy operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization, all of which are defined in section 4 of the Indian Health Care Improvement Act, 25 U.S.C. 1603.

Long-term care facility means a skilled nursing facility as defined in section 1819(a) of the Act, or a medical institution or nursing facility for which payment is made for an institutionalized individual under section 1902(q)(1)(B) of the Act.

Long-term care pharmacy means a pharmacy owned by or under contract with a long-term care facility to provide prescription drugs to the facility's residents.

Long-term care network pharmacy means a long-term care pharmacy that is a network pharmacy.

Negotiated prices means prices for covered Part D drugs that-

(1) Are available to beneficiaries at the point of sale at network pharmacies;

(2) Are reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remunerations that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale; and

(3) Includes any dispensing fees.

Network pharmacy means a licensed pharmacy that is under contract with a Part D sponsor to provide covered Part D drugs at negotiated prices to its Part D plan enrollees.

Non-preferred pharmacy means a network pharmacy that offers covered Part D drugs at negotiated prices to Part D enrollees at higher cost-sharing levels than apply at a preferred pharmacy.

Or otherwise means through a government-funded health program.

Out-of-network pharmacy means a licensed pharmacy that is not under contract with a Part D sponsor to provide negotiated prices to Part D plan enrollees.

Part D drug means—

(1) Unless excluded under number (2) of this definition, any of the following if used for a medically accepted indication (as defined in section 1927(k)(6) of the Act)—

(i) A drug that may be dispensed only upon a prescription and that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act;

(ii) A biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act;

(iii) Insulin described in section 1927(k)(2)(C) of the Act;

(iv) Medical supplies associated with the injection of insulin, including syringes, needles, alcohol swabs, and gauze; or

(v) A vaccine licensed under section 351 of the Public Health Service Act.

(2) Does not include—

(i) Drugs for which payment as so prescribed and dispensed or administered to an individual is available for that individual under Part A or Part B (even though a deductible may apply, or even though the individual is eligible for coverage under Part A or Part B but has declined to enroll in Part A or Part B); and

(ii) Drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under sections 1927(d)(2) or (d)(3) of the Act, except for smoking cessation agents.

Person means a natural person, corporation, mutual company, unincorporated association, partnership, joint venture, limited liability company, trust, estate, foundation, not-for-profit corporation, unincorporated organization, government or governmental subdivision or agency.

Personal health savings vehicle means a vehicle through which individuals can set aside their own funds to pay for health care expenses, including covered Part D drugs, on a tax-free basis including any of the following—

(1) A Health Savings Account (as defined under section 220 of the Internal Revenue Code);

(2) A Flexible Spending Account (as defined in section 106(c)(2) of the Internal Revenue Code) offered in conjunction with a cafeteria plan under section 125 of the Internal Revenue Code; and

(3) An Archer Medical Savings Account (as defined under section 223 of the Internal Revenue Code);

but specifically excluding a Health Reimbursement Arrangement (as described under Internal Revenue Ruling 2002–41 and Internal Revenue Notice 2002–45)

Plan allowance means the amount Part D plans that offer coverage other than defined standard coverage may use to determine their payment and Part D enrollees' cost-sharing for covered Part D drugs purchased at an out-of-network pharmacy or in a physician's office in accordance with the requirements of § 423.124(b).

Preferred drug means a covered Part D drug on a Part D plan's formulary for which beneficiary cost-sharing is lower than for a non-preferred drug in the plan's formulary.

Preferred pharmacy means a network pharmacy that offers covered Part D drugs at negotiated prices to Part D enrollees at lower levels of cost-sharing than apply at a non-preferred pharmacy under its pharmacy network contract with a Part D plan.

Qualified prescription drug coverage means any standard prescription drug coverage or alternative prescription drug coverage

Retail pharmacy means any licensed pharmacy that is not a mail order pharmacy from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy.

Required prescription drug coverage means coverage of Part D drugs under an MA-PD plan that consists of either—

(1) Basic prescription drug coverage; or

(2) Enhanced alternative coverage, provided there is no MA monthly supplemental beneficiary premium (as defined under section 1854(b)(2)(C) of the Act) applied under the plan due to the application of a credit against the premium of a rebate under § 422.266(b) of this chapter.

Rural means a five-digit ZIP code in which the population density is less than 1,000 individuals per square mile.

Standard prescription drug coverage means coverage of Part D drugs that meets the requirements of § 423.104(d). The term standard prescription drug coverage must be either—

(1) *Defined standard coverage* (standard prescription drug coverage that provides for cost-sharing as described in § 423.104(d)(2)(i)(A) and (d)(5)(i)); or

(2) *Actuarially equivalent standard coverage* (standard prescription drug coverage that provides for cost-sharing as described in § 423.104(d)(2)(i)(B) or cost-sharing as described in § 423.104(d)(5)(ii), or both).

Suburban means a five-digit ZIP code in which the population density is between 1,000 and 3,000 individuals per square mile.

Supplemental benefits means benefits that meet the requirements of § 423.104(f)(1)(ii).

Therapeutically equivalent refers to drugs that are rated as therapeutic equivalents under the Food and Drug Administration's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations.''

Third party payment arrangement means any contractual or similar arrangement under which a person has a legal obligation to pay for covered Part D drugs.

Urban means a five-digit ZIP code in which the population density is greater than 3,000 individuals per square mile.

Usual and customary (U&C) price means the price that an out-of-network pharmacy or a physician's office charges a customer who does not have any form of prescription drug coverage for a covered Part D drug.

§ 423.104 Requirements related to qualified prescription drug coverage.

(a) *General.* Subject to the conditions and limitations set forth in this subpart, a Part D sponsor must provide enrollees with coverage of the benefits described in paragraph (c) of this section. The benefits may be provided directly by the Part D sponsor or through arrangements with other entities. CMS reviews and approves these benefits consistent with § 423.272, and using written policy guidelines and requirements in this part and other CMS instructions.

(b) *Availability of prescription drug plans.* A PDP sponsor offering a prescription drug plan must offer that plan to all Part D eligible beneficiaries residing in the plan's service area.

(c) *Types of benefits.* The coverage provided by a Part D plan must be qualified prescription drug coverage.

(d) *Standard prescription drug coverage.* Standard prescription drug coverage includes access to negotiated prices as described under paragraph (g)(1) of this section, provides coverage of Part D drugs, and must meet the following requirements

(1) *Deductible.* An annual deductible equal to—

(i) *For 2006.* $250; or

(ii) *For years subsequent to 2006.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest multiple of $5.

(2) *Cost-sharing under the initial coverage limit.*

(i) *25 Percent coinsurance.* Coinsurance for actual costs for covered Part D drugs covered under the Part D plan above the annual deductible specified in paragraph (d)(1) of this section, and up to the initial coverage limit under paragraph (d)(3) of this section, that is—

(A) Equal to 25 percent of actual cost; or

(B) Actuarially equivalent to an average expected coinsurance of no more than 25 percent of actual cost, as determined through processes and methods established under § 423.265(c) and (d).

(ii) *Tiered copayments.* A Part D plan providing actuarially equivalent standard coverage may apply tiered copayments, provided that any tiered copayments are consistent with paragraph (d)(2)(i)(B) of this section and are approved as described in § 423.272(b)(2).

(3) *Initial coverage limit.* The initial coverage limit is equal to—

(i) *For 2006.* $2,250.

(ii) *For years subsequent to 2006.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest multiple of $10.

(4) *Cost-sharing between the initial coverage limit and the annual out-of-pocket threshold.* Coinsurance for costs for covered Part D drugs above the initial coverage limit described in paragraph (d)(3) of this section and annual out-of-pocket threshold described in paragraph (d)(5)(iii) of this section that is equal to 100 percent of actual costs.

(5) *Protection against high out-of-pocket expenditures.* (i) After an enrollee's incurred costs exceed the annual out-of-pocket threshold described in paragraph (d)(5)(iii) of this section, cost-sharing equal to the greater of—

(A) *Copayments.* (1) In 2006, $2 for a generic drug or preferred drug that is a multiple source drug (as defined in section 1927(k)(7)(A)(i) of the Act) and $5 for any other drug; and

(2) For subsequent years, the copayment amounts specified in this paragraph for the previous year increased by the annual percentage increase described in paragraph (d)(5)(iv) of this section and rounded to the nearest multiple of 5 cents; or

(B) *Coinsurance.* Coinsurance of five percent of actual cost.

(ii) As determined through processes and methods established under § 423.265(c) and (d), a Part D plan may substitute for cost-sharing under paragraph (d)(5)(i) of this section an amount that is actuarially equivalent to expected cost-sharing under paragraph (d)(5)(i) of this section.

(iii) *Annual out-of-pocket threshold.* For purposes of this part, the annual out-of-pocket threshold equals—

(A) *For 2006.* $3,600.

(B) *For years subsequent to 2006.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest multiple of $50.

(iv) *Annual percentage increase.* The annual percentage increase for each year is equal to the annual percentage increase in average per capita aggregate expenditures for Part D drugs in the United States for Part D eligible individuals and is based on data for the 12-month period ending in July of the previous year.

(e) *Alternative prescription drug coverage.* Alternative prescription drug coverage includes access to negotiated prices as described under paragraph (g)(1) of this section, provides coverage of Part D drugs, and must meet the following requirements—

(1) Has an annual deductible that does not exceed the annual deductible specified in paragraph (d)(1) of this section;

(2) Imposes cost-sharing no greater than that specified in paragraphs (d)(5)(i) or (ii) of this section once the annual out-of-pocket threshold described in paragraph (d)(5)(iii) of this section is met;

(3) Has a total or gross value that is at least equal to the total or gross value of defined standard coverage.

(4) Has an unsubsidized value that is at least equal to the unsubsidized value of standard prescription drug coverage. For purposes of this subparagraph, the unsubsidized value of coverage is the amount by which the actuarial value of the coverage exceeds the actuarial value of the subsidy payments under § 423.782 for the coverage; and

(5) Provides coverage that is designed, based upon an actuarially representative pattern of utilization, to provide for the payment, for costs incurred for covered Part D drugs, that are equal to the initial coverage limit under paragraph (d)(3) of this section, of an amount equal to at least the product of -

(i) The amount by which the initial coverage limit described in paragraph (d)(3) of this section for the year exceeds the deductible described in paragraph (d)(1) of this section; and

(ii) 100 percent minus the coinsurance percentage specified in paragraph (d)(2)(i) of this section.

(f) *Enhanced alternative coverage.* (1) Enhanced alternative coverage must meet the requirements under paragraph (e) of this section and includes-

(i) Basic prescription drug coverage, as defined in § 423.100; and

(ii) Supplemental benefits, which include-

(A) Coverage of drugs that are specifically excluded as Part D drugs under paragraph (2)(ii) of the definition of Part D drug under § 423.100; or

(B) Any of the following changes or combination of changes that increase the actuarial value of benefits under the Part D plan above the actuarial value of defined standard prescription drug coverage, as determined through processes and methods established under § 423.265—

(*1*) A reduction in the annual deductible described in paragraph (d)(1) of this section;

(*2*) A reduction in the cost-sharing described in paragraphs (d)(2) or (d)(5) of this section, or

(*3*) An increase in the initial coverage limit described in paragraph (d)(3) of this section.

(C) Both the coverage described in paragraph (f)(1)(ii)(A) of this section and the changes or combination of changes described in paragraph (f)(1)(ii)(B) of this section.

(2) *Restrictions on the offering of enhanced alternative coverage by PDP sponsors.* A PDP sponsor may not offer enhanced alternative coverage in a service area unless the PDP sponsor also offers a prescription drug plan in that service area that provides basic prescription drug coverage.

(3) *Restrictions on the offering of enhanced alternative coverage by MA organizations.* Effective January 1, 2006, an MA organization—

(i) May not offer an MA coordinated care plan, as defined in § 422.4 of this chapter, in an area unless either that plan (or another MA plan offered by the MA organization in that same service area) includes required prescription drug coverage; and

(ii) May not offer prescription drug coverage (other than that required under Parts A and B of title XVIII of the Act) to an enrollee—

(A) Under an MSA plan, as defined in § 422.2 of this chapter; or

(B) Under another MA plan (including a private fee-for-service plan, as defined in § 422.4 of this chapter) unless the drug coverage under the other plan provides qualified prescription drug coverage and unless the requirements of paragraph (f)(3)(i) of this section are met.

(4) *Restrictions on the offering of enhanced alternative coverage by cost plans.*

(i) A cost plan that elects to offer qualified prescription drug coverage may offer enhanced alternative coverage as an optional supplemental benefit under § 417.440(b)(2)(ii) of this chapter only if the cost plan also offers basic prescription drug coverage. An enrollee in the cost plan may, at the individual's option, elect whether to receive qualified prescription drug coverage under the cost plan and, if so, whether to receive basic prescription drug coverage or, if offered by the cost plan, enhanced alternative coverage.

(ii) A cost plan that offers qualified prescription drug coverage as an optional supplemental benefit under § 417.440(b)(2)(ii) of this chapter may not offer prescription drug coverage that is not qualified prescription drug coverage. A cost plan that does not offer qualified prescription drug coverage under § 417.440(b)(2)(ii) of this chapter may offer prescription drug coverage that is not qualified prescription drug coverage under § 417.440(b)(2)(i) of this chapter.

(g) *Negotiated prices.* (1) *Access to negotiated prices.* A Part D sponsor is required to provide its Part D enrollees with access to negotiated prices for covered Part D drugs included in its Part D plan's formulary. Negotiated prices must be provided even if no benefits are payable to the beneficiary for covered Part D drugs because of the application of any deductible or 100 percent coinsurance requirement following satisfaction of any initial coverage limit.

(2) *Interaction with Medicaid best price.* Prices negotiated with a pharmaceutical manufacturer, including discounts, subsidies, rebates, and other price concessions, for covered Part D drugs by the following entities are not taken into account in establishing Medicaid's best price under section 1927(c)(1)(C) of the Act—

(i) A Part D plan, as defined in § 423.4; or

(iii) A qualified retiree prescription drug plan (as defined in § 423.882) for Part D eligible individuals.

(3) *Disclosure.* (i) A Part D sponsor is required to disclose to CMS data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers, as well as data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers that are passed through to beneficiaries, via pharmacies and other dispensers, in the form of lower subsidies paid by CMS on behalf of low-income individuals described in § 423.782, or in the form of lower monthly beneficiary premiums or lower covered Part D drug prices at the point of sale.

(ii) Information on negotiated prices disclosed to CMS under paragraph (g)(3) of this section is protected under the confidentiality provisions applicable under section 1927(b)(3)(D) of the Act.

(4) *Audits.* CMS and the Office of the Inspector General may conduct periodic audits of the financial statements and all records of Part D sponsors pertaining to any qualified prescription drug coverage they may offer under a Part D plan.

§ 423.112 Establishment of prescription drug plan service areas.

(a) *Service area for prescription drug plans.* The service area for a prescription drug plan other than a fallback prescription drug plan consists of one or more PDP regions as established under paragraphs (b) and (c) of this section.

(b) *Establishment of PDP regions.* (1) *General.* CMS establishes PDP regions in a manner consistent with the requirements for the establishment of MA regions as described at § 422.455 of this chapter.

(2) *Relation to MA regions.* To the extent practicable, PDP regions are the same as MA regions. CMS may establish

PDP regions that are not the same as MA regions if CMS determines that the establishment of these regions improves access to prescription drug plan benefits for Part D eligible individuals.

(c) *Authority for territories.* CMS establishes a PDP region or regions for States that are not within the 50 States and the District of Columbia.

(d) *Revision of PDP regions.* CMS may revise the PDP regions established under paragraphs (b) and (c) of this section.

(e) *Regional or national plan.* Nothing in this section prevents a prescription drug plan from being offered in two or more PDP regions in their entirety or in all PDP regions in their entirety.

§ 423.120 Access to covered Part D drugs.

(a) *Assuring pharmacy access.* (1) *Standards for convenient access to network pharmacies.* Except as provided in paragraph (a)(7) of this section, a Part D plan must have a contracted pharmacy network consisting of retail pharmacies sufficient to ensure that for beneficiaries residing in each State in a prescription drug plan's service area(as defined in § 423.112(a)), each State in a regional MA-PD plan's service area (as defined in § 422.2 and § 422.455(a) of this chapter), a local MA-PD plan's service area (as defined in § 422.2 of this chapter), or a cost plan's geographic area (as defined in § 417.401 of this chapter), the following requirements are satisfied:

(i) At least 90 percent of Medicare beneficiaries, on average, in urban areas served by the Part D plan live within 2 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section;

(ii) At least 90 percent of Medicare beneficiaries, on average, in suburban areas served by the Part D plan live within 5 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section; and

(iii) At least 70 percent of Medicare beneficiaries, on average, in rural areas served by the Part D plan live within 15 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section.

(2) *Applicability of some non-retail pharmacies to standards for convenient access.* Part D plans may count I/T/U pharmacies and pharmacies operated by Federally Qualified Health Centers and Rural Health Centers toward the standards for convenient access to network pharmacies in paragraph (a)(1) of this section.

(3) *Access to non-retail pharmacies.* A Part D plan's contracted pharmacy network may be supplemented by non-retail pharmacies, including pharmacies offering home delivery via mail-order and institutional pharmacies, provided the requirements of paragraph (a)(1) of this section are met.

(4) *Access to home infusion pharmacies.* A Part D plan's contracted pharmacy network must provide adequate access to home infusion pharmacies consistent with written policy guidelines and other CMS instructions.

(5) *Access to long-term care pharmacies.* A Part D plan must offer standard contracting terms and conditions, including performance and service criteria for long-term care pharmacies that CMS specifies, to all long-term care pharmacies in its service area. The plan must provide convenient access to long-term care pharmacies consistent with written policy guidelines and other CMS instructions.

(6) *Access to I/T/U pharmacies.* A Part D plan must offer standard contracting terms and conditions conforming to the model addendum that CMS develops, to all I/T/U pharmacies in its service area. The plan must provide convenient access to I/T/U pharmacies consistent with written policy guidelines and other CMS instructions.

(7) *Waiver of pharmacy access requirements.* CMS waives the requirements under paragraph (a)(1) of this section in the case of—

(i) An MA-PD plan or cost plan (as described in section 1876(h) of the Act) that provides its enrollees with access to covered Part D drugs through pharmacies owned and operated by the MA organization or cost plan, provided the organization's or plan's pharmacy network meets the access standard set forth under § 422.112 of this chapter for an MA plan, or § 417.416(e) of this chapter for a cost plan.

(ii) An MA private fee-for-service plan described in § 422.4 of this chapter that—

(A) Offers qualified prescription drug coverage; and

(B) Provides plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies and without charging cost-sharing in excess of that described in § 423.104(d)(2) and (d)(5).

(8) *Pharmacy network contracting requirements.* In establishing its contracted pharmacy network, a Part D sponsor offering qualified prescription drug coverage—

(i) Must contract with any pharmacy that meets the Part D plan's standard terms and conditions; and

(ii) May not require a pharmacy to accept insurance risk as a condition of participation in the Part D plan's contracted pharmacy network.

(9) *Differential cost-sharing for preferred pharmacies.* A Part D sponsor offering a Part D plan that provides coverage other than defined standard coverage may reduce copayments or coinsurance for covered Part D drugs obtained through a preferred pharmacy relative to the copayments or coinsurance applicable for such drugs when obtained through a non-preferred pharmacy. Such differentials are taken into account in determining whether the requirements under § 423.104(d)(2) and (d)(5) and § 423.104(e) are met. Any cost-sharing reduction under this section must not increase CMS payments to the Part D plan under § 423.329.

(10) *Level playing field between mail-order and network pharmacies.* A Part D sponsor must permit its Part D plan enrollees to receive benefits, which may include a 90-day supply of covered Part D drugs, at any of its network pharmacies that are retail pharmacies. A Part D plan may require an enrollee obtaining a covered Part D drug at a network pharmacy that is a retail pharmacy to pay any higher cost-sharing applicable to that covered Part D drug at the network pharmacy that is a retail pharmacy instead of the cost-sharing applicable to that covered Part D drug at the network pharmacy that is a mail-order pharmacy.

(b) *Formulary requirements.* A Part D sponsor that uses a formulary under its qualified prescription drug coverage must meet the following requirements—

(1) *Development and revision by a pharmacy and therapeutic committee.* A Part D sponsor's formulary must be developed and reviewed by a pharmacy and therapeutic committee that—

(i) Includes a majority of members who are practicing physicians and/or practicing pharmacists.

(ii) Includes at least one practicing physician and at least one practicing pharmacist who are independent and free of conflict relative to-

(A) The Part D sponsor and Part D plan; and

(B) Pharmaceutical manufacturers.

(iii) Includes at least one practicing physician and one practicing pharmacist who are experts regarding care of elderly or disabled individuals.

(iv) Bases clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such

information as it determines appropriate.

(v) Considers whether the inclusion of a particular Part D drug in a formulary or formulary tier has any therapeutic advantages in terms of safety and efficacy.

(vi) Reviews policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, generic substitution, and therapeutic interchange.

(vii) Evaluates and analyzes treatment protocols and procedures related to the plan's formulary at least annually consistent with written policy guidelines and other CMS instructions.

(viii) Documents in writing its decisions regarding formulary development and revision and utilization management activities.

(ix) Meets other requirements consistent with written policy guidelines and other CMS instructions.

(2) Provision of an adequate benefit. A Part D plan's formulary must-

(i) Except as provided in paragraph (b)(2)(ii) of this section, include within each therapeutic category and class of Part D drugs at least two Part D drugs that are not therapeutically equivalent and bioequivalent, with different strengths and dosage forms available for each of those drugs, except that only one Part D drug must be included in a particular category or class of covered Part D drugs if the category or class includes only one Part D drug.

(ii) Include at least one Part D drug within a particular category or class of Part D drugs to the extent the Part D plan demonstrates, and CMS approves, the following-

(A) That only two drugs are available in that category or class of Part D drugs; and

(B) That one drug is clinically superior to the other drug in that category or class of Part D drugs.

(iii) Include adequate coverage of the types of drugs most commonly needed by Part D enrollees, as recognized in national treatment guidelines.

(iv) Be approved by CMS consistent with § 423.272(b)(2).

(3) *Transition Process.* A Part D sponsor must provide for an appropriate transition process for new enrollees prescribed Part D drugs that are not on its Part D plan's formulary. The transition policy must meet requirements consistent with written policy guidelines and other CMS instructions.

(4) *Limitation on changes in therapeutic classification.* Except as CMS may permit to account for new therapeutic uses and newly approved Part D drugs, a Part D sponsor may not change the therapeutic categories and classes in a formulary other than at the beginning of each plan year.

(5) *Provision of notice regarding formulary changes*

(i) Prior to removing a covered Part D drug from its Part D plan's formulary, or making any change in the preferred or tiered cost-sharing status of a covered Part D drug, a Part D sponsor must provide at least 60 days notice to CMS, State Pharmaceutical Assistance Programs (as defined in § 423.454), entities providing other prescription drug coverage (as described in § 423.464(f)(1)), authorized prescribers, network pharmacies, and pharmacists prior to the date such change becomes effective, and must either—

(A) Provide direct written notice to affected enrollees at least 60 days prior to the date the change becomes effective; or

(B) At the time an affected enrollee requests a refill of the Part D drug, provide such enrollee with a 60 day supply of the Part D drug under the same terms as previously allowed, and written notice of the formulary change.

(ii) The written notice must contain the following information-

(A) The name of the affected covered Part D drug;

(B) Whether the plan is removing the covered Part D drug from the formulary, or changing its preferred or tiered cost-sharing status;

(C) The reason why the plan is removing such covered Part D drug from the formulary, or changing its preferred or tiered cost-sharing status;

(D) Alternative drugs in the same therapeutic category or class or cost-sharing tier and expected cost-sharing for those drugs; and

(E) The means by which enrollees may obtain a coverage determination under § 423.566 or exception under § 423.578.

(iii) Part D sponsors may immediately remove from their Part D plan formularies covered Part D drugs deemed unsafe by the Food and Drug Administration or removed from the market by their manufacturer without meeting the requirements of paragraphs (b)(5)((i) of this section. Part D sponsors must provide retrospective notice of any such formulary changes to affected enrollees, CMS, State Pharmaceutical Assistance Programs (as defined in § 423.454), entities providing other prescription drug coverage (as described in § 423.464(f)(1)), authorized prescribers, network pharmacies, and pharmacists consistent with the requirements of paragraphs (b)(5)(ii)(A), (b)(5)(ii)(B), (b)(5)(ii)(C), and (b)(5)(ii)(D) of this section.

(6) *Limitation on formulary changes prior to the beginning of a contract year.* Except as provided under paragraph (b)(5)(iii) of this section, a Part D sponsor may not remove a covered Part D drug from its Part D plan's formulary, or make any change in the preferred or tiered cost-sharing status of a covered Part D drug on its plan's formulary, between the beginning of the annual coordinated election period described in § 423.38(b) and 60 days after the beginning of the contract year associated with that annual coordinated election period.

(7) *Provider and patient education.* A Part D sponsor must establish policies and procedures to educate and inform health care providers and enrollees concerning its formulary.

(c) *Use of standardized technology.* A Part D sponsor must issue and reissue, as necessary, a card or other type of technology that its enrollees may use to access negotiated prices for covered Part D drugs as provided under § 423.104(g). The card or other technology must comply with standards CMS establishes.

§ 423.124 Special rules for out-of-network access to covered Part D drugs at out-of-network pharmacies.

(a) *Out-of-network access to covered part D drugs.* (1) Out-of-network pharmacy access. A Part D sponsor must ensure that Part D enrollees have adequate access to covered Part D drugs dispensed at out-of-network pharmacies when the enrollees—

(i) Cannot reasonably be expected to obtain such drugs at a network pharmacy; and

(ii) Do not access covered Part D drugs at an out-of-network pharmacy on a routine basis.

(2) Physician's office access. A Part D sponsor must ensure that Part D enrollees have adequate access to vaccines and other covered Part D drugs appropriately dispensed and administered by a physician in a physician's office.

(b) *Financial responsibility for out-of-network access to covered Part D drugs.* A Part D sponsor that provides its Part D enrollees with coverage other than defined standard coverage may require its Part D enrollees accessing covered Part D drugs as provided in paragraph (a) of this section to assume financial responsibility for any differential between the out-of-network pharmacy's (or provider's) usual and customary price and the Part D sponsor's plan allowance, consistent with the requirements of § 423.104(d)(2)(i)(B) and § 423.104(e).

(c) *Limits on out-of-network access to covered Part D.* A Part D sponsor must establish reasonable rules to appropriately limit out-of-network access to covered Part D drugs.

§ 423.128 Dissemination of Part D plan information.

(a) *Detailed description.* A Part D sponsor must disclose the information specified in paragraph (b) of this section in the manner specified by CMS.—

(1) To each enrollee of a Part D plan offered by the Part D sponsor under this part;

(2) In a clear, accurate, and standardized form; and

(3) At the time of enrollment and at least annually thereafter.

(b) *Content of Part D plan description.* The Part D plan description must include the following information about the qualified prescription drug coverage offered under the Part D plan—

(1) *Service area.* The plan's service area.

(2) *Benefits.* The benefits offered under the plan, including-

(i) Applicable conditions and limitations.

(ii) Premiums.

(iii) Cost-sharing (such as copayments,

deductibles, and coinsurance), and cost-sharing for subsidy eligible individuals.

(iv) Any other conditions associated with receipt or use of benefits.

(3) *Cost-sharing.* A description of how a Part D eligible individual may obtain more information on cost-sharing requirements, including tiered or other copayment levels applicable to each drug (or class of drugs), in accordance with paragraph (d) of this section.

(4) *Formulary.* Information about the plan's formulary, including-

(i) A list of drugs included on the plan's formulary;

(ii) The manner in which the formulary (including any tiered formulary structure and utilization management procedures used) functions;

(iii) The process for obtaining an exception to a plan's formulary or tiered cost-sharing structure; and

(iv) A description of how a Part D eligible individual may obtain additional information on the formulary, in accordance with paragraph (d) of this section.

(5) *Access.* The number, mix, and distribution (addresses) of network pharmacies from which enrollees may reasonably be expected to obtain covered Part D drugs and how the Part D sponsor meets the requirements of § 423.120(a)(1) for access to covered Part D drugs;

(6) *Out-of-network coverage.* Provisions for access to covered Part D drugs at out-of-network pharmacies, consistent with § 423.124(a).

(7) *Grievance, coverage determinations, and appeals procedures.* All grievance, reconsideration, exceptions, coverage determination, reconsideration, exceptions, and appeal rights and procedures required under § 423.564 et. seq.

(8) *Quality assurance policies and procedures.* A description of the quality assurance policies and procedures required under § 423.153(c), as well as the medication therapy management program required under § 423.153(d).

(9) *Disenrollment rights and responsibilities.*

(10) Potential for contract termination. The fact that a Part D sponsor may terminate or refuse to renew its contract, or reduce the service area included in its contract, and the effect that any of those actions may have on individuals enrolled in a Part D plan;

(c) *Disclosure upon request of general coverage information, utilization, and grievance information.* Upon request of a Part D eligible individual, a Part D sponsor must provide the following information—

(1) *General coverage information.* General coverage information, including—

(i) *Enrollment procedures.* Information and instructions on how to exercise election options under this part;

(ii) *Rights.* A general description of procedural rights (including grievance, coverage determination, reconsideration, exceptions, and appeals procedures) under this part;

(iii) *Benefits.* (A) Covered services under the Part D plan;

(B) Any beneficiary cost-sharing, such as deductibles, coinsurance, and copayment amounts, including cost-sharing for subsidy eligible individuals;

(C) Any maximum limitations on out-of-pocket expenses;

(D) The extent to which an enrollee may obtain benefits from out-of-network providers;

(E) The types of pharmacies that participate in the Part D plan's network and the extent to which an enrollee may select among those pharmacies; and

(F) The Part D plan's out-of-network pharmacy access policy.

(iv) Premiums;

(v) The Part D plan's formulary;

(vi) The Part D plan's service area; and

(vii) Quality and performance indicators for benefits under the Part D plan as determined by CMS.

(2) The procedures the Part D sponsor uses to control utilization of services and expenditures.

(3) The number of disputes, and the disposition in the aggregate, in a manner and form described by CMS. These disputes are categorized as—

(i) Grievances according to § 423.564;

(ii) Appeals according to § 423.580 et. seq.; and

(iii) Exceptions according to § 423.578.

(4) Financial condition of the Part D sponsor, including the most recently audited information regarding, at a minimum, a description of the financial condition of the Part D sponsor offering the Part D plan.

(d) *Provision of specific information.* Each Part D sponsor offering qualified prescription drug coverage under a Part D plan must have mechanisms for providing specific information on a timely basis to current and prospective enrollees upon request. These mechanisms must include—

(1) A toll-free customer call center that—

(i) Is open during usual business hours.

(ii) Provides customer telephone service, including to pharmacists, in accordance with standard business practices.

(2) An Internet website that—

(i) Includes, at a minimum, the information required in paragraph (b) of this section.

(ii) Includes a current formulary for its Part D plan, updated at least monthly.

(iii) Provides current and prospective Part D enrollees with at least 60 days notice regarding the removal or change in the preferred or tiered cost-sharing status of a Part D drug on its Part D plan's formulary.

(3) The provision of information in writing, upon request.

(e) *Claims information.* A Part D sponsor must furnish directly to enrollees, in the manner specified by CMS and in a form easily understandable to such enrollees, a written explanation of benefits when prescription drug benefits are provided under qualified prescription drug coverage. The explanation of benefits must—

(1) List the item or service for which payment was made and the amount of the payment for each item or service.

(2) Include a notice of the individual's right to request an itemized statement.

(3) Include the cumulative, year-to-date total amount of benefits provided, in relation to—

(i) The deductible for the current year.

(ii) The initial coverage limit for the current year.

(iii) The annual out-of-pocket threshold for the current year.

(4) Include the cumulative, year-to-date total of incurred costs to the extent practicable.

(5) Include any applicable formulary changes for which Part D plans are required to provide notice as described in § 423.120(b)(5).

(6) Be provided during any month when prescription drug benefits are provided under this part, including for covered Part D spending between the initial coverage limit described in § 423.104(d)(3) and the out-of-pocket threshold described in § 423.104(d)(5)(iii).

§ 423.132 Public disclosure of pharmaceutical prices for equivalent drugs.

(a) *General requirements.* Except as provided under paragraph (c) of this section, a Part D sponsor must require a pharmacy that dispenses a covered Part D drug to inform an enrollee of any differential between the price of that drug and the price of the lowest priced generic version of that covered Part D drug that is therapeutically equivalent and bioequivalent and available at that pharmacy, unless the particular covered Part D drug being purchased is the lowest-priced therapeutically equivalent and bioequivalent version of that drug available at that pharmacy.

(b) *Timing of notice.* Subject to paragraph (d) of this section, the information under paragraph (a) of this section must be provided after the drug is dispensed at the point of sale or, in the case of dispensing by mail order, at the time of delivery of the drug.

(c) *Waiver of public disclosure requirement.* CMS waives the requirement under paragraph (a) of this section in the case of—

(1) An MA private fee-for-service plan described in § 422.4 of this chapter that—

(i) Offers qualified prescription drug coverage and provides plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies; and

(ii) Does not charge additional cost-sharing for access to covered Part D drugs dispensed at out-of-network pharmacies.

(2) An out-of-network pharmacy;

(3) An I/T/U network pharmacy;

(4) A network pharmacy that is located in any of the U.S. territories; and

(5) Other circumstances where CMS deems compliance with the requirements of paragraph (a) of this section to be impossible or impracticable.

(d) *Modification of timing requirement.* CMS modifies the requirement under paragraph (b) of this section as follows—

(1) For long-term care network pharmacies, which must meet the requirement in paragraph (a) of this section by providing such information to Part D plans for inclusion in the written explanations of benefits required under § 423.128(e); and

(2) Under other circumstances where CMS deems compliance with the requirement under paragraph (b) of this section to be impossible or impracticable.

§ 423.136 Privacy, confidentiality, and accuracy of enrollee records.

For any medical records or other health and enrollment information it maintains with respect to enrollees, a PDP sponsor must establish procedures to do the following—

(a) Abide by all Federal and State laws regarding confidentiality and disclosure of medical records, or other health and enrollment information. The PDP sponsor must safeguard the privacy of any information that identifies a particular enrollee and have procedures that specify—

(1) For what purposes the information is used within the organization; and

(2) To whom and for what purposes it discloses the information outside the organization.

(b) Ensure that medical information is released only in accordance with applicable Federal or State law, or under court orders or subpoenas.

(c) Maintain the records and information in an accurate and timely manner.

(d) Ensure timely access by enrollees to the records and information that pertain to them.

Subpart D—Cost Control and Quality Improvement Requirements for Part D Plans

§ 423.150 Scope.

This subpart sets forth the requirements relating to the following:

(a) Drug utilization management programs, quality assurance measures and systems, and medication therapy management programs (MTMP) for Part D sponsors.

(b) Consumer satisfaction surveys of Part D plans.

(c) Electronic prescription program.

(d) Quality improvement organization (QIO) activities.

(e) Compliance deemed on the basis of accreditation.

(f) Accreditation organizations.

(g) Procedures for the approval of accreditation

organizations as a basis for deeming compliance.

§ 423.153 Drug utilization management, quality assurance, and medication therapy management programs (MTMPs).

(a) *General rule.* Each Part D sponsor must have established, for covered Part D drugs furnished through a Part D plan, a drug utilization management program, quality assurance measures and systems, and an MTMP as described in paragraphs (b), (c), and (d) of this section.

(b) *Drug utilization management.* A Part D sponsor must have established a reasonable and appropriate drug utilization management program that—

(1) Includes incentives to reduce costs when medically appropriate;

(2) Maintains policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications; and

(3) Provides CMS with information concerning the procedures and performance of its drug utilization management program, according to guidelines specified by CMS.

(c) *Quality assurance.* A Part D sponsor must have established quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use that include all of the following—

(1) Representation that network providers are required to comply with minimum standards for pharmacy practice as established by the States.

(2) Concurrent drug utilization review systems, policies, and procedures designed to ensure that a review of the prescribed drug therapy is performed before each prescription is dispensed to an enrollee in a sponsor's Part D plan, typically at the point-of-sale or point of distribution. The review must include, but not be limited to,

(i) Screening for potential drug therapy problems due to therapeutic duplication.

(ii) Age/gender-related contraindications.

(iii) Over-utilization and under-utilization.

(iv) Drug-drug interactions.

(v) Incorrect drug dosage or duration of drug therapy. (vi) Drug-allergy contraindications.

(vii) Clinical abuse/misuse.

(3) Retrospective drug utilization review systems, policies, and procedures designed to ensure ongoing periodic examination of claims data and other records, through computerized drug claims processing and information retrieval systems, in order to identify patterns of inappropriate or medically unnecessary care among enrollees in a sponsor's Part D plan, or associated with specific drugs or groups of drugs.

(4) Internal medication error identification and reduction systems.

(5) Provision of information to CMS regarding its quality assurance measures and systems, according to guidelines specified by CMS.

(d) *Medication therapy management program (MTMP).*

(1) *General rule.* A Part D sponsor must have established a MTMP that—

(i) Is designed to ensure that covered Part D drugs prescribed to targeted beneficiaries described in paragraph (d)(2) of this section are appropriately used to optimize therapeutic outcomes through improved medication use;

(ii) Is designed to reduce the risk of adverse events, including adverse drug interactions, for targeted beneficiaries described in paragraph (d)(2) of this section;

(iii) May be furnished by a pharmacist or other qualified provider; and

(iv) May distinguish between services in ambulatory and institutional settings.

(2) *Targeted beneficiaries.* Targeted beneficiaries for the MTMP described in paragraph (d)(1) of this section are enrollees in the sponsor's Part D plan who —

(i) Have multiple chronic diseases;

(ii) Are taking multiple Part D drugs; and

(iii) Are likely to incur annual costs for covered Part D drugs that exceed a predetermined level as specified by the Secretary.

(3) *Use of experts.* The MTMP must be developed in cooperation with licensed and practicing pharmacists and physicians.

(4) *Coordination with care management plans.* The MTMP must be coordinated with any care management plan established for a targeted individual under a chronic care improvement program (CCIP) under section 1807 of the Act. A Part D sponsor must provide drug claims data to CCIPs for those beneficiaries that are enrolled in CCIPs in a manner specified by CMS.

(5) *Considerations in pharmacy fees.* An applicant to become a Part D sponsor must—

(i) Describe in its application how it takes into account the resources used and time required to implement the MTMP it chooses to adopt in establishing fees for pharmacists or others providing MTMP services for covered Part D drugs under a Part D plan.

(ii) Disclose to CMS upon request the amount of the management and dispensing fees and the portion paid for MTMP services to pharmacists and others upon request. Reports of these amounts are protected under the provisions of section 1927(b)(3)(D) of the Act.

(6) *MTMP reporting.* A Part D sponsor must provide CMS with information regarding the procedures and performance of its MTMP, according to guidelines specified by CMS.

(e) *Exception for private fee-for-service MA plans offering qualified prescription drug coverage.* In the case of an MA plan described in § 422.4(a)(3) of this chapter providing qualified prescription drug coverage, the requirements under paragraphs (b) and (d) of this section do not apply.

§ 423.156 Consumer satisfaction surveys.

CMS conducts consumer satisfaction surveys of Part D plan enrollees similar to the surveys it conducts of MA enrollees under § 422.152 (b) of this chapter.

§ 423.159 Electronic prescription program.

(a) [Reserved]

(b) [Reserved]

(c) *Requirement.* Part D sponsors must support and comply with electronic prescription standards relating to covered Part D drugs for Part D enrollees developed by CMS once final standards are effective.

(d) *Promotion of electronic prescribing by MA-PD plans.* An MA organization offering an MA-PD plan may provide for a separate or differential payment to a participating physician that prescribes covered Part D drugs in accordance with electronic prescription standards, including initial standards and final standards established by CMS once final standards are effective. Any payments must be in compliance with applicable Federal and State laws related to fraud and abuse, including the physician self-referral prohibition (section 1877 of the Act) and the Federal anti kickback statute (section 1128B(b) of the Act).

§ 423.162 Quality improvement organization activities.

(a) *General rule.* Quality improvement organizations (QIOs) are required to offer providers, practitioners, and Part D sponsors quality improvement assistance pertaining to health care services, including those related to prescription drug therapy, in accordance with contracts established with the Secretary.

(b) *Collection of information.* Information collected, acquired, or generated by a QIO in the performance of its responsibilities under this section is subject to the confidentiality provisions of part 480 of this chapter. Part D sponsors are required to provide specified information to CMS for distribution to the QIOs as well as directly to QIOs.

(c) *Applicability of QIO confidentiality provisions.* The provisions of part 480 of this chapter apply to Part D sponsors in the same manner as such provisions apply to institutions under part 480 of this chapter.

§ 423.165 Compliance deemed on the basis of accreditation.

(a) *General rule.* A Part D sponsor is deemed to meet all of the requirements of any of the areas described in paragraph (b) of this section if—

(1) The Part D sponsor is fully accredited (and periodically reaccredited) for the standards related to the applicable area under paragraph (b) of this section by a private, national accreditation organization approved by CMS; and

(2) The accreditation organization uses the standards approved by CMS for the purposes of assessing the Part D sponsor's compliance with Medicare requirements.

(b) Deemable requirements. The requirements relating to the following areas are deemable:

(1) Access to covered drugs, as provided under § 423.120 and § 423.124.

(2) Drug utilization management programs, quality assurance measures and systems, and MTMPs as provided under § 423.153.

(3) Privacy, confidentiality, and accuracy of enrollee records, as provided under § 423.136.

(4) A program to protect against fraud, waste and abuse, as described in § 423.504(b)(4)(vi)(H).

(c) *Effective date of deemed status.* The date the Part D sponsor is deemed to meet the applicable requirements is the later of the following:

(1) The date the accreditation organization is approved by CMS.

(2) The date the Part D sponsor is accredited by the accreditation organization.

(d) *Obligations of deemed Part D sponsors.* A Part D sponsor deemed to meet Medicare requirements must—

(1) Submit to surveys by CMS to validate its accreditation organization's accreditation process; and

(2) Authorize its accreditation organization to release to CMS a copy of its most recent accreditation survey, together with any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements).

(e) *Removal of deemed status.* CMS removes part or all of a Part D sponsor's deemed status for any of the following reasons—

(1) CMS determines, on the basis of its own investigation, that the Part D sponsor does not meet the Medicare requirements for which deemed status was granted.

(2) CMS withdraws its approval of the accreditation organization that accredited the Part D sponsor.

(3) The Part D sponsor fails to meet the requirements of paragraph (d) of this section.

(f) *Enforcement authority*. CMS retains the authority to initiate enforcement action against any Part D sponsor that it determines, on the basis of its own survey or the results of an accreditation survey, no longer meets the Medicare requirements for which deemed status was granted.

§ 423.168 Accreditation organizations.

(a) *Conditions for approval*. CMS may approve an accreditation organization for a given standard under this part if the organization meets the following conditions:

(1) In accrediting Part D sponsors and Part D plans, it applies and enforces standards that are at least as stringent as Medicare requirements for the standard or standards in question.

(2) It complies with the application and reapplication procedures set forth in § 423.171.

(3) It ensures that—

(i) Any individual associated with it, who is also associated with an entity it accredits, does not influence the accreditation decision concerning that entity;

(ii) The majority of the membership of its governing body is not comprised of managed care organizations, Part D sponsors or their representatives; and

(iii) Its governing body has a broad and balanced representation of interests and acts without bias.

(b) *Notice and comment*. (1) *Proposed notice*. CMS publishes a notice in the **Federal Register** whenever it is considering granting an accreditation organization's application for approval. The notice-

(i) Announces CMS's receipt of the accreditation organization's application for approval;

(ii) Describes the criteria CMS uses in evaluating the application; and

(iii) Provides at least a 30-day comment period.

(2) *Final notice*. (i) After reviewing public comments, CMS publishes a final notice in the **Federal Register** indicating whether it has granted the accreditation organization's request for approval.

(ii) If CMS grants the request, the final notice specifies the effective date and the term of the approval that may not exceed 6 years.

(c) *Ongoing responsibilities of an approved accreditation organization*. An accreditation organization approved by CMS must undertake the following activities on an ongoing basis:

(1) Provide to CMS in written form and on a monthly basis all of the following:

(i) Copies of all accreditation surveys, together with any survey-related information that CMS may require including corrective action plans and summaries of unmet CMS requirements).

(ii) Notice of all accreditation decisions.

(iii) Notice of all complaints related to deemed Part D sponsors.

(iv) Information about any Part D sponsor against which the accrediting organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the Part D sponsor's accreditation. (The accreditation organization must provide this information within 30 days of taking the remedial or adverse action.)

(v) Notice of any proposed changes in its accreditation standards or requirements or survey process. If the organization implements the changes before or without CMS approval, CMS may withdraw its approval of the accreditation organization.

(2) Within 30 days of a change in CMS requirements, submit the following to CMS—

(i) An acknowledgment of CMS's notification of the change.

(ii) A revised crosswalk reflecting the new requirements.

(iii) An explanation of how the accreditation organization plans to alter its standards to conform to CMS's new requirements, within the timeframes specified in the notification of change it receives from CMS.

(3) Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(4) Within 3 days of identifying, in an accredited Part D sponsor, a deficiency that as determined by the accrediting organization poses immediate jeopardy to the plan's enrollees or to the general public, give CMS written notice of the deficiency.

(5) Within 10 days of CMS's notice of withdrawal of approval, give written notice of the withdrawal to all accredited Part D sponsors.

(6) On an annual basis, provide summary data specified by CMS that relate to the past year's accreditation activities and trends.

(d) *Continuing Federal oversight of approved accreditation organizations*. Specific criteria and procedures for continuing oversight and for withdrawing approval of an accreditation organization include the following:

(1) *Equivalency review*. CMS compares the accreditation organization's standards and its application and enforcement of those standards to the comparable CMS requirements and processes when—

(i) CMS imposes new requirements or changes its survey process;

(ii) An accreditation organization proposes to adopt new standards or changes in its survey process; or

(iii) The term of an accreditation organization's approval expires.

(2) *Validation review*. CMS or its agent may conduct a survey of an accredited organization, examine the results of the accreditation organization's own survey, or attend the accreditation organization's survey to validate the organization's accreditation process. At the conclusion of the review, CMS identifies any accreditation programs for which validation survey results indicate—

(i) A 20 percent rate of disparity between certification by the accreditation organization and certification by CMS or its agent on standards that do not constitute immediate jeopardy to patient health and safety if unmet;

(ii) Any disparity between certification by the accreditation organization and certification by CMS or its agent on standards that constitute immediate jeopardy to patient health and safety if unmet; or

(iii) That, regardless of the rate of disparity, there are widespread or systematic problems in an organization's accreditation process that accreditation no longer provides assurance that the Medicare requirements are met or exceeded.

(3) *Onsite observation*. CMS may conduct an onsite inspection of the accreditation organization's operations and offices to verify the organization's representations and assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to the following:

(i) Reviewing documents.

(ii) Auditing meetings concerning the accreditation process.

(iii) Evaluating survey results or the accreditation status decision-making process.

(iv) Interviewing the organization's staff.

(4) *Notice of intent to withdraw approval*. If an equivalency review, validation review, onsite observation, or CMS's daily experience with the accreditation organization suggests that

the accreditation organization is not meeting the requirements of this subpart, CMS gives the organization written notice of its intent to withdraw approval.

(5) *Withdrawal of approval.* CMS may withdraw its approval of an accreditation organization at any time if CMS determines that—

(i) Deeming, based on accreditation, no longer guarantees that the Part D sponsor meets the requirements for offering qualified prescription drug coverage, and failure to meet those requirements may jeopardize the health or safety of Medicare enrollees and constitute a significant hazard to the public health; or

(ii) The accreditation organization has failed to meet its obligations under this section or under § 423.165 or § 423.171.

(6) *Reconsideration of withdrawal of approval.* An accreditation organization dissatisfied with a determination to withdraw CMS approval may request a reconsideration of that determination in accordance with subpart D of part 488 of this chapter.

§ 423.171 Procedures for approval of accreditation as a basis for deeming compliance.

(a) *Required information and materials.* A private, national accreditation organization applying for approval must furnish to CMS all of the following information and materials (when reapplying for approval, the organization need furnish only the particular information and materials requested by CMS):

(1) The types of Part D plans and sponsors that it reviews as part of its accreditation process.

(2) A detailed comparison of the organization's accreditation requirements and standards with the Medicare requirements (for example, a crosswalk).

(3) Detailed information about the organization's survey process, including the following:

(i) Frequency of surveys and whether surveys are announced or unannounced.

(ii) Copies of survey forms, and guidelines and instructions to surveyors.

(iii) Descriptions of—

(A) The survey review process and the accreditation status decision making process;

(B) The procedures used to notify accredited Part D sponsors of deficiencies and to monitor the correction of those deficiencies; and

(C) The procedures used to enforce compliance with accreditation requirements.

(4) Detailed information about the individuals who perform surveys for the accreditation organization, including the—

(i) Size and composition of accreditation survey teams for each type of plan reviewed as part of the accreditation process;

(ii) Education and experience requirements surveyors must meet;

(iii) Content and frequency of the in-service training provided to survey personnel;

(iv) Evaluation systems used to monitor the performance of individual surveyors and survey teams; and

(v) Organization's policies and practice for the participation, in surveys or in the accreditation decision process by an individual who is professionally or financially affiliated with the entity being surveyed.

(5) A description of the organization's data management and analysis system for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system.

(6) A description of the organization's procedures for responding to and investigating complaints against accredited organizations, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and ombudsmen programs.

(7) A description of the organization's policies and procedures for the withholding or removal of accreditation for failure to meet the accreditation organization's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements.

(8) A description of all types (for example, full or partial) and categories (for example, provisional, conditional, or temporary) of accreditation offered by the organization, the duration of each type and category of accreditation, and a statement identifying the types and categories that serve as a basis for accreditation if CMS approves the accreditation organization.

(9) A list of all currently accredited Part D sponsors and MA organizations and the type, category, and expiration date of the accreditation held by each of them.

(10) A list of all full and partial accreditation surveys scheduled to be performed by the accreditation organization as requested by CMS.

(11) The name and address of each person with an ownership or control interest in the accreditation organization.

(b) *Required supporting documentation.* A private, national accreditation organization applying or reapplying for approval also must submit the following supporting documentation—

(1) A written presentation that demonstrates its ability to furnish CMS with electronic data in CMS compatible format.

(2) A resource analysis that demonstrates that it's staffing, funding, and other resources are adequate to perform the required surveys and related activities.

(3) A statement acknowledging that, as a condition for approval, it agrees to comply with the ongoing responsibility requirements of § 423.168(c).

(c) *Additional information.* If CMS determines that it needs additional information for a determination to grant or deny the accreditation organization's request for approval, it notifies the organization and allows time for the organization to provide the additional information.

(d) *Onsite visit.* CMS may visit the accreditation organization's offices to verify representations made by the organization in its application, including, but not limited to, review of documents and interviews with the organization's staff.

(e) *Notice of determination.* CMS gives the accreditation organization, within 210 days of receipt of its completed application, a formal notice that—

(1) States whether the request for approval is granted or denied;

(2) Gives the rationale for any denial; and

(3) Describes the reconsideration and reapplication procedures.

(f) *Withdrawal.* An accreditation organization may withdraw its application for approval at any time before it receives the formal notice specified in paragraph (e) of this section.

(g) *Reconsideration of adverse determination.* An accreditation organization that has received a notice of denial of its request for approval may request a reconsideration in accordance with subpart D of part 488 of this chapter.

(h) *Request for approval following denial.* (1) Except as provided in paragraph (h)(2) of this section, an accreditation organization that has received notice of denial of its request for approval may submit a new request if it—

(i) Has revised its accreditation program to correct the deficiencies on which the denial was based.

(ii) Can demonstrate that the Part D sponsors that it has accredited meet or exceed applicable Medicare requirements; and

(iii) Resubmits the application in its entirety.

(2) An accreditation organization that has requested reconsideration of CMS' denial of its request for approval may not submit a new request until the reconsideration is administratively final.

Subpart E—[Reserved]

Subpart F—Submission of Bids and Monthly Beneficiary Premiums; Plan Approval

§ 423.251 Scope.

This section sets forth the requirements and limitations on submission, review, negotiation and approval of competitive bids for prescription drug plans and MA-PD plans; the calculation of the national average bid amount; and the determination of enrollee premiums.

§ 423.258 Definitions.

For the purposes of this subpart, the following definitions apply:

Full risk plan means a prescription drug plan that is not a limited risk plan or a fallback prescription drug plan.

Limited risk plan means a prescription drug plan that provides basic prescription drug coverage and for which the PDP sponsor includes a modification of risk level described in § 423.265(d) in its bid submitted for the plan. This term does not include a fallback prescription drug plan.

Standardized bid amount means, for a prescription drug plan that provides basic prescription drug coverage, the PDP approved bid; for a prescription drug plan that provides supplemental prescription drug coverage, the portion of the PDP approved bid that is attributable to basic prescription drug coverage; for a MA-PD plan, the portion of the accepted bid amount that is attributable to basic prescription drug coverage.

§ 423.265 Submission of bids and related information.

(a) *Eligibility for bidding.* An applicant may submit a bid to become a Part D plan sponsor.

(b) *Bid submission.* Not later than the first Monday in June, each potential Part D sponsor must submit bids and supplemental information described in this section for each Part D plan it intends to offer in the subsequent calendar year.

(c) *Basic rule for bid.* Each potential Part D sponsor must submit a bid and supplemental information in a format to be specified by CMS for each Part D plan it offers. Each bid must reflect a uniform benefit package, including premium (except as provided for the late enrollment penalty described in § 423.286(d)(3)) and all applicable cost sharing, for all individuals enrolled in the plan. Each bid must reflect the applicant's estimate of its average monthly revenue requirements to provide qualified prescription drug coverage (including any supplemental coverage) for a Part D eligible individual with a national average risk profile for the factors described in § 423.329(b)(1).

(1) *Included costs.* The bid includes costs (including administrative costs and return on investment/profit) for which the plan is responsible in providing basic and supplemental benefits.

(2) *Excluded costs.* The bid does not include costs associated with payments by the enrollee for deductible, co-payments, coinsurance, and liability above the plan allowance in the case of out-of-network claims, payments projected to be made by CMS for reinsurance, or any other costs for which the sponsor is not responsible.

(3) *Actuarial valuation.* The bid must be prepared in accordance with CMS actuarial guidelines based on generally accepted actuarial principles. A qualified actuary must certify the plan's actuarial valuation (which may be prepared by others under his or her direction or review), and must be a member of the American Academy of Actuaries to be deemed qualified. Applicants may use qualified outside actuaries to prepare their bids.

(d) *Specific requirements for bids.* The bid and supplemental information submission must include the following information:

(1) *Coverage.* A description of the coverage to be provided under the plan, including any supplemental coverage and the deductible and other cost sharing.

(2) *Actuarial value of bid components.* The applicant must provide the following information on bid components, as well as actuarial certification that the values are calculated according to CMS guidelines on actuarial valuation, including adjustment for the effect that providing alternative prescription drug coverage (rather than defined standard prescription drug coverage) has on drug utilization, if applicable.

(i) The actuarial value of the qualified prescription drug coverage to be offered under each plan for a Part D eligible individual with a national average risk profile for the factors described in § 423.329(b)(1) and the basis for the estimate.

(ii) The portion of the bid attributable to basic prescription drug coverage and the portion (if any) attributable to supplemental benefits.

(iii) The assumptions regarding reinsurance amounts payable under § 423.329(c) used in calculating the bid.

(iv) The assumptions regarding low-income cost-sharing payable under § 423.329(d) used in calculating the bid.

(v) The amount of administrative costs and return on investment or profit included in the bid.

(3) *Service area.* A description of the service area of the plan.

(4) *Level of risk assumed.* For a potential Part D sponsor, the level of risk assumed in the bid specified in paragraph (e) of this section.

(5) *Plan Average Risk Score.* An estimate of the plan's average prescription drug risk score (as established under § 423.329(b)) for all projected enrollees for purposes of risk adjusting any supplemental premium.

(6) *Additional information.* Additional information CMS requests to support bid amounts and facilitate negotiation.

(e) *Special rule for PDP sponsors.* Bids for all plans offered by a potential PDP sponsor in a region, but not those of potential MA organizations offering MA-PD plans, PACE organizations offering PACE plans including qualified prescription drug coverage, and cost-based HMOs or CMPs offering section 1876 cost plans including qualified prescription drug coverage, may include a uniform modification of the amount of risk assumed (based on a process to be specified) as described in one or more of the following paragraphs. Any such modification applies to all plans offered by the PDP sponsor in a PDP region.

(1) *Increase in Federal percentage assumed in initial risk corridor.* An equal percentage point increase in the percents applied for costs between the first and second threshold limits under § 423.336(b)(2)(i) and (b)(2)(ii)(A) and § 423.336 (b)(3)(i) and (b)(3)(ii)(A). This provision does not affect the application of a higher percentage for plans in 2006 or 2007 under § 423.336(b)(2)(iii).

(2) *Increase in Federal percentage assumed in second risk corridor.* An equal percentage point increase in the percents applied for costs above the second threshold upper limit or below the second threshold upper limit under paragraphs § 423.336(b)(2)(ii)(B) and (b)(3)(ii)(B).

(3) *Decrease in size of risk corridors.* A decrease in the size of the risk corridors by means of reductions in the threshold risk percentages specified in § 423.336(a)(2)(ii)(A) and/or (a)(2)(ii)(B).

(f) *Special rule for fallback prescription drug plans.* Fallback prescription drug plan bids are not

subject to the rules in this section. They must follow requirements specified in § 423.863.

§ 423.272 Review and negotiation of bid and approval of plans submitted by potential Part D sponsors.

(a) *Review and negotiation regarding information, terms and conditions.* CMS reviews the information filed under § 423.265(c) in order to conduct negotiations regarding the terms and conditions of the proposed bid and benefit plan. In addition to its general negotiating authority under section 1860D–11(d)(2)(A) of the Act, CMS has authority similar to that of the Director of the Office of Personnel Management for health benefit plans under Chapter 89 of title 5, U.S.C..

(b) *Approval of proposed plans.* CMS approves the Part D plan only if the plan and the Part D sponsor offering the plan comply with all applicable CMS Part D requirements, including those related to the provision of qualified prescription drug coverage and actuarial determinations.

(1) *Application of revenue requirements standard.* CMS approves a bid submitted under § 423.265 only if it determines that the portions of the bid attributable to basic and supplemental prescription drug coverage are supported by the actuarial bases provided and reasonably and equitably reflect the revenue requirements (as used for purposes of section 1302(8)(C) of the Public Health Service Act) for benefits provided under that plan, less the sum (determined on a monthly per capita basis) of the actuarial value of the reinsurance payments under section § 423.329(c).

(2) *Plan design.* (i) CMS does not approve a bid if it finds that the design of the plan and its benefits (including any formulary and tiered formulary structure) or its utilization management program are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan.

(ii) If the design of the categories and classes within a formulary is consistent with the model guidelines (if any) established by the United States Pharmacopeia, the formulary categories and classes alone will not be found to discourage enrollment.

(iii) A plan that adopts the categories and classes discussed in paragraph (b)(2)(ii) of this section may nevertheless be found to discourage enrollment because it excludes specific drugs from the formulary.

(c) *Limited risk plans.* (1) Application of limited risk plans. There is no limit on the number of full risk plans that CMS approves under paragraph (b) of this section. CMS approves a limited risk plan in accordance with paragraphs (c)(2) and (c)(3) of this section only if the access requirements under § 423.859 are not otherwise met for a PDP region.

(2) *Maximizing assumption of risk.* CMS gives priority in approval for those limited risk plans bearing the highest level of risk, but may take into account the level of the bids submitted by the plans and is not required to accept the limited risk plan with the highest assumption of risk. In no case does CMS approve a limited risk plan under which the modification of risk level provides for no (or a minimal) level of financial risk.

(3) *Limited exercise of authority.* CMS approves only the minimum number of limited risk plans needed to meet the access requirements.

(d) *Special rules for private fee-for-service (PFFS) plans that offer prescription drug coverage.* PFFS plans (as defined at § 422.4(a)(3)) choosing to offer prescription drug coverage are subject to all MA-PD bid submission and approval requirements applicable to MA-PD plans with the following exceptions:

(1) *Exemption from negotiations.* These plans are exempt from the review and negotiation process in paragraph (a) of this section, and are not held to the revenue requirements standard in paragraph (b)(1) of this section.

(2) *Requirements regarding negotiated prices.* These plans are not required to provide access to negotiated prices. However, if they do, they must meet the applicable requirements of § 423.104(h).

(3) *Modification of pharmacy access standard and disclosure requirement.* If the plan provides coverage for drugs purchased from all pharmacies, without charging additional cost sharing and without regard to whether they are network pharmacies, § 423.120(a) and § 423.132 requiring certain network access standards and the disclosure of the availability of lower cost bioequivalent generic drugs does not apply to the plan.

(e) *Special rule for plans with standardized bids sufficiently below the national average monthly bid to result in a negative premium.* In the event of a negative premium, as described in § 423.286(d)(1), CMS negotiates the incorporation of the negative premium amount into the bid as either a reduction in the supplemental premium if the Part D plan already submitted a bid with an enhanced alternative benefit, or CMS requires the addition of new enhanced alternative benefit of no less value than the amount of the negative premium.

§ 423.279 National average monthly bid amount.

(a) Bids included. For each year (beginning with 2006) CMS computes a national average monthly bid amount from approved bids submitted under § 423.265 in order to calculate the base beneficiary premium, as provided in § 423.286(c). The national average monthly bid amount is equal to a weighted average of the standardized bid amounts for each prescription drug plan (not including fallbacks) and for each MA-PD plan described in section 1851(a)(2)(A)(i) of the Act. The calculation does not include bids submitted by MSA plans, MA private fee-for-service plans, specialized MA plans for special needs individuals, PACE programs under section 1894, and contracts under reasonable cost reimbursement contracts under section 1876(h) of the Act.

(b) Calculation of weighted average. (1) The national average monthly bid amount is a weighted average, with the weight for each plan equal to a percentage with the numerator equal to the number of Part D eligible individuals enrolled in the plan in the reference month (as defined in § 422.258(c)(1) of this chapter) and the denominator equal to the total number of Part D eligible individuals enrolled in a reference month in all Part D plans except MSA plans, fallbacks, MA private fee-for-service plans, specialized MA plans for special needs individuals, PACE programs under section 1894, and contracts under reasonable cost reimbursement contracts under section 1876(h) of the Act.

(2) For purposes of calculating the monthly national average monthly bid amount for 2006, CMS assigns equal weighting to PDP sponsors (other than fallback entities) and assigns MA-PD plans included in the national average bid a weight based on prior enrollment (new MA-PD plans are assigned zero weight).

(c) Geographic adjustment. (1) Upon the development of an appropriate methodology, the national average monthly bid amount for Part D plans will be adjusted to take into account differences in prices for Part D drugs among PDP regions.

(2) CMS does not apply any geographic adjustments if CMS determines that price variations among PDP regions are negligible.

(3) CMS applies any geographic adjustment in a budget neutral manner so as to not result in a change in the aggregate payments that may have been made if CMS had not applied an adjustment.

(4) CMS does not apply any geographic adjustment until an appropriate methodology is developed.

§ 423.286 Rules regarding premiums.

(a) *General rule.* Except as provided in paragraphs (d)(3) and (e) of this section, and with regard to employer group waivers, the monthly beneficiary premium for a Part D plan in a PDP region is the same for all Part D eligible individuals enrolled in the plan. The monthly beneficiary premium for a Part D plan is the base beneficiary premium, as determined in paragraph (c) of this section, adjusted as described in paragraph (d) of this section for the difference between the bid and the national average monthly bid amount, any supplemental benefits and for any late enrollment penalties.

(b) *Beneficiary premium percentage.* The beneficiary premium percentage for any year is a fraction, the—

(1) Numerator of which is 25.5 percent; and

(2) Denominator of which is as follows:

(i) 100 percent minus the percentage established in paragraph (b)(2)(ii) of this section.

(ii) The percentage established in this paragraph equals:

(A) The total reinsurance payments that CMS estimates will be paid under § 423.329(c) for the coverage year; divided by—

(B) The amount estimated under paragraph (b)(2)(ii)(A) of this section for the year plus total payments that CMS estimates will be paid to Part D plans that are attributable to the standardized bid amount during the year, taking into account amounts paid by both CMS and enrollees.

(c) *Base beneficiary premium.* The base beneficiary premium for a Part D plan for a month is equal to the product of the—

(1) Beneficiary premium percentage as specified in paragraph (b) of this section; and

(2) National average monthly bid amount (computed under § 423.279) for the month.

(d) *Adjustments to base beneficiary premium.* The base beneficiary premium may be adjusted to reflect any of the following scenarios, if applicable.

(1) *Adjustment to reflect difference between bid and national average bid.* If the amount of the standardized bid amount exceeds the adjusted national average monthly bid amount, the monthly base beneficiary premium is increased by the amount of the excess. If the amount of the adjusted national average monthly bid amount exceeds the standardized bid amount, the monthly base beneficiary premium is decreased by the amount of the excess. If the amount of the adjusted national average monthly bid amount exceeds the standardized bid amount by an amount greater than the base beneficiary premium and results in a negative premium, then the beneficiary premium is zero, and the excess amount is applied to supplemental Part D benefits as described in § 423.272(e).

(2) *Increase for supplemental prescription drug benefits.* The portion of the Part D plan approved bid that is attributable to supplemental prescription drug benefits increases the beneficiary premium. This supplemental portion of the bid may be adjusted to reflect the average risk of enrollees in the plan as determined based on negotiations between CMS and the Part D sponsor offering the plan.

(3) *Increase for late enrollment penalty.* The base beneficiary premium for a Part D enrollee subject to the late enrollment penalty is increased by the amount of any late enrollment penalty.

(i) *Late enrollment penalty amount.* The penalty amount for a Part D eligible individual for a continuous period of eligibility (as provided in § 423.46(a)) is the greater of—

(A) An amount that CMS determines is actuarially sound for each uncovered month in the same continuous period of eligibility; or

(B) 1 percent of the base beneficiary premium (computed under paragraph (c) of this section) for each uncovered month in the period.

(ii) *Special rule for 2006 and 2007.* In 2006 and 2007 the penalty amount discussed in paragraph (d)(3) of this chapter equals the amount referenced in paragraph (d)(3)(i)(B) of this section unless another amount is specified in a separate issuance based on available analysis or other information as determined by the Secretary.

(e) *Decrease in monthly beneficiary premium for low-income assistance.* The monthly beneficiary premium may be eliminated or decreased in the case of a subsidy-eligible individual under § 423.780.

(f) *Special rules for fallback prescription drug plans.* The monthly beneficiary premium charged under a fallback prescription drug plan is calculated under § 423.867(a) and not under this section, except that enrollees in fallback prescription drug plans are subject to late enrollment penalties under paragraph (d)(3) of this section and fallback prescription drug plan premiums are reduced or eliminated in the case of a subsidy-eligible individual, as described in paragraph (e) of this section.

§ 423.293 Collection of monthly beneficiary premium.

(a) *General rule.* Part D sponsors must charge enrollees a consolidated monthly Part D premium equal to the sum of the Part D monthly premium for basic prescription drug coverage (if any) and the premium for supplemental coverage (if any and if the beneficiary has enrolled in such supplemental coverage). Part D sponsors must also permit each enrollee, at the enrollee's option, to make payment of premiums (if any) under this part to the sponsor using any of the methods listed in § 422.262(f) of this chapter.

(b) *Crediting of late enrollment penalty.* CMS estimates and specifies the portion of the late enrollment penalty imposed under § 423.286(d)(3) attributable to increased actuarial costs assumed by the Part D sponsor and not taken into account through risk adjustment provided under § 423.329(b)(1) or through reinsurance payments under § 423.329(c)) as a result of the late enrollment.

(c) *Collection of late enrollment penalty.* (1) *Collection through withholding.* In the case of a late enrollment penalty that is collected by the government from a Part D eligible individual in the manner described in § 422.262(f)(1) of this chapter, CMS pays only the portion of the late enrollment penalty described in paragraph (b) of this section to the Part D sponsor offering the Part D plan in which the individual is enrolled.

(2) *Collection by plan.* In the case of a late enrollment penalty collected from a Part D eligible individual in a manner other than the manner described in § 422.262(f)(1) of this chapter, CMS reduces payments otherwise made to the Part D plan by an amount equal to the portion of the late enrollment penalty.

(d) *Special rule for fallback plans.* This section does not apply to fallback prescription drug plans. The fallback plans follow the requirements set forth in § 423.867(b).

Subpart G—Payments to Part D Plan Sponsors For Qualified Prescription Drug Coverage

§ 423.301 Scope.

This subpart sets forth rules for the calculation and payment of CMS direct and reinsurance subsidies for Part D plans; the application of risk corridors and risk-sharing adjustments to payments; and retroactive adjustments and reconciliations to actual enrollment and interim payments. This subpart does not apply to fallback entities or fallback prescription drug plans.

§ 423.308 Definitions and terminology.

For the purposes of this subpart, the following definitions apply-

Actually paid means that the costs must be actually incurred by the Part D sponsor and must be net of any direct or indirect remuneration (including discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers) from any source (including manufacturers, pharmacies, enrollees, or any other person) that would serve to decrease the costs incurred by the Part D sponsor for the drug.

Allowable reinsurance costs means the subset of gross covered prescription drug costs actually paid that are attributable to basic prescription drug coverage for covered Part D drugs only and that are actually paid by the Part D sponsor or by (or on behalf of) an enrollee under the Part D plan. The costs for any Part D plan offering enhanced alternative coverage must be adjusted not only to exclude any costs attributable to benefits beyond basic prescription drug coverage, but also to exclude any costs determined to be attributable to increased utilization over the standard prescription drug coverage as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation.

Allowable risk corridor costs means the subset of actually paid costs for covered Part D drugs (not including administrative costs, but including dispensing fees) that are attributable to basic prescription drug coverage only and that are incurred and actually paid by the Part D sponsor under the Part D plan. Costs must be based upon imposition of the maximum amount of copayments permitted under § 423.782. The costs for any Part D plan offering enhanced alternative coverage must be adjusted not only to exclude any costs attributable to benefits beyond basic prescription drug coverage, but also to exclude any prescription drug coverage costs determined to be attributable to increased utilization over standard prescription drug coverage as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation.

Coverage year means a calendar year in which covered Part D drugs are dispensed if the claim for those drugs (and payment on the claim) is made not later than 3 months after the end of the year

Gross covered prescription drug costs means those actually paid costs incurred under a Part D plan, excluding administrative costs, but including dispensing fees during the coverage year and costs relating to the deductible. They equal-

(1) All reimbursement paid by a Part D sponsor to a pharmacy (or other intermediary) or to indemnify an enrollee when the reimbursement is associated with an enrollee obtaining drugs under the Part D plan; plus

(2) All amounts paid under the Part D plan by or on behalf of an enrollee (such as the deductible, coinsurance, cost-sharing, or amounts between the initial coverage limit and the out-of-pocket threshold) in order to obtain drugs covered under the Part D plan. These costs are determined regardless of whether the coverage under the plan exceeds basic prescription drug coverage.

Target amount for any Part D plan equals the total amount of payments (from both CMS and by or on behalf of enrollees) to that plan for the coverage year for all standardized bid amounts as risk adjusted under § 423.329(b)(1), less the administrative expenses (including return on investment) assumed in the standardized bids.

§ 423.315 General payment provisions.

(a) *Source of payments.* CMS payments under this section are made from the Medicare Prescription Drug Account.

(b) *Monthly payments.* CMS provides a direct subsidy in the form of advance monthly payments equal to the Part D plan's standardized bid, risk adjusted for health status as provided in § 423.329(b), minus the monthly beneficiary premium as determined in § 423.286.

(c) *Reinsurance subsidies.* CMS provides reinsurance subsidy payments described in § 423.329(c) on a monthly basis during a year based on either estimated or incurred allowable reinsurance costs as provided under § 423.329(c)(2)(i), and final reconciliation to actual allowable reinsurance costs as provided in § 423.343(c).

(d) *Low-income subsidies.* CMS makes payments for premium and cost sharing subsidies, including additional coverage above the initial coverage limit, on behalf of certain subsidy-eligible individuals as provided in § 423.780 and § 423.782. CMS provides low-income cost-sharing subsidy payments described in § 423.782 through interim payments of amounts as provided under § 423.329(d)(2)(i) and reconciliation to actual allowable reinsurance costs as provided in § 423.343(d).

(e) *Risk-sharing arrangements.* CMS may issue lump-sum payments or adjust monthly payments in the following payment year based on the relationship of the Part D plan's adjusted allowable risk corridor costs to predetermined risk corridor thresholds in the coverage year as provided in § 423.336.

(f) *Retroactive adjustments and reconciliations.* CMS reconciles payment year disbursements with updated enrollment and health status data, actual low-income cost-sharing costs and actual allowable reinsurance costs as provided in § 423.343.

(g) *Special rules for private fee-for-service plans.*

(1) *Application of reinsurance.* For private fee-for-service plans (as defined by § 422.4(a)(3) of this chapter) offering qualified prescription drug coverage, CMS determines the amount of reinsurance payments as provided under § 423.329(c)(3).

(2) *Exemption from risk corridor provisions.* The provisions of § 423.336 regarding risk sharing do not apply.

§ 423.322 Requirement for disclosure of information.

(a) *Payment conditional upon provision of information.* Payments to a Part D sponsor are conditioned upon provision of information to CMS that is necessary to carry out this subpart, or as required by law.

(b) *Restriction on use of information.* Officers, employees and contractors of the Department of Health and Human Services may use the information disclosed or obtained in accordance with the provisions of this subpart only for the purposes of, and to the extent necessary in, carrying out this subpart including, but not limited to, determination of payments and payment-related oversight and program integrity activities. This restriction does not limit OIG's authority to fulfill the Inspector General's responsibilities in accordance with applicable Federal law.

§ 423.329 Determination of payments.

(a) *Subsidy payments.* (1) *Direct subsidy.* CMS makes a direct subsidy payment for each Part D eligible beneficiary enrolled in a Part D plan for a month equal to the amount of the plan's approved standardized bid, adjusted for health status (as determined under § 423.329(b)(1)), and reduced by the base beneficiary premium for the plan (as determined under § 423.286(c) and adjusted in § 423.286(d)(1)). The direct subsidy payment may be increased by the excess amount of a

negative premium as described in § 423.286(d)(1), if applicable.

(2) *Subsidy through reinsurance.* CMS makes reinsurance subsidy payments as provided under paragraph (c) of this section.

(3) *Low-income cost-sharing subsidy.* CMS makes low-income cost-sharing subsidy payments as provided under paragraph (d) of this section.

(b) *Health status risk adjustment.* (1) *Establishment of risk factors.* CMS establishes an appropriate methodology for adjusting the standardized bid amount to take into account variation in costs for basic prescription drug coverage among Part D plans based on the differences in actuarial risk of different enrollees being served. Any risk adjustment is designed in a manner so as to be budget neutral in the aggregate to the risk of the Part D eligible individuals who enroll in Part D plans.

(2) *Considerations.* In establishing the methodology under paragraph (b)(1) of this section, CMS takes into account the similar methodologies used under § 422.308(c) of this chapter to adjust payments to MA organizations for benefits under the original Medicare fee-for-service program option.

(3) *Data collection.* In order to carry out this paragraph, CMS requires—

(i) PDP sponsors to submit data regarding drug claims that can be linked at the individual level to Part A and Part B data in a form and manner similar to the process provided under § 422.310 of this chapter and other information as CMS determines necessary; and

(ii) MA organizations that offer MA-PD plans to submit data regarding drug claims that can be linked at the individual level to other data that the organizations are required to submit to CMS in a form and manner similar to the process provided under § 422.310 of this chapter and other information as CMS determines necessary.

(4) *Publication.* At the time of publication of risk adjustment factors under § 422.312(a)(1)(ii) of this chapter, CMS publishes the risk adjusters established under this paragraph of this section for the upcoming calendar year.

(c) *Reinsurance payment amount.* (1) *General rule.* The reinsurance payment amount for a Part D eligible individual enrolled in a Part D plan for a coverage year is an amount equal to 80 percent of the allowable reinsurance costs attributable to that portion of gross covered prescription drug costs incurred in the coverage year after the individual has incurred true out-of-pocket costs that exceed the annual out-of-pocket threshold specified in § 423.104(d)(5)(iii).

(2) *Payment method.* Payments under this section are based on a method that CMS determines.

(i) Payments during the coverage year. CMS establishes a payment method by which payments of amounts

under this section are made on a monthly basis during a year based on either estimated or incurred allowable reinsurance costs.

(ii) *Final payments.* CMS reconciles the payments made during the coverage year to final actual allowable reinsurance costs as provided in § 423.343(c).

(3) *Special rules for private fee-for-service Plans offering prescription drug coverage.* CMS determines the amount of reinsurance payments for private fee-for-service plans as defined by § 422.4(a)(3) of this chapter offering qualified prescription drug coverage using a methodology that—

(i) Bases the amount on CMS' estimate of the amount of the payments that are payable if the plan were an MA-PD plan described in section 1851(a)(2)(A)(i) of the Act; and

(ii) Takes into account the average reinsurance payments made under § 423.329(c) for populations of similar risk under MA-PD plans described in section 1851(a)(2)(A)(i) of the Act.

(d) *Low-income cost sharing subsidy payment amount.*

(1) *General rule.* The low-income cost-sharing subsidy payment amount on behalf of a low-income subsidy eligible individual enrolled in a Part D plan for a coverage year is the amount described in § 423.782.

(2) *Payment method.* Payments under this section are based on a method that CMS determines.

(i) *Interim payments.* CMS establishes a payment method by which interim payments of amounts under this section are made during a year based on the low-income cost-sharing assumptions submitted with plan bids under § 423.265(d)(2)(iv) and negotiated and approved under § 423.272.

(ii) *Final payments.* CMS reconciles the interim payments to actual incurred low-income cost-sharing costs as provided in § 423.343(d).

§ 423.336 Risk-sharing arrangements.

(a) *Portion of total payments to a Part D sponsor subject to risk.* (1) *Adjusted allowable risk corridor costs.* For purposes of this paragraph, the term adjusted allowable risk corridor costs means—

(i) The allowable risk corridor costs for the Part D plan for the coverage year, reduced by—

(ii) The sum of—

(A) The total reinsurance payments made under § 423.329(c) to the Part D sponsor of the Part D plan for the year; and

(B) The total non-premium subsidy payments made under § 423.782 to the Part D sponsor of the Part D plan for the coverage year.

(2) *Establishment of risk corridors.* (i) *Risk corridors.* For each year, CMS establishes a risk corridor for each Part D plan. The risk corridor for a plan for a coverage year is equal to a range as follows:

(A) *First threshold lower limit.* The first threshold lower limit of the corridor is equal to—

(*1*) The target amount for the plan; minus

(*2*) An amount equal to the first threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(A) of this section) of the target amount.

(B) *Second threshold lower limit.* The second threshold lower limit of the corridor is equal to—

(*1*) The target amount for the plan; minus

(*2*) An amount equal to the second threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(B) of this section) of the target amount.

(C) *First threshold upper limit.* The first threshold upper limit of the corridor is equal to the sum of—

(*1*) The target amount; and

(*2*) An amount equal to the first threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(A) of this section) of the target amount.

(D) *Second threshold upper limit.* The second threshold upper limit of the corridor is equal to the sum of—

(*1*) The target amount; and

(*2*) An amount equal to the second threshold risk percentage for the plan (as determined under paragraph (a)(2)(ii)(B) of this section) of the target amount.

(ii) *First and second threshold risk percentage defined.* (A) *First threshold risk percentage.* Subject to paragraph (a)(2)(iii) of this section, the first threshold risk percentage is for—

(*1*) 2006 and 2007, 2.5 percent;

(*2*) 2008 through 2011, 5 percent; and

(*3*) 2012 and subsequent years, a percentage CMS establishes, but in no case less than 5 percent.

(B) *Second threshold risk percentage.* Subject to paragraph (a)(2)(iii) of this section, the second threshold risk percentage is for—

(1) 2006 and 2007, 5.0 percent;

(2) 2008 through 2011, 10 percent

(3) 2012 and subsequent years, a percentage CMS establishes that is greater than the percent established for

the year under paragraph (a)(2)(ii)(A)(3) of this section, but in no case less than 10 percent.

(iii) *Reduction of risk percentage to ensure two Plans in an area.* In accordance with § 423.265(e), a PDP sponsor may submit a bid that requests a decrease in the applicable first or second threshold risk percentages or an increase in the percents applied under paragraph (b) of this section. Only a PDP sponsor may request a reduction of risk under this paragraph. An MA organization offering an MA-PD plan, a PACE program offering qualified prescription drug coverage, and a cost-based HMO or CMP offering qualified prescription drug coverage may not request a reduction of risk under this paragraph.

(3) *Plans at risk for entire amount of supplemental prescription drug coverage.* A Part D sponsor that offers a Part D plan that provides supplemental prescription drug benefits is at full financial risk for the provision of the supplemental benefits.

(b) *Payment adjustments.* (1) *No adjustment if adjusted allowable risk corridor costs within risk corridor.* If the adjusted allowable risk corridor costs for the Part D plan for the coverage year are at least equal to the first threshold lower limit of the risk corridor (specified in paragraph (a)(2)(i)(A) of this section) but not greater than the first threshold upper limit of the risk corridor (specified in paragraph (a)(2)(i)(C) of this section) for the Part D plan for the coverage year, CMS makes no payment adjustment.

(2) *Increase in payment if adjusted allowable risk corridor costs above upper limit of risk corridor.*

(i) *Costs between first and second threshold upper limits.* If the adjusted allowable risk corridor costs for the Part D plan for the year are greater than the first threshold upper limit, but not greater than the second threshold upper limit, of the risk corridor for the Part D plan for the year, CMS increases the total of the payments made to the Part D sponsor offering the Part D plan for the year under this section by an amount equal to 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions described in paragraph (b)(2)(iii) of this section are met for the year) of the difference between the adjusted allowable risk corridor costs and the first threshold upper limit of the risk corridor.

(ii) *Costs above second threshold upper limits.* If the adjusted allowable risk corridor costs for the Part D plan for the year are greater than the second threshold upper limit of the risk corridor for the Part D plan for the year, CMS increases the total of the payments made to the Part D sponsor offering the Part D plan for the year under this section by an amount equal to the sum of—

(A) 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions specified in paragraph (b)(2)(iii) of this section are met for the year) of the difference between the second threshold upper limit and the first threshold upper limit; and

(B) 80 percent of the difference between the adjusted allowable risk corridor costs and the second threshold upper limit of the risk corridor.

(iii) *Conditions for application of higher percentage for 2006 and 2007.* The conditions specified in this paragraph are met for 2006 or 2007 if CMS determines for the year that—

(A) At least 60 percent of Part D plans to which this paragraph applies have adjusted allowable risk corridor costs for the Part D plan for the year that are more than the first threshold upper limit of the risk corridor for the Part D plan for the year; and

(B) Such plans represent at least 60 percent of Part D eligible individuals enrolled in any Part D plan.

(3) *Reduction in payment if adjusted allowable risk corridor costs below lower limit of risk corridor.*

(i) *Costs between first and second threshold lower limits.* If the adjusted allowable risk corridor costs for the Part D plan for the coverage year are less than the first threshold lower limit, but not less than the second threshold lower limit, of the risk corridor for the Part D plan for the coverage year, CMS reduces the total of the payments made to the Part D plan for the coverage year under this section by an amount (or otherwise recovers from the Part D sponsor an amount) equal to 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit of the risk corridor and the adjusted allowable risk corridor costs.

(ii) *Costs below second threshold lower limit.* If the adjusted allowable risk corridor costs for the Part D plan for the coverage year are less the second threshold lower limit of the risk corridor for the Part D plan for the coverage year, CMS reduces the total of the payments made to the Part D sponsor for the coverage year under this section by an amount (or otherwise recovers from the Part D sponsor an amount) equal to the sum of—

(A) 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit and the second threshold lower limit; and

(B) 80 percent of the difference between the second threshold upper limit of the risk corridor and the adjusted allowable risk corridor costs.

(c) *Payment methods.* CMS makes payments after a coverage year after obtaining all of the cost data information in paragraph (c)(1) of this section necessary to determine the amount of payment. CMS will not make payments under this section if the Part D sponsor fails to provide the cost data information in paragraph (c)(1) of this section.

(1) *Submission of cost data.* Within 6 months of the end of a coverage year, the Part D sponsor must provide the information that CMS requires.

(2) *Lump sum and adjusted monthly payments.* CMS at its discretion makes either lump-sum payments or adjusts monthly payments in the following payment year based on the relationship of the plan's adjusted allowable risk corridor costs to the predetermined risk corridor thresholds in the coverage year, as determined under this section.

(d) *No effect on monthly premium.* No adjustment in payments made by reason of this section may affect the monthly beneficiary premium for qualified prescription drug coverage.

§ 423.343 Retroactive adjustments and reconciliations.

(a) *Application of enrollee adjustment.* The provisions of § 422.308(f) of this chapter apply to payments to Part D sponsors under this section in the same manner as they apply to payments to MA organizations under section 1853(a) of the Act.

(b) *Health status.* CMS makes adjustments to payments made under § 423.329(a)(1) to account for updated health status risk adjustment data as provided under § 422.310(g)(2) of this chapter. CMS may recover payments associated with health status adjustments if the Part D sponsor fails to provide the information described in § 423.329(b)(3).

(c) *Reinsurance.* CMS makes final payment for reinsurance after a coverage year after obtaining all of the information necessary to determine the amount of payment.

(1) *Submission of cost data.* Within 6 months of the end of a coverage year, the Part D sponsor must provide the information that CMS requires.

(2) *Payments.* CMS at its discretion either makes lump-sum payments or adjusts monthly payments throughout the remainder of the payment year following the coverage year based on the difference between monthly reinsurance payments made during the coverage year and the amount payable in § 423.329(c) for the coverage year. CMS may recover payments made through a

lump sum recovery or by adjusting monthly payments throughout the remainder of the coverage year if the monthly reinsurance payments made during the coverage year exceed the amount payable under § 423.329(c) or if the Part D sponsor does not provide the data in paragraph (c)(1) of this section.

(d) *Low-income cost-sharing subsidy.* CMS makes final payment for low-income cost-sharing subsidies after a coverage year after obtaining all of the information necessary to determine the amount of payment.

(1) *Submission of cost data.* Within 6 months of the end of a coverage year, the Part D sponsor must provide the information that CMS requires.

(2) *Payments.* CMS at its discretion either makes lump-sum payments or adjusts monthly payments throughout the remainder of the payment year following the coverage year based on the difference between interim low-income cost-sharing subsidy payments and total low-income cost-sharing subsidy costs eligible for subsidy under § 423.782 submitted by the plan for the coverage year. CMS may recover payments made through a lump sum recovery or by adjusting monthly payments throughout the remainder of the coverage year if interim low-income cost-sharing subsidy payments exceed the amount payable under § 423.782 or if the Part D sponsor does not provide the data in paragraph (d)(1) of this section. In the event adequate data is not provided for risk corridor costs, CMS assumes that the Part D plan's adjusted allowable risk corridor costs are 50 percent of the target amount.

§ 423.346 Reopening.

(a) CMS may reopen and revise an initial or reconsidered final payment determination (including a determination on the final amount of direct subsidy described in § 423.329(a)(1), final reinsurance payments described in § 423.329(c), the final amount of the low income subsidy described in § 423.329(d), or final risk corridor payments as described in § 423.336)—

(1) For any reason, within 12 months from the date of the notice of the final determination to the Part D sponsor

(2) After that 12-month period, but within 4 years after the date of the notice of the initial or reconsidered determination to the Part D sponsor, upon establishment of good cause for reopening; or

(3) At any time, in instances of fraud or similar fault of the Part D sponsor or any subcontractor of the Part D sponsor.

(b) For purposes of this section, CMS will find good cause if—

(1) New and material evidence that was not readily available at the time the final determination was made is furnished;

(2) A clerical error in the computation of payments was made; or

(3) The evidence that was considered in making the determination clearly shows on its face that an error was made.

(c) For purposes of this section, CMS will not find good cause if the only reason for reopening is a change of legal interpretation or administrative ruling upon which the final determination was made.

(d) A decision not to reopen under this section is final and is not subject to review.

§ 423.350 Payment appeals.

(a) *Payment determinations.* (1) *Payment methods subject to appeal.* If CMS did not apply its stated payment methodology correctly, a Part D sponsor may appeal the following:

(i) The reconciled health status risk adjustment of the direct subsidy as provided in § 423.343(b).

(ii) The reconciled reinsurance payments under § 423.343(c).

(iii) The reconciled final payments made for low-income cost sharing subsidies provided in § 423.343(d); or

(iv) Final risk-sharing payments made under § 423.336).

(2) *Payment information not subject to appeal.* Payment information submitted to CMS under § 423.322 and reconciled under § 423.343 is final and may not be appealed nor may the appeals process be used to submit new information after the submission of information necessary to determine retroactive adjustments and reconciliations.

(b) *Request for reconsideration.* (1) *Time for filing a request.* The request for reconsideration must be filed within 15 days from the date of the notice of the adverse determination.

(2) *Content of request.* The request for reconsideration must specify the findings or issues with which the Part D sponsor disagrees and the reasons for the disagreements. Excluding new payment information, the request for reconsideration may include additional documentary evidence the sponsor wishes CMS to consider.

(3) *Conduct of informal written reconsideration.*

In conducting the reconsideration, CMS reviews the payment determination, the evidence and findings upon which it was based, and any other written evidence submitted by the Part D sponsor or by CMS before notice of the reconsidered determination is made.

(4) *Decision of the informal written reconsideration.* CMS informs the sponsor of the decision orally or through electronic mail. CMS sends a written decision to the Part D sponsor on the sponsor's request.

(5) *Effect of CMS informal written reconsideration.*

A reconsideration decision, whether delivered orally or in writing, is final and binding unless a request for hearing is filed in accordance with paragraph (c) of this section, or it is revised in accordance with § 423.346.

(c) *Right to informal hearing.* A Part D sponsor dissatisfied with the CMS reconsideration decision is entitled to an informal hearing as provided in this section.

(1) *Manner and timing for request.* A request for a hearing must be made in writing and filed with CMS within 15 days of the date the Part D sponsor receives the CMS reconsideration decision.

(2) *Content of request.* The request for informal hearing must include a copy of the CMS reconsideration decision (if any) and must specify the findings or issues in the decision with which the Part D sponsor disagrees and the reasons for the disagreements.

(3) *Informal hearing procedures.* (i) CMS provides written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The hearing are conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence that was not presented with the reconsideration request. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made both its initial and reconsideration determinations.

(iii) If CMS did not issue a written reconsideration decision, the hearing officer may request, but not require, a written statement from CMS or its contractors explaining CMS' determination, or CMS or its contractors may, on their own, submit the written statement to the hearing officer. Failure of CMS to submit a written statement does not result in any adverse findings against CMS and may not in any way be taken into account by the hearing officer in reaching a decision.

(4) *Decision of the CMS hearing officer.* The CMS hearing officer decides the case and sends a written decision to the Part D sponsor, explaining the basis for the decision.

(5) *Effecting of hearing officer decision.* The hearing officer decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (d) of this section.

(d) *Review by the Administrator.* (1) A Part D sponsor that has received a hearing officer decision upholding a CMS initial or reconsidered determination may request review by the Administrator within 15 days of receipt of the hearing officer's decision.

(2) The Administrator may review the hearing officer's decision, any written documents submitted to CMS or to the hearing officer, as well as any other information included in the record of the hearing officer's decision and determine whether to uphold, reverse or modify the hearing officer's decision.

(3) The Administrator's determination is final and binding.

Subpart H—[Reserved]

Subpart I—Organization Compliance with State Law and Preemption by Federal Law

§ 423.401 General requirements for PDP sponsors.

(a) *General requirements.* Each PDP sponsor of a prescription drug plan must meet the following requirements:

(1) *Licensure.* Except in cases where there is a waiver as specified at § 423.410 or § 423.415, the sponsor is organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan. If not otherwise licensed, the sponsor obtains certification from the State that the organization meets a level of financial solvency and other standards as the State may require for it to operate as a PDP sponsor.

(2) *Assumption of financial risk for unsubsidized coverage.* The PDP sponsor assumes financial risk on a prospective basis for benefits that it offers under a prescription drug plan and that is not covered under section 1860D–15(b) of the Act.

(b) *Reinsurance permitted.* The PDP sponsor may obtain insurance or make other arrangements for the cost of coverage provided to any enrollee to the extent that the sponsor is at risk for providing the coverage.

(c) *Solvency for unlicensed sponsors.* In the case of a PDP sponsor that is not described in § 423.401(a)(1) and for which a waiver is approved under § 423.410 or § 423.415, the sponsor must meet the requirements in § 423.420.

§ 423.410 Waiver of certain requirements to expand choice.

(a) *Authorizing waiver.* In the case of an entity that seeks to offer a prescription drug plan in a State, CMS waives the licensure requirement at § 423.401(a)(1), which requires that the entity be licensed in that State if CMS determines, based on the application and other evidence presented, that any of the grounds for approval of the application described in paragraphs (b), (c), or (d) of this section are met.

(b) *Grounds for approval of waivers.* Subject to the waiver requirements specified in § 423.410(e), waivers may be granted under any of the following conditions:

(1) *Failure to act on licensure application on a timely basis.* The State failed to complete action on the licensing application within 90 days of the date that the State received a substantially complete application.

(2) *Denial of application based on discriminatory treatment.* The State denied the license application on either of the following bases—-

(i) The State imposed material requirements,

procedures, or standards (other than solvency requirements) not generally applied by the State to other entities engaged in a substantially similar business; or

(ii) The State required, as a condition of licensure, that the organization offer any product or plan other than a prescription drug plan.

(3) *Denial of application based on application of solvency requirements.* The State denied the licensure application, in whole or in part, on the basis of the PDP sponsor's failure to meet solvency requirements and

(i) The solvency requirements are different from the solvency standards CMS establishes in accordance with § 423.420; or

(ii) CMS determines that the State imposed, as a condition of licensing, any documentation or information requirements relating to solvency that are different from the standards CMS establishes in accordance with § 423.420.

(4) *Grounds other than those required by Federal Law.* The application by a State of any grounds other than those required under Federal law.

(c) *Waiver when licensing process not in effect.* The grounds for approval specified in paragraph (b)(1) of this section are deemed met if CMS determines that the State does not have a licensing process in effect for PDP sponsors.

(d) *Special waiver for plan years beginning before January 1, 2008.* For plan years beginning before January 1, 2008, if the State has a prescription drug plan or PDP sponsor licensing process in effect, CMS grants a waiver upon a demonstration that an applicant to become a PDP sponsor has submitted a fully completed application for licensure to the State.

(e) *Waiver requirements.* The following rules apply to waiver applications or waivers granted under this section.

(1) *Treatment of waiver.* The waiver applies only to that State, is effective for 36 months, and cannot be renewed.

(2) *Prompt action on application.* CMS grants or denies a waiver application under this section within 60 days after CMS determines that a substantially complete waiver application is received by CMS.

(3) *A State that does not have a PDP sponsor.* In the case of a State that does not have a PDP sponsor licensing process, the 36 month limitation on the waiver discussed in paragraph (e)(1) of this section does not apply, and the waiver may continue in effect for a given State as long as CMS determines that the State does not have a PDP sponsor licensing process in effect, and the PDP sponsor meets the solvency standards of § 423.420(a).

§ 423.415 Temporary waivers for entities seeking to offer a prescription drug plan in more than one State in a region

(a) *General rule.* Subject to paragraphs (b) and (c) of this section, if an applicant seeking to become a PDP sponsor wishes to operate in more than one State in a region, and is licensed as a risk bearing entity in at least one State in the region, then the applicant may receive a temporary regional plan waiver for the States in which it is not licensed.

(b) *Filing of application.* The applicant must demonstrate to the satisfaction of CMS that it filed the necessary licensure applications with each State in the region for which it does not already have State licensure, except that no application is necessary if CMS determines that the State does not have a licensing process for potential PDP sponsors.

(c) *Processing of application for temporary waiver.* The Secretary determines the time period appropriate for the timely processing of the application for temporary waiver.

(d) *Time limit for temporary waiver.* The temporary waiver expires at the end of time period that the Secretary determines is appropriate for timely processing of the application by the State or States, but in no case is a waiver extend beyond the end of the calendar year.

§ 423.420 Solvency standards for non-licensed entities.

(a) *Establishment and publication.* CMS establishes and publishes reasonable financial solvency and

capital adequacy standards for entities specified in paragraph (b) of this section.

(b) *Compliance with standards.* A PDP sponsor that is not licensed by a State and for which a waiver application is approved by CMS under § 423.410 or § 423.415 must maintain reasonable financial solvency and capital adequacy in accordance with the standards established by CMS under paragraph (a) of this section.

§ 423.425 Licensure does not substitute for or constitute certification.

The fact that a Part D sponsor is State licensed or has a waiver application approved under § 423.410 or § 423.415 does not deem the sponsor to meet other requirements imposed under this part for a Part D sponsor.

§ 423.440 Prohibition of State imposition of premium taxes; relation to State laws.

(a) *Federal preemption of State law.* The standards established under this part supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) for Part D plans offered by Part D plan sponsors..

(b) *State premium taxes prohibited.* (1) *Basic rule.* No premium tax, fee, or other similar assessment may be imposed by any State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa, the Mariana Islands or any of their political subdivisions or other governmental authorities for any payment CMS makes on behalf of Part D plan or enrollees under this part (including the direct subsidy, reinsurance payments, and risk corridor payments); or for any payment made to Part D plans by a beneficiary or by a third party on behalf of a beneficiary.

(2) *Construction.* Nothing in this section may be construed to exempt any Part D plan sponsor from taxes, fees, or other monetary assessments related to the net income or profit that accrues to, or is realized by, the organization from business conducted under this part, if that tax, fee, or payment is applicable to a broad range of business activity.

Subpart J—Coordination of Part D Plans With Other Prescription Drug Coverage

§ 423.452 Scope.

This section sets forth the application of Part D rules to Part C plans; establishes waivers for MA-PD plans, employer-sponsored group prescription drug plans, cost plans, and PACE organizations; and establishes requirements for coordination of benefits with State Pharmaceutical Assistance Programs and other providers of prescription drug coverage.

§ 423.454 Definitions.

For purposes of this part, the following definitions apply—

Employer-sponsored group prescription drug plan means prescription drug coverage offered to retirees who are Part D eligible individuals under employment-based retiree health coverage (as defined in § 423.882) approved by CMS as a prescription drug plan.

State Pharmaceutical Assistance Program (SPAP) means a State program that meets the requirements described under § 423.464(e)(1).

§ 423.458 Application of Part D rules to certain Part D plans on and after January 1, 2006.

(a) *Relationship to Part C.* Except as otherwise provided in this Part, the requirements of this Part apply to prescription drug coverage provided by MA-PD plans offered by MA organizations beginning on or after January 1, 2006.

(b) *MA waiver.* CMS waives any provision of this Part otherwise applicable to MA-PD plans or MA organizations under paragraph (a) of this section to the extent CMS determines that the provision duplicates, or is in conflict with, provisions otherwise applicable to the MA organizations or MA-PD plans under Part C of Medicare, or as may be necessary in order to improve coordination of this part with the benefits under Part C.

(1) *Application of waiver.* Any waiver or modification granted by CMS under this section applies to any other similarly situated organization offering or seeking to offer a MA-PD plan that meets the conditions of the waiver.

(2) *Request for waivers.* Organizations offering or

seeking to offer a MA-PD plan may request from CMS in writing—

(i) A waiver of those requirements under this part otherwise applicable to the MA-PD plan or MA organization under paragraph (a) of this section that are duplicative of, or that are in conflict with, provisions otherwise applicable to the MA-PD plan, proposed MA-PD plan, or a MA organization under Part C of Medicare.

(ii) A waiver of a requirement under this part otherwise applicable to the MA-PD plan or MA organization under paragraph (a) of this section, if such waiver improves coordination of benefits provided under Part C of Medicare with benefits under this Part.

(c) *Employer group waiver.* (1) *General rule.* CMS may waive or modify any requirement under this part that hinders the design of, the offering of, or the enrollment in an employer-sponsored group prescription drug plan, including authorizing the establishment of separate premium amounts for enrollees of the employer-sponsored group prescription drug plan and limitations on enrollment in such plan to Part D eligible individuals participating in the sponsor's employment-based retiree health coverage. Any entity seeking to offer, sponsor, or administer an employer-sponsored group prescription drug plan may request, in writing, a waiver or modification of additional requirements under this Part that hinder its design of, the offering of, or the enrollment in, such employer-sponsored group prescription drug plan.

(2) *Use of waiver.* Waivers or modifications approved by CMS under this section apply to any similarly situated entity seeking to offer, sponsor, or administer an employer-sponsored group prescription drug plan, meeting the conditions of the waiver or modification.

(d) *Other waivers.* CMS waives any provision of this Part as applied to a cost plan (as defined in § 417.401 of this chapter) or PACE organization (as defined in § 460.6 of this chapter) that offers qualified prescription drug coverage under Part D to the extent CMS determines that the provision duplicates, or is in conflict with, provisions otherwise applicable to the cost plan under section 1876 of the Act or provisions applicable to PACE organizations under sections 1894 and 1934 of the Act, or as necessary in order to improve coordination of this Part with the benefits offered by cost plans or PACE organizations.

(1) *Application of waiver.* Any waiver or modification granted by CMS under this paragraph applies to any other similarly situated organization offering or seeking to offer qualified prescription drug coverage as a cost plan under section 1876 of the Act or as a PACE organization under sections 1894 and 1934 of the Act.

(2) *Request for waivers.* Cost plans or PACE organizations seeking to offer qualified prescription drug coverage may request from CMS in writing-

(i) A waiver of those requirements under this part otherwise applicable to cost plans or PACE organizations that are duplicative of, or that are in conflict with, provisions otherwise applicable to cost plans or PACE organizations.

(ii) A waiver of a requirement under this part otherwise applicable to cost plans or PACE organizations, if such waiver improves coordination of

benefits provided by the cost plan under section 1876 of the Act, or by the PACE organization under section 1934 of the Act, with the benefits under Part D.

§ 423.462 Medicare secondary payer procedures.

The provisions of § 422.108 of this chapter regarding Medicare secondary payer procedures apply to Part D sponsors and Part D plans (with respect to the offering of qualified prescription drug coverage) in the same way as they apply to MA organizations and MA plans under Part C of title XVIII of the Act, except all references to MA organizations and MA plans are considered references to Part D sponsors and Part D plans.

§ 423.464 Coordination of benefits with other providers of prescription drug coverage.

(a) *General rule.* A Part D plan must permit SPAPs (described in paragraph (e)(1) of this section) and entities providing other prescription drug coverage (described in paragraph (f)(1) of this section) to coordinate benefits with such plan. A Part D plan must comply with all administrative processes and requirements established by CMS to ensure effective exchange of information and coordination between such plan and SPAPs and entities providing other prescription drug coverage for—

(1) Payment of premiums and coverage; and

(2) Payment for supplemental prescription drug benefits as described in § 423.104(f)(1)(ii)(including payment to a Part D plan on a lump sum per capita basis) for Part D eligible individuals enrolled in the Part D plan and the SPAP or entity providing other prescription drug coverage.

(b) *Medicare as primary payer.* The requirements of this subpart do not change or affect the primary or secondary payer status of a Part D plan and a SPAP or other prescription drug coverage. A Part D plan is always the primary payer relative to a State Pharmaceutical Assistance Program.

(c) *User fees.* CMS may impose user fees on Part D plans for the transmittal of information necessary for benefit coordination in accordance with administrative processes and requirements established by CMS to ensure effective exchange of information and coordination between a Part D plan and SPAPs and entities providing other prescription drug coverage in a manner similar to the manner in which user fees are imposed under section 1842(h)(3)(B) of the Act, except that CMS may retain a portion of user fees to defray its costs in carrying out such procedures. CMS will not impose user fees under this subpart on a SPAP or entities providing other prescription drug coverage.

(d) *Cost management tools.* The requirements of this subpart do not prevent a Part D sponsor from using cost management tools (including differential payments) under all methods of operation.

(e) *Coordination with State Pharmaceutical Assistance Programs.* (1) *Requirements to be a State Pharmaceutical Assistance Program (SPAP).* A State program is considered to be a State Pharmaceutical Assistance Program for purposes of this part if it-

(i) Provides financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of Part D eligible individuals;

(ii) Provides assistance to Part D eligible individuals in all Part D plans without discriminating based upon the Part D plan in which an individual enrolls;

(iii) Meets the benefit coordination requirements specified in this subpart;

(iv) Does not follow or adopt rules that change or affect the primary payer status of a Part D plan.

The definition of SPAP excludes State Medicaid programs, section 1115 demonstration programs, and any other program where program funding is from Federal grants, awards, contracts, entitlement programs, or other Federal sources of funding; and

(v) Provides supplemental drug coverage to individuals based on financial need, age, or medical condition, and not based on current or former employment status.

(2) *Use of a single card.* A card that is issued under § 423.120(c) for use under a Part D plan may also be used in connection with coverage of benefits provided under a SPAP and, in such a case, may contain an emblem or symbol indicating such connection.

(3) *Construction.* Nothing in this subpart requires a SPAP to coordinate with, or provide financial assistance to enrollees in, any Part D plan.

(f) *Coordination with other prescription drug coverage.* (1) *Definition of other prescription drug coverage.* Entities that provide other prescription drug coverage include any of the following:

(i) *Medicaid programs.* A State plan under title XIX of the Act, including such a plan operating under a waiver under section 1115 of the Act, if it meets the requirements of paragraph (e)(1)(ii) of this section.

(ii) Group health plans.

(iii) *FEHBP.* The Federal Employee Health Benefits Program under chapter 89 of title 5, United States Code.

(iv) *Military coverage (including TRICARE).* Coverage under chapter 55 of title 10, United States Code.

(v) *Indian Health Service.* Coverage under Chapter 18 of title 28 of the United States Code.

(vi) *Federally qualified health centers.* Federally qualified health centers as defined under section 1861(aa)(4) of the Act.

(vii) *Rural health centers.* Rural health centers as defined under section 1861(aa)(2) of the Act.

(viii) *Other prescription drug coverage.* Other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of Part D drugs on behalf of Part D eligible individuals as CMS may specify.

(2) *Treatment under out-of-pocket rule.* A Part D plan must exclude expenditures for covered Part D drugs made by insurance or otherwise, a group health plan, or other third party payment arrangements, including expenditures by plans offering other prescription drug coverage for purposes of determining whether a Part D plan enrollee has satisfied the out-of-pocket threshold provided under § 423.104(d)(5)(iii). A Part D enrollee must disclose all these expenditures to a Part D plan in accordance with requirements under § 423.32(b)(ii).

(3) *Imposition of fees.* A Part D sponsor may not impose fees on SPAPs and entities offering other prescription drug coverage that are unrelated to the cost of the coordination of benefits.

(4) *Authority to recover expenditures due to incorrect information on true out-of-pocket costs.* In the event that a Part D plan learns that it has made an erroneous payment due to inaccurate or incomplete information on the satisfaction of the out-of-pocket threshold under § 423.104(d)(5)(iii), that plan is authorized to recover such costs directly from the Part D enrollee on whose behalf the costs were incurred. A Part D enrollee must reimburse the Part D plan for payment made for these costs.

Subpart K—Application Procedures and Contracts with Part D plan sponsors

§ 423.500 Scope.

This subpart sets forth application procedures and contracts with Part D plans: application procedures and requirements; contract terms; procedures for termination of contracts; reporting by Part D plans. For purposes

of this subpart, Medicare Advantage (MA) organizations offering Part D plans follow the requirements of part 422 of this chapter for MA organizations, except in cases where the requirements for the qualified prescription drug coverage involve additional requirements.

§ 423.501 Definitions

For purposes of this subpart, the following definitions apply:

Business transaction means any of the following kinds of transactions:

(1) Sale, exchange, or lease of property.

(2) Loan of money or extension of credit.

(3) Goods, services, or facilities furnished for a monetary consideration, including management services, but not including—

(i) Salaries paid to employees for services performed in the normal course of their employment; or

(ii) Health services furnished to the Part D plan sponsor's enrollees by pharmacies and other providers, by Part D plan sponsor staff, medical groups, or independent practice associations, or by any combination of those entities.

Downstream entity means any party that enters into a written arrangement, acceptable to CMS, below the level of the arrangement between a Part D plan sponsor (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

First tier entity means any party that enters into a written arrangement, acceptable to CMS, with a Part D plan sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under Part D.

Party in interest means the following:

(1) Any director, officer, partner, or employee responsible for management or administration of a Part D plan sponsor.

(2) Any person who is directly or indirectly the beneficial owner of more than 5 percent of the organization's equity; or the beneficial owner of a mortgage, deed of trust, note, or other interest secured by and valuing more than 5 percent of the organization.

(3) In the case of a PDP sponsor organized as a nonprofit corporation, an incorporator or member of the corporation under applicable State corporation law.

(4) Any entity in which a person specified in paragraphs (1), (2), or (3) of this definition—

(i) Is an officer, director, or partner; or

(ii) Has the kind of interest described in paragraphs (1), (2), or (3) of this definition.

(5) Any person that directly or indirectly controls, is controlled by, or is under common control with the Part D plan sponsor.

(6) Any spouse, child, or parent of an individual specified in paragraphs (1), (2), or (3) of this definition.

Related entity means any entity that is related to the PDP sponsor by common ownership or control and—

(1) Performs some of the Part D plan sponsor's management functions under contract or delegation;

(2) Furnishes services to Medicare enrollees under an oral or written agreement; or

(3) Leases real property or sells materials to the Part D plan sponsor at a cost of more than $2,500 during a contract period.

Significant business transaction means any business transaction or series of transactions of the kind specified in the above definition of business transaction that, during any fiscal year of the Part D plan sponsor, have a total value that exceeds $25,000 or 5 percent of the PDP sponsor's total operating expenses, whichever is less.

§ 423.502 Application requirements.

(a) *Scope*. This section sets forth application requirements for an entity that seeks a determination from CMS that it is qualified to contract as a sponsor of a Part D plan.

(b) *Completion of an application*. (1) In order to obtain a determination on whether it meets the requirements to become a Part D plan sponsor, an entity, or an individual authorized to act for the entity (the applicant), must complete a certified application in the form and manner required by CMS, including the following:

(i) Documentation of appropriate State licensure or State certification that the entity is able to offer health insurance or health benefits coverage that meets State-specified standards as specified in subpart I of this part; or

(ii) A Federal waiver as specified in subpart I of this part.

(2) The authorized individual must describe thoroughly how the entity is qualified to meet the requirements described in this part.

(c) *Responsibility for making determinations*. (1) CMS is responsible for determining whether an entity is qualified to contract as a Part D plan sponsor and meets the requirements of this part.

(2) A CMS determination that an entity is qualified to act as a Part D plan sponsor is distinct from the bid negotiations that occur under subpart F of part 423 and such negotiations are not subject to the appeals provisions included in subpart N of this part.

(d) *Disclosure of application information under the Freedom of Information Act*. An applicant submitting material that he or she believes is protected from disclosure under 5 USC 552, the Freedom of Information Act, or because of exemptions provided in 45 CFR part 5 (the Department's regulations providing exemptions to disclosure), must label the material ''privileged'' and include an explanation of the applicability of an exemption specified in 45 CFR part 5.

§ 423.503 Evaluation and determination procedures for applications to be determined qualified to act as a sponsor.

(a) *Basis for evaluation and determination*. (1) CMS evaluates an entity's application on the basis of information contained in the application itself and any additional information that CMS obtains through on-site visits, publicly available information, and any other appropriate procedures.

(2) After evaluating all relevant information, CMS determines whether the application meets the applicable requirements specified in § 423.504 and § 423.505.

(b) *Use of information from a prior contracting period*. If a Part D plan sponsor fails to comply with the terms of a previous year's contract (or in the case of a fallback entity, the previous 3-year contract) with CMS under title XVIII of the Act, or fails to complete a corrective action plan during the term of the contract, CMS may deny an application based on the applicant's failure to comply with that prior contract with CMS even if the applicant currently meets all of the requirements of this part..

(c) *Notice of determination*. Except for fallback entities, which are governed under subpart Q of this part, CMS notifies each applicant that applies to be determined qualified to contract as a Part D plan sponsor, under this part, of its determination on the application and the basis for the determination. The determination may be one of the following:

(1) *Approval of application*. If CMS approves the application, it gives written notice to the applicant, indicating that it qualifies to contract as Part D plan sponsor.

(2) *Intent to deny*. (i) If CMS finds that the applicant does not appear qualified to contract as a Part D plan sponsor and/or has not provided enough information to evaluate the application, it gives the

applicant notice of intent to deny the application and a summary of the basis for this preliminary finding.

(ii) Within 10 days from the date of the notice, the applicant may respond in writing to the issues or other matters that were the basis for CMS's preliminary finding and may revise its application to remedy any defects CMS identified.

(3) Denial of application. If CMS denies the application, it gives written notice to the applicant indicating—

(i) That the applicant is not qualified to contract as a Part D sponsor under Part D of title XVIII of the Act;

(ii) The reasons why the applicant does is not so qualified; and

(iii) The applicant's right to request reconsideration in accordance with the procedures specified in subpart N.

(d) *Oversight of continuing compliance.* (1) CMS oversees a Part D plan sponsor's continued compliance with the requirements for a Part D plan sponsor.

(2) If a Part D plan sponsor no longer meets those requirements, CMS terminates the contract in accordance with § 423.509.

§ 423.504 General provisions.

(a) *General rule.* Subject to the provisions at § 423.265(a)(1) concerning submission of bids, to enroll beneficiaries in any Part D drug plan it offers and be paid on behalf of Part D eligible individuals enrolled in those plans, a Part D plan sponsor must enter into a contract with CMS. The contract may cover more than one Part D plan.

(b) *Conditions necessary to contract as a Part D plan sponsor.* Any entity seeking to contract as a Part D plan sponsor must—

(1) Complete an application as described in § 423.502 demonstrating that the entity has the capability to meet the requirements of this Part, including those listed in § 423.505.

(2) Be organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a Part D plan, or have secured a Federal waiver, as described in subpart I of this part. (Fallback entity applicants need not be licensed as risk-bearing entities, nor are they required to obtain State licensure demonstrating that the applicant is eligible to offer health insurance or health benefits coverage in each State in which it applies to operate.)

(3) Meet the minimum enrollment requirements of § 423.512(a) unless waived under § 423.512(b).

(4) Have administrative and management arrangements satisfactory to CMS, as demonstrated by at least the following:

(i) A policy making body that exercises oversight and control over the Part D plan sponsor's policies and personnel to ensure that management actions are in the best interest of the organization and its enrollees.

(ii) Personnel and systems sufficient for the Part D plan sponsor to organize, implement, control, and evaluate financial and marketing activities, the furnishing of prescription drug services, the quality assurance, medical therapy management, and drug and or utilization management programs, and the administrative and management aspects of the organization.

(iii) At a minimum, an executive manager whose appointment and removal are under the control of the policy making body.

(iv) A fidelity bond or bonds, procured and maintained by the Part D sponsor, in an amount fixed by its policymaking body but not less than $100,000 per individual, covering each officer and employee entrusted with the handling of its funds. The bond may have reasonable deductibles, based upon the financial strength of the Part D plan sponsor.

(v)Insurance policies or other arrangements, secured and maintained by the Part D plan sponsor and approved by CMS to insure the Part D plan sponsor against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks.

(vi) A compliance plan that consists of the following—

(A)Written policies, procedures, and standards of conduct articulating the organization's commitment to comply with all applicable Federal and State standards.

(B)The designation of a compliance officer and compliance committee accountable to senior management.

(C)Effective training and education between the compliance officer and organization employees, contractors, agents, and directors.

(D)Effective lines of communication between the compliance officer and the organization's employees, contractors, agents, directors, and members of the compliance committee.

(E)Enforcement of standards through well-publicized disciplinary guidelines.

(F) Procedures for effective internal monitoring and auditing.

(G) Procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives relating to the organization's contract as a Part D plan sponsor.

(*1*) If the Part D sponsor discovers evidence of misconduct related to payment or delivery of prescription drug items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct;

(*2*) The Part D sponsor must conduct appropriate corrective actions (for example, repayment of overpayments and disciplinary actions against responsible individuals) in response to the potential violation referenced above.

(H) A comprehensive fraud and abuse plan to detect, correct, and prevent fraud, waste, and abuse. This fraud and abuse plan should include procedures to voluntarily self-report potential fraud or misconduct related to the Part D program to the appropriate government authority.

(5) Not have non-renewed a contract under § 423.507 within the past 2 years unless—

(i) During the 6-month period, beginning on the date the entity notified CMS of the intention to non-renew the most recent previous contract, there was a change in the statute or regulations that had the effect of increasing Part D sponsor payments in the payment area or areas at issue; or

(ii) CMS has otherwise determined that circumstances warrant special consideration.

(6) For a full risk or limited risk PDP applicant, not submitted a bid or offered a fallback prescription drug plan in accordance with the following rules.

(i) CMS does not contract with a potential PDP sponsor for the offering of a full risk or limited risk prescription drug plan in a PDP region for a year if the applicant—

(A) Submitted a bid under § 423.863 for the year (as the first year of a contract period under § 423.863 to offer a fallback prescription drug plan in any PDP region;

(B) Offers a fallback prescription drug plan in any PDP region during the year; or

(C) Offered a fallback prescription drug plan in that PDP region during the previous year.

(ii) *Construction.* For purposes of this paragraph (b)(6), an entity is treated as submitting an application to become qualified to contract as a full risk or limited risk PDP sponsor, if the entity is acting as a subcontractor for an integral part of the drug benefit management activities of a full risk or limited risk PDP sponsor or applicant. The previous sentence does not apply to entities that are subcontractors of an MA organization except insofar as the MA organization is applying to act as a full risk or limited risk PDP sponsor.

(c) *Contracting authority*. CMS may enter into contracts under this part, or in order to carry out this part, without regard to Federal and Departmental acquisition regulations set forth in Title 48 of the CFR and provisions of law or other regulations relating to the making, performance, amendment, or modification of contracts of the United States if CMS determines that those provisions are inconsistent with the efficient and effective administration of the Medicare program.

(d) *Protection against fraud and beneficiary protections*. (1) CMS annually audits the financial records (including, but not limited to, data relating to Medicare utilization and costs, including allowable reinsurance and risk corridor costs as well as low income subsidies and other costs) under this part of at least one-third of the Part D sponsors offering Part D drug plans.

(2) Each contract under this section must provide that CMS, or any person or organization designated by CMS, has the right to—

(i) Inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the Part D plan sponsor's contract;

(ii) Inspect or otherwise evaluate the facilities of the Part D sponsor when there is reasonable evidence of some need for the inspection; and

(iii) Audit and inspect any books, contracts, and records of the Part D plan sponsor that pertain to—

(A) The ability of the organization or its first tier or downstream providers to bear the risk of potential financial losses; or

(B) Services performed or determinations of amounts payable under the contract.

(e) *Severability of contracts*. The contract must provide that, upon CMS' request—

(1) The contract could be amended to exclude any State-licensed entity, or a Part D plan specified by CMS; and

(2) A separate contract for any excluded plan or entity must be deemed to be in place when a request is made.

§ 423.505 Contract provisions.

(a) *General rule*. The contract between the Part D plan sponsor and CMS must contain the provisions specified in paragraph (b) of this section.

(b) *Requirements for contracts*. The Part D plan sponsor agrees to—

(1) All the applicable requirements and conditions set forth in this part and in general instructions.

(2) Accept new enrollments, make enrollments effective, process voluntary disenrollments, and limit involuntary disenrollments, as provided in subpart B of this part.

(3) Comply with the prohibition in § 423.34(a) on discrimination in beneficiary enrollment.

(4) Provide the basic prescription drug coverage as defined under § 423.100 and, to the extent applicable, supplemental benefits as defined in § 423.100. (Fallback entities may offer only standard prescription drug coverage as specified in § 423.855.)

(5) Disclose information to beneficiaries in the manner and the form specified by CMS under § 423.128.

(6) Operate quality assurance, cost and utilization management, medication therapy management, and support e-prescribing as required under subpart D of this part.

(7) Comply with all requirements in subpart M of this part governing coverage determinations, grievances, and appeals, and formulary exceptions.

(8) Comply with the reporting requirements in § 423.514 and the requirements in § 423.329(b) for submitting drug claims and related information to CMS for its use in risk adjustment calculations.

(9) Provide CMS with the information CMS determines is necessary to carry out payment provisions in subpart G of this part (or for fallback entities, the information necessary to carry out the payment provisions in subpart Q of this part).

(10) Allow CMS to inspect and audit any books and records of a Part D plan sponsor that pertain to the information regarding costs provided to CMS under paragraph (b)(9) of this section, or, if a fallback entity, the information submitted under subpart Q.

(11) Be paid under the contract in accordance with the payment rules in subpart G of this part, or, if a fallback entity, in accordance with the payment rules of subpart Q of this part.

(12) Except for fallback entities, submit a future year's bid, including all required information on premiums, benefits, and cost-sharing, by any applicable due date, as provided in subpart F so that CMS and the Part D plan sponsor may conduct negotiations regarding the terms and conditions of the proposed bid and benefit plan renewal.

(13) Permit CMS to determine that it is not qualified to renew its contract or that its contract may be terminated in accordance with this subpart and subpart N of this part. (Subpart N applies to fallback entities only to the extent a fallback contract is terminated.)

(14) Comply with the confidentiality and enrollee record accuracy specified in § 423.136.

(15) Comply with State law and preemption by Federal law requirements described in subpart I of this part.

(16) Comply with the coordination requirements with SPAPs and plans that provide other prescription drug coverage as described in subpart J of this part.

(17) Provide benefits by means of point of service systems to adjudicate in a drug claims in a timely and efficient manner in compliance with CMS standards, except when necessary to provide access in underserved areas, I/T/U pharmacies (as defined in § 423.100), and long-term care pharmacies (as defined in § 423.100).

(18) To agree to have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy.

(c) *Communication with CMS*. The Part D plan sponsor must have the capacity to communicate with CMS electronically in accordance with CMS requirements.

(d) *Maintenance of records*. The Part D plan sponsor agrees to maintain, for 10 years, books, records, documents, and other evidence of accounting procedures and practices that-

(1) Are sufficient to do the following:

(i) Accommodate periodic auditing of the financial records (including data related to Medicare utilization, costs, and computation of the bid of part D plan sponsors).

(ii) Enable CMS to inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the contract and the facilities of the organization.

(iii) Enable CMS to audit and inspect any books and records of the Part D plan sponsor that pertain to the ability of the organization to bear the risk of potential financial losses, or to services performed or determinations of amounts payable under the contract.

(iv) Except for fallback entities, properly reflect all direct and indirect costs claimed to have been incurred and used in the preparation of the Part D plan sponsor's bid and necessary for the calculation of gross covered prescription drug costs, allowable reinsurance costs, and allowable risk corridor costs (as defined in § 423.308).

(v) Except for fallback entities, establish the basis for the components, assumptions, and analysis used by the Part D plan in determining the actuarial valuation of standard, basic alternative, or enhanced alternative coverage offered in accordance with the CMS guidelines specified in § 423.265(c)(3).

(2) Include records of the following:

(i) Ownership and operation of the Part D sponsor's financial, medical, and other record keeping systems.

(ii) Financial statements for the current contract period and 10 prior periods.

(iii) Federal income tax or informational returns for the current contract period and 10 prior periods.

(iv) Asset acquisition, lease, sale, or other actions.

(v) Agreements, contracts, and subcontracts.

(vi) Franchise, marketing, and management agreements.

(vii) Matters pertaining to costs of operations.

(viii) Amounts of income received by source and payment.

(ix) Cash flow statements.

(x) Any financial reports filed with other Federal programs or State authorities.

(xi) All prescription drug claims for the current contract period and 10 prior periods.

(xii) All price concessions (including concessions offered by manufacturers) for the current contract period and 10 prior periods accounted for separately from other administrative fees.

(e) *Access to facilities and records.* The Part D plan sponsor agrees to the following:

(1) HHS, the Comptroller General, or their designee may evaluate, through inspection or other means—

(i) The quality, appropriateness, and timeliness of services furnished to Medicare enrollees under the contract;

(ii) The facilities of the Part D plan sponsor; and

(iii) The enrollment and disenrollment records for the current contract period and 10 prior periods.

(2) HHS, the Comptroller General, or their designees may audit, evaluate, or inspect any books, contracts, medical record s, patient care documentation, and other records of the Part D plan sponsor, related entity(s), contractor(s), subcontractor(s), or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract, or as the Secretary may deem necessary to enforce the contract.

(3) The Part D plan sponsor agrees to make available, for the purposes specified in paragraph (d) of this section, its premises, physical facilities and equipment, records relating to its Medicare enrollees, and any additional relevant information that CMS may require.

(4) HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through 10 years from the end of the final contract period or completion of audit, whichever is later unless—

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the Part D plan sponsor at least 30 days before the normal disposition date;

(ii) There is a termination, dispute, or allegation of fraud or similar fault by the Part D plan sponsor, in which case the retention may be extended to 6 years from the date of any resulting final resolution of the termination, dispute, or fraud or similar fault; or

(iii) CMS determines that there is a reasonable possibility of fraud or similar fault, in which case CMS may inspect, evaluate, and audit the Part D plan sponsor at any time.

(f) *Disclosure of information.* The Part D plan sponsor agrees to submit to CMS—

(1) Certified financial information that must include the following:

(i) Information as CMS may require demonstrating that the organization has a fiscally sound operation.

(ii) Information as CMS may require pertaining to the disclosure of ownership and control of the Part D plan sponsor.

(2) All information to CMS that is necessary for CMS to administer and evaluate the program and to simultaneously establish and facilitate a process for current and prospective beneficiaries to exercise choice in obtaining prescription drug coverage. This information includes, but is not limited to:

(i) The benefits covered under a Part D plan.

(ii) The Part D plan monthly basic beneficiary premium and Part D plan monthly supplemental beneficiary premium, if any, for the plan. Fallback entities submit the monthly beneficiary premium for standard prescription drug coverage.

(iii) The service area of each plan.

(iv) Plan quality and performance indicators for the benefits under the plan including—

(A) Disenrollment rates for Medicare enrollees electing to receive benefits through the plan for the previous 2 years;

(B) Information on Medicare enrollee satisfaction;

(C) The recent records regarding compliance of the plan with requirements of this part, as determined by CMS; and

(D) Other information determined by CMS to be necessary to assist beneficiaries in making an informed choice regarding Part D plans.

(v) Information about beneficiary appeals and their disposition, and formulary exceptions.

(vi) Information regarding all formal actions, reviews, findings, or other similar actions by States, other regulatory bodies, or any other certifying or accrediting organization.

(vii) Information on other matters that CMS may require, including, but not limited to, program monitoring and oversight, performance measures, quality assessment, research and evaluation, CMS outreach activities, payment-related oversight*, and fraud, abuse, and waste*, as specified in CMS guidelines.

(viii) Any other information deemed necessary to CMS for the administration or evaluation of the Medicare program.

(3)To its enrollees, all informational requirements under § 423.128 and, upon an enrollee's request, the financial disclosure information required under § 423.128(c)(4).

(g) *Beneficiary financial protections.* The Part D plan sponsor agrees to comply with the following requirements:

(1) Each Part D plan sponsor must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability for payment of any fees that are the legal obligation of the Part D sponsor. To meet this requirement, the Part D plan sponsor must—

(i) Ensure that all contractual or other written arrangements prohibit the sponsor's contracting agents from holding any beneficiary enrollee liable for payment of any such fees; and

(ii) Indemnify the beneficiary enrollee for payment of any fees that are the legal obligation of the Part D plan sponsor for covered prescription drugs furnished by non-contracting pharmacists, or that have not otherwise entered into an agreement with the Part D plan sponsor, to provide services to the organization's beneficiary enrollees.

(2) In meeting the requirements of this paragraph, other than the provider contract requirements specified in paragraph (g)(1)(i) of this section, the Part D plan sponsor may use—

(i) Contractual arrangements;

(ii) Insurance acceptable to CMS;

(iii) Financial reserves acceptable to CMS; or

(iv) Any other arrangement acceptable to CMS.

(h) *Requirements of other laws and regulations.*

The Part D plan sponsor agrees to comply with-

(1) Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to

applicable provisions of Federal criminal law, the False Claims Act (32 U.S.C. §§ 3729 *et seq.*), and the anti-kickback statute (section 1128B(b) of the Act).

(2) HIPAA Administrative Simplification rules at 45 CFR parts 160, 162, and 164.

(i) *Relationship with related entities, contractors, and subcontractors.* (1) Notwithstanding any relationship(s) that the Part D plan sponsor may have with related entities, contractors, or subcontractors, the Part D sponsor maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS.

(2) The Part D plan sponsor agrees to require all related entities, contractors, or subcontractors to agree that—

(i) HHS, the Comptroller General, or their designees have the right to inspect, evaluate, and audit any pertinent contracts, books, documents, papers, and records of the related entity(s), contractor(s), or subcontractor(s) involving transactions related to CMS' contract with the Part D plan sponsor; and

(ii) HHS', the Comptroller General's, or their designee's right to inspect, evaluate, and audit any pertinent information for any particular contract period exists through 10 years from the final date of the contract period or from the date of completion of any audit, whichever is later.

(3) All contracts or written arrangements between Part D plan sponsors and pharmacies or other providers, related entities, contractors, subcontractors, first tier and downstream entities must contain the following:

(i) Enrollee protection provisions that provide, consistent with paragraph (g)(1) of this section, arrangements that prohibit pharmacies or other providers from holding an enrollee liable for payment of any fees that are the obligation of the Part D plan sponsor.

(ii) Accountability provisions that indicate that the Part D sponsor may delegate activities or functions to a pharmacy, related entity, contractor, or subcontractor only in a manner consistent with requirements set forth at paragraph (i)(4) of this section.

(iii) A provision requiring that any services or other activity performed by a related entity, contractor, subcontractor, or first-tier or downstream entity in accordance with a contract or written agreement are consistent and comply with the Part D plan sponsor's contractual obligations.

(4) If any of the Part D plan sponsors' activities or responsibilities under its contract with CMS is delegated to other parties, the following requirements apply to any related entity, contractor, subcontractor, or pharmacy:

(i) Written arrangements must specify delegated activities and reporting responsibilities.

(ii) Written arrangements must either provide for revocation of the delegation activities and reporting responsibilities described in paragraph (i)(4)(i) of this section or specify other remedies in instances when CMS or the Part D plan sponsor determine that the parties have not performed satisfactorily.

(iii) Written arrangements must specify that the Part D plan sponsor on an ongoing basis monitors the performance of the parties.

(iv) All contracts or written arrangements must specify that the related entity, contractor, or subcontractor must comply with all applicable Federal laws, regulations, and CMS instructions.

(5) If the Part D plan sponsor delegates selection of its prescription drug providers to another organization, the Part D sponsor's written arrangements with that organization must state that the CMS-contracting Part D plan sponsor retains the right to approve, suspend, or terminate any such arrangement.

(j) *Additional contract terms.* The Part D plan sponsor agrees to include in the contract other terms and conditions as CMS may find necessary and appropriate in order to implement requirements in this part.

(k) *Certification of data that determine payment.*

(1) *General rule.* As a condition for receiving a monthly payment under subpart G of this part (or for fallback entities, payment under subpart Q of this part),, the Part D plan sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data may include specified enrollment information, claims data, bid submission data, and other data that CMS specifies.

(2) *Certification of enrollment and payment information.* The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that each enrollee for whom the organization is requesting payment is validly enrolled in a program offered by the organization and the information CMS relies on in determining payment is accurate, complete, and truthful and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.

(3) *Certification of claims data.* The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits under § 423.329(b)(3) (or for fallback entities, under § 423.871(f)) are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement. If the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement.

(4) *Certification of bid submission information.* The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information in its bid submission and assumptions related to projected reinsurance and low income cost sharing subsidies is accurate, complete, and truthful and fully conforms to the requirements in § 423.265.

(5) *Certification of allowable costs for risk corridor and reinsurance information.* The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information provided for purposes of supporting allowable costs, as defined in § 423.308, is accurate, complete, and truthful and fully conforms to the requirements in § 423.336 and § 423.343 and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.

(6) *Certification of Accuracy of Data for Price Comparison.* The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information provided for purposes of

price comparison is accurate, complete, and truthful.

§ 423.506 Effective date and term of contract.

(a) *Effective date.* The contract is effective on the date specified in the contract between the Part D plan sponsor and CMS.

(b) *Term of contract.* Each contract is for a period of 12 months.

(c) *Qualification to renew a contract.* In accordance with § 423.507 of this subpart, an entity is determined qualified to renew its contract annually only if—

(1) CMS informs the Part D plan sponsor that it is qualified to renew its contract; and

(2) The Part D plan sponsor has not provided CMS with a notice of intention not to renew.

(d) *Renewal of contract contingent on reaching agreement on the bid.* Although a Part D plan sponsor may be determined qualified to renew its contract under this section, if the sponsor and CMS cannot reach agreement on the bid under subpart F, no renewal takes place, and the failure to reach agreement is not subject to the appeals provisions in subpart N of this part.

(e) The provisions of this section do not apply to fallback entities.

§ 423.507 Nonrenewal of contract.

(a) *Nonrenewal by a Part D plan sponsor.* (1) Except for fallback entities, a Part D plan sponsor may elect not to renew its contract with CMS, effective at the end of the term of the contract for any reason provided it meets the timeframes for doing so set forth in paragraphs (a)(2) and (a)(3) of this section.

(2) If a Part D plan sponsor does not intend to renew its contract, it must notify—

(i) CMS in writing by the first Monday of June in the year in which the contract ends;

(ii) Each Medicare enrollee, at least 90 days before the date on which the nonrenewal is effective. This notice must include a written description of alternatives available for obtaining qualified prescription drug coverage within the PDP region, including MA-PD plans , and other PDPs, and must receive CMS approval prior to issuance; and

(iii) The general public, at least 90 days before the end of the current calendar year, by publishing a notice in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.

(3) If a Part D plan sponsor does not renew a contract under this paragraph (a), CMS cannot enter into a contract with the organization for 2 years unless there are special circumstances that warrant special consideration, as determined by CMS.

(4) If a Part D plan sponsor does not renew a contract under this paragraph (a), it must ensure the timely transfer of any data or files.

(b) *CMS decision that a Part D plan sponsor is not qualified to renew.* (1) Except for fallback entities, CMS may determine that a Part D plan sponsor is not qualified to renew its contract for any of the following reasons:

(i) The reasons listed in § 423.509(a) that also permit CMS to terminate the contract.

(ii) The Part D plan sponsor has committed any of the acts in § 423.752 that support the imposition of intermediate sanctions or civil money penalties under § 423.750.

(2) *Notice of decision.* CMS provides notice of its decision of whether a Part D plan sponsor is qualified to renew its contract as follows:

(i) To the Part D plan sponsor by May 1 of the current contract year.

(ii) If CMS decides that a Part D plan sponsor is not qualified to renew its contract, to the Part D plan sponsor's Medicare enrollees by mail at least 90 days before the end of the current calendar year.

(iii) If CMS determines that the Part D plan sponsor is not qualified to renew its contract, to the general public at least 90 days before the end of the current calendar year, by publishing a notice in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.

(iv) The notice provisions in paragraphs (b)(2)(ii) and (iii) of this section also apply in cases where a non-renewal results because CMS and the Part D plan sponsor are unable to reach agreement on the bid under subpart F.

(3) *Notice of appeal rights.* CMS gives the Part D plan sponsor written notice of its right to appeal the decision that the sponsor is not qualified renew its contract in accordance with § 423.642(b).

§ 423.508 Modification or termination of contract by mutual consent.

(a) *General rule.* A contract may be modified or terminated at any time by written mutual consent.

(b) *Notification of termination.* If the contract is terminated by mutual consent, the Part D plan sponsor must provide notice to its Medicare enrollees and the general public as provided in paragraph (c) of this section.

(c) *Notification of modification.* If the contract is modified by mutual consent, the Part D plan sponsor must notify its Medicare enrollees of any changes that CMS determines are appropriate for notification within timeframes specified by CMS.

(d) *Timely transfer of data and files.* If a contract is terminated under paragraph (a) of this section, the Part D plan sponsor must ensure the timely transfer of any data or files.

§ 423.509 Termination of contract by CMS.

(a) *Termination by CMS.* CMS may terminate a contract for any of the following reasons if the Part D sponsor—

(1) Failed substantially to carry out the terms of its contract with CMS;

(2) Is carrying out its contract with CMS in a manner that is inconsistent with the effective and efficient implementation of this part;

(3) No longer meets the requirements of this part for being a contracting organization;

(4) There is credible evidence that the Part D sponsor committed or participated in false, fraudulent, or abusive activities affecting the Medicare program, including submission of false or fraudulent data;

(5) Experiences financial difficulties so severe that its ability to provide necessary prescription drug coverage is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that a risk to health exists;

(6) Substantially fails to comply with the requirements in subpart M of this part relating to grievances and appeals;

(7) Fails to provide CMS with valid risk adjustment, reinsurance and risk corridor related data as required under § 423.322 and § 423.329 (or, for fallback entities, fails to provide the information in § 423.871(f)).

(8) Substantially fails to comply with the service access requirements in § 423.120;

(9) Substantially fails to comply with the marketing requirements in § 423.128;

(10) Substantially fails to comply with the coordination with plans and programs that provide prescription drug coverage as described in subpart J of this part; or

(11) Substantially fails to comply with the cost and utilization management, quality improvement, medication therapy management and fraud, abuse and waste program requirements as specified in subparts D and K of this part.

(b) *Notice of termination.* If CMS decides to terminate a contract for

reasons other than the grounds specified in paragraph (a)(4) or (a)(5) of this section, it gives notice of the termination as follows:

(1) *Termination of contract by CMS.* (i) CMS notifies the Part D plan in writing 90 days before the intended date of the termination.

(ii) The Part D plan sponsor notifies its Medicare enrollees of the termination by mail at least 30 days before the effective date of the termination.

(iii) The Part D plan sponsor notifies the general public of the termination at least 30 days before the effective date of the termination by publishing a notice in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.

(iv) If a Part D plan sponsor's contract is terminated under paragraph (a) of this section, it must ensure the timely transfer of any data or files.

(2) *Immediate termination of contract by CMS.* (i) For terminations based on violations specified in paragraph (a)(4) or paragraph (a)(5) of this section, CMS notifies the Part D plan sponsor in writing that its contract is terminated effective the date of the termination decision by CMS. If termination is effective in the middle of a month, CMS has the right to recover the prorated share of the prospective monthly payments made to the Part D sponsor covering the period of the month following the contract termination.

(ii) CMS notifies the Part D plan sponsor's Medicare enrollees in writing of CMS's decision to terminate the Part D plan sponsor's contract. This notice occurs no later than 30 days after CMS notifies the plan of its decision to terminate the Part D plan sponsor's contract. CMS simultaneously informs the Medicare enrollees of alternative options for obtaining qualified prescription drug coverage, including alternative PDP sponsors and MA-PDs in a similar geographic area.

(iii) CMS notifies the general public of the termination no later than 30 days after notifying the plan of CMS's decision to terminate the Part D plan sponsor's contract. This notice is published in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.

(c) *Corrective action plan.* (1) *General rule.* Before terminating a contract for reasons other than the grounds specified in paragraph (a)(4) or (a)(5) of this section, CMS provides the Part D plan sponsor with reasonable opportunity to develop and receive CMS approval of a corrective action plan to correct the deficiencies that are the basis of the proposed termination.

(2) *Exception.* If a contract is terminated under paragraph (a)(4) or (a)(5) of this section, the Part D plan sponsor does not have the opportunity to submit a corrective action plan.

(d) *Appeal rights.* If CMS decides to terminate a contract, it sends written notice to the Part D plan sponsor informing it of its termination appeal rights in accordance with § 423.642.

§ 423.510 Termination of contract by the Part D sponsor.

(a) *Cause for termination.* The Part D plan sponsor may terminate its contract if CMS fails to substantially carry out the terms of the contract.

(b) *Notice of termination.* The Part D plan sponsor must give advance notice as follows:

(1) To CMS, at least 90 days before the intended date of termination. This notice must specify the reasons why the Part D sponsor is requesting contract termination.

(2) To its Medicare enrollees, at least 60 days before the termination effective date. This notice must include a written description of alternatives available for obtaining qualified prescription drug coverage within the services area, including alternative PDPs, MA-PDPs, and original Medicare and must receive CMS approval.

(3) To the general public, at least 60 days before the termination effective date by publishing a CMS-approved notice in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's geographic area.

(c) *Effective date of termination.* The effective date of the termination is determined by CMS and is at least 90 days after the date CMS receives the Part D plan sponsor's notice of intent to terminate.

(d) *CMS's liability.* CMS's liability for payment to the Part D plan sponsor ends as of the first day of the month after the last month for which the contract is in effect.

(e) *Effect of termination by the organization.* CMS does not enter into an agreement with an organization that has terminated its contract within the preceding 2 years unless there are circumstances that warrant special consideration, as determined by CMS.

(f) *Timely transfer of data and files.* If a contract is terminated under paragraph (a) of this section, the Part D plan sponsor must ensure the timely transfer of any data or files.

§ 423.512 Minimum enrollment requirements.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, CMS does not enter into a contract under this subpart unless the organization meets the following minimum enrollment requirement:

(1) At least 5,000 individuals are enrolled for the purpose of receiving prescription drug benefits from the organization; or

(2) At least 1,500 individuals are enrolled for purposes of receiving prescription drug benefits from the organization and the organization primarily serves individuals residing outside of urbanized areas as defined in § 412.62(f) of this chapter;

(3) Except as provided for in paragraph (b) of this section, a Part D plan sponsor must maintain a minimum enrollment as defined in paragraphs (a)(1) and (a)(2) of this section for the duration of its contract.

(b) *Minimum enrollment waiver.* CMS waives the requirement of paragraphs (a)(1) and (a)(2) of this section during the first contract year for a sponsor in a region.

§ 423.514 Reporting requirements.

(a) *Required information.* Each Part D plan sponsor must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, statistics indicating the following—

(1) The cost of its operations.

(2) The patterns of utilization of its services.

(3) The availability, accessibility, and acceptability of its services.

(4) Information demonstrating that the Part D plan sponsor has a fiscally sound operation.

(5) Other matters that CMS may require.

(b) *Significant business transactions.* Each Part D plan sponsor must report to CMS annually, within 120 days of the end of its fiscal year (unless, for good cause shown, CMS authorizes an extension of time), the following:

(1) A description of significant business transactions, as defined in § 423.501, between the Part D plan sponsor and a party in interest, including the following:

(i) Indication that the costs of the transactions listed in paragraph (c) of this section do not exceed the costs that would be incurred if these transactions were with someone who is not a party in interest; or

(ii) If they do exceed, a justification that the higher costs are consistent with

prudent management and fiscal soundness requirements.

(2) A combined financial statement for the Part D plan sponsor and a party in interest if either of the following conditions is met:

(i) Thirty five percent or more of the costs of operation of the Part D sponsor go to a party in interest.

(ii) Thirty five percent or more of the revenue of a party in interest is from the Part D plan sponsor.

(c) *Requirements for combined financial statements.* (1) The combined financial statements required by paragraph (b)(2) of this section must display in separate columns the financial information for the Part D plan sponsor and each of the parties in interest.

(2) Inter-entity transactions must be eliminated in the consolidated column.

(3) The statements must be examined by an independent auditor in accordance with generally accepted accounting principles and must include appropriate opinions and notes.

(4) Upon written request from a Part D plan sponsor showing good cause, CMS may waive the requirement that the organization's combined financial statement include the financial information required in this paragraph (c) of this section for a particular entity.

(d) *Reporting and disclosure under Employee Retirement Income Security Act of 1974 (ERISA).* (1) For any employees' health benefits plan that includes a Part D plan sponsor in its offerings, the PDP sponsor must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (for the particular PDP sponsor) under the Employee Retirement Income Security Act of 1974 (ERISA).

(2) The PDP sponsor must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term ''administrator'' is defined in ERISA.

(e) *Loan information.* Each Part D plan sponsor must notify CMS of any loans or other special financial arrangements it makes with contractors, subcontractors and related entities.

(f) *Enrollee access to information.* Each Part D plan sponsor must make the information reported to CMS under this section available to its enrollees upon reasonable request.

§ 423.516 Prohibition of midyear implementation of significant new regulatory requirements.

CMS may not implement, other than at the beginning of a calendar year, regulations under this section that impose new, significant regulatory requirements on a PDP sponsor or a prescription drug plan.

Subpart L—Effect of Change of Ownership or Leasing of Facilities During Term of Contract

§ 423.551 General provisions.

(a) *Change of ownership.* The following constitute a change of ownership:

(1) *Partnership.* The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law, constitutes a change of ownership.

(2) *Asset transfer.* Transfer of substantially all the assets of the sponsor to another party constitutes a change of ownership.

(3) *Corporation.* The merger of the PDP sponsor's corporation into another corporation or the consolidation of the PDP sponsor's organization with one or more other corporations, resulting in a new corporate body.

(b) *Change of ownership, exception.* Transfer of corporate stock or the merger of another corporation into the PDP sponsor's corporation, with the PDP sponsor surviving, does not ordinarily constitute change of ownership.

(c) *Advance notice requirement.* (1) A PDP sponsor that has a Medicare contract in effect under § 423.502 and is considering or is negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change. The PDP sponsor must also provide updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) If the PDP sponsor fails to give CMS the required notice in a timely manner, it continues to be liable for payments that CMS makes to it on behalf of Medicare enrollees after the date of change of ownership.

(d) *Novation agreement defined.* A novation agreement is an agreement among the current owner of the PDP sponsor, the prospective new owner, and CMS that—

(1) Is embodied in a document executed and signed by all 3 parties;

(2) Meets the requirements of § 423.552; and

(3) Recognizes the new owner as the successor in interest to the current owner's Medicare contract.

(e) *Effect of change of ownership without novation agreement.* Except to the extent provided in paragraph (c)(2) of this section, the effect of a change of ownership without a novation agreement is that—

(1) The existing contract becomes invalid; and

(2) If the new owner wishes to participate in the Medicare program, it must apply for, and enter into, a contract in accordance with subpart K of this part.

(f) *Effect of change of ownership with novation agreement.* If the PDP sponsor submits a novation agreement that meets the requirements of § 423.552 and CMS signs it, the new owner becomes the successor in interest to the current owner's Medicare contract under § 423.502.

§ 423.552 Novation agreement requirements.

(a) *Conditions for CMS approval of a novation agreement.* CMS approves a novation agreement if the following conditions are met:

(1) *Advance notification.* The PDP sponsor notifies CMS at least 60 days before the date of the proposed change of ownership. The PDP sponsor also provides CMS with updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) *Advance submittal of agreement.* The PDP sponsor submits to CMS, at least 30 days before the proposed change of ownership date, three signed copies of the novation agreement containing the provisions specified in paragraph (b) of this section, and one copy of other relevant documents required by CMS.

(3) *CMS's determination.* When reviewing a novation agreement, CMS makes a determination concerning the following:

(i) The proposed new owner is in fact a successor in interest to the contract.

(ii) Recognition of the new owner as a successor in interest to the contract is in the best interest of the Medicare program.

(iii) The successor organization meets the requirements to qualify as a PDP sponsor under subpart K of this part.

(b) *Provisions of a novation agreement.* A valid novation agreement requires the following:

(1) *Assumption of contract obligations.* The new owner must assume all obligations under the contract.

(2) *Waiver of right to reimbursement.* The previous owner must waive its rights to reimbursement for covered services furnished during the rest of the current contract period.

(3) *Guarantee of performance.* The previous owner must—

(i) Guarantee performance of the contract by the new owner during the contract period; or

(ii) Post a performance bond that is satisfactory to CMS.

(4) *Records access.* The previous owner must agree to make its books and records and other necessary information available to the new owner and to CMS to permit an accurate determination of costs for the final settlement of the contract period.

§ 423.553 Effect of leasing of a PDP sponsor's facilities.

(a) *General effect of leasing.* If a PDP sponsor leases all or part of its facilities to another entity, the other entity does not acquire PDP sponsor status under section 1860D–12(b) of the Act.

(b) *Effect of lease of all facilities.* (1) If a PDP sponsor leases all of its facilities to another entity, the contract terminates.

(2) If the other entity wishes to participate in Medicare as a PDP sponsor, it must apply for and enter into a contract in accordance with § 423.502.

(c) *Effect of partial lease of facilities.* If the PDP sponsor leases part of its facilities to another entity, its contract with CMS remains in effect while CMS surveys the PDP sponsor to determine whether it continues to be in compliance with the applicable requirements and qualifying conditions specified in subpart K of this part.

Subpart M—Grievances, Coverage Determinations, and Appeals

§ 423.560 Definitions.

As used in this subpart, unless the context indicates otherwise—

Appeal means any of the procedures that deal with the review of adverse coverage determinations made by the Part D plan sponsor on the benefits under a Part D plan the enrollee believes he or she is entitled to receive, including delay in providing or approving the drug coverage (when a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for the drug coverage, as defined in § 423.566(b). These procedures include redeterminations by the Part D plan sponsor, reconsiderations by the independent review entity, ALJ hearings, reviews by the Medicare Appeals Council (MAC), and judicial reviews.

Appointed representative means an individual either appointed by an enrollee or authorized under State or other applicable law to act on behalf of the enrollee in obtaining a coverage determination or in dealing with any of the levels of the appeals process. Unless otherwise stated in this subpart, the appointed representative has all of the rights and responsibilities of an enrollee in obtaining a coverage determination or in dealing with any of the levels of the appeals process, subject to the rules described in part 422, subpart M of this chapter.

Drug Use means an enrollee is receiving the drug in the course of treatment, including time off if it is part of the treatment.

Enrollee means a Part D eligible individual who has elected or has been enrolled in a Part D plan.

Grievance means any complaint or dispute, other than one that involves a coverage determination, expressing dissatisfaction with any aspect of the operations, activities, or behavior of a Part D plan sponsor, regardless of whether remedial action is requested.

Physician has the meaning given the term in section 1861(r) of the Act.

Projected value means the charges incurred by the enrollee and future charges that are incurred within 12 months from the date the request for coverage determination or exception is received by the plan. Projected value includes enrollee co-payments, all expenditures incurred after an enrollee's expenditures exceed the initial coverage limit, and expenditures paid by other entities.

Reconsideration means a review of an adverse coverage determination by an independent review entity (IRE), the evidence and findings upon which it was based, and any other evidence the enrollee submits or the IRE obtains.

Redetermination means a review of an adverse coverage determination by a Part D plan sponsor, the evidence and findings upon which it is based, and any other evidence the enrollee submits or the Part D plan sponsor obtains.

§ 423.562 General provisions.

(a) *Responsibilities of the Part D plan sponsor.* A Part D plan sponsor must meet all of the following requirements.

(1) A Part D plan sponsor, for each Part D plan that it offers, must establish and maintain—

(i) A grievance procedure as described in § 423.564 for addressing issues that do not involve coverage determinations;

(ii) A procedure for making timely coverage determinations, including determinations on requests for exceptions to a tiered cost-sharing structure or to a formulary; and

(iii) Appeal procedures that meet the requirements of this subpart for issues that involve coverage determinations.

(2) A Part D plan sponsor must ensure that all enrollees receive written information about the—

(i) Grievance and appeal procedures that are available to them through the Part D plan sponsor; and

(ii) Complaint process available to the enrollee under the QIO process as set forth under section 1154(a)(14) of the Act.

(3) A Part D plan sponsor must arrange with its network pharmacies to post or distribute notices instructing enrollees to contact their plans to obtain a coverage determination or request an exception if they disagree with the information provided by the pharmacist.

(4) In accordance with subpart K of this part, if the Part D plan sponsor delegates any of its responsibilities under this subpart to another entity or individual through which the Part D plan sponsor provides covered benefits, the Part D plan sponsor is ultimately responsible for ensuring that the entity or individual satisfies the relevant requirements of this subpart.

(b) *Rights of enrollees.* In accordance with the provisions of this subpart, enrollees have all of the following rights under Part D plans:

(1) The right to have grievances between the enrollee and the Part D plan sponsor heard and resolved by the plan sponsor, as described in § 423.564.

(2) The right to a timely coverage determination by the Part D plan sponsor, as specified in § 423.566 and § 423.568, including the right to request from the Part D plan sponsor an exception to its tiered cost-sharing structure or formulary, as specified in § 423.578.

(3) The right to request from the Part D plan sponsor an expedited coverage determination, as specified in § 423.570.

(4) If dissatisfied with any part of a coverage determination, all of the following appeal rights:

(i) The right to a redetermination of the adverse coverage determination by the Part D plan sponsor, as specified in § 423.580.

(ii) The right to request an expedited redetermination, as provided under § 423.584.

(iii) If, as a result of a redetermination, a Part D plan sponsor affirms, in whole or in part, its adverse coverage determination, the right to a reconsideration or expedited reconsideration by an independent review entity (IRE) contracted by CMS, as specified in § 423.600.

(iv) If the IRE affirms the plan's adverse coverage determination, in whole or in part, the right to an ALJ hearing if the amount in controversy meets the requirements in § 423.610.

(v) If the ALJ affirms the IRE's adverse coverage determination, in whole or in part, the right to request MAC review of the ALJ hearing decision, as specified in § 423.620.

(vi) If the MAC affirms the ALJ's adverse coverage determination, in whole or in part, the right to judicial review of the hearing decision if the amount in controversy meets the requirements in § 423.630.

(c) *When other regulations apply.* Unless this subpart provides otherwise, the regulations in part 422, subpart M of this chapter (concerning the administrative review and hearing processes under titles II and XVIII, and representation of parties under title XVIII of the Act) and any interpretive rules or CMS rulings issued under these regulations, apply under this subpart to the extent they are appropriate.

(d) *Relation to ERISA Requirements.* Consistent with section 1860D–22(b) of the Act, provisions of this subpart may, to the extent applicable under the regulations adopted by the Secretary of Labor, apply to claims for benefits under group health plans subject to the Employee Retirement Income Security Act.

§ 423.564 Grievance procedures.

(a) *General rule.* Each Part D plan sponsor must provide meaningful procedures for timely hearing and resolving grievances between enrollees and the Part D plan sponsor or any other entity or individual through whom the Part D plan sponsor provides covered benefits under any Part D plan it offers.

(b) *Distinguished from appeals.* Grievance procedures are separate and distinct from appeal procedures, which address coverage determinations as defined in § 423.566(b). Upon receiving a complaint, a Part D plan sponsor must promptly determine and inform the enrollee whether the complaint is subject to its grievance procedures or its appeal procedures.

(c) *Distinguished from the quality improvement organization complaint process.* Under section 1154(a)(14) of the Act, the quality improvement organization (QIO) must review enrollees' written complaints about the quality of services they have received under the Medicare program. This process is separate and distinct from the grievance procedures of the Part D plan sponsor. For quality of care issues, an enrollee may file a grievance with the Part D plan sponsor, file a written complaint with the QIO, or both. For any complaint submitted to a QIO, the Part D plan sponsor must cooperate with the QIO in resolving the complaint.

(d) *Method for filing a grievance.* (1) An enrollee may file a grievance with the Part D plan sponsor either orally or in writing.

(2) An enrollee must file a grievance no later than 60 days after the event or incident that precipitates the grievance.

(e) *Grievance disposition and notification.* (1) The Part D plan sponsor must notify the enrollee of its decision as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 days after the date the Part D plan sponsor receives the oral or written grievance.

(2) The Part D plan sponsor may extend the 30-day timeframe by up to 14 days if the enrollee requests the extension or if the Part D plan sponsor justifies a need for additional information and documents how the delay is in the interest of the enrollee. When the Part D plan sponsor extends the deadline, it must immediately notify the enrollee in writing of the reason(s) for the delay.

(3) The Part D plan sponsor must inform the enrollee of the disposition of the grievance in accordance with the following procedures:

(i) All grievances submitted in writing must be responded to in writing.

(ii) Grievances submitted orally may be responded to either orally or in writing, unless the enrollee requests a written response.

(iii) All grievances related to quality of care, regardless of how the grievance is filed, must be responded to in writing. The response must include a description of the enrollee's right to file a written complaint with the QIO. For any complaint submitted to a QIO, the Part D plan sponsor must cooperate with the QIO in resolving the complaint.

(f) *Expedited grievances.* A Part D plan sponsor must respond to an enrollee's grievance within 24 hours if the complaint involves a refusal by the Part D plan sponsor to grant an enrollee's request for an expedited coverage determination under § 423.570 or an expedited redetermination under § 423.584, and the enrollee has not yet purchased or received the drug that is in dispute.

(g) *Record keeping.* The Part D plan sponsor must have an established process to track and maintain records on all grievances received both orally and in writing, including, at a minimum, the date of receipt, final disposition of the grievance, and the date that the enrollee was notified of the disposition.

§ 423.566 Coverage determinations.

(a) Responsibilities of the Part D plan sponsor. Each Part D plan sponsor must have a procedure for making timely coverage determinations in accordance with the requirements of this subpart regarding the prescription drug benefits an enrollee is entitled to receive under the plan, including basic prescription drug coverage as specified in § 423.100 and supplemental benefits as specified in § 423.104(f)(1)(ii), and the amount, including cost sharing, if any, that the enrollee is required to pay for a drug. The Part D plan sponsor must have a standard procedure for making determinations, in accordance with § 423.568, and an expedited procedure for situations in which applying the standard procedure may seriously jeopardize the enrollee's life, health, or ability to regain maximum function, in accordance with § 423.570.

(b) Actions that are coverage determinations. The following actions by a Part D plan sponsor are coverage determinations:

(1) A decision not to provide or pay for a Part D drug (including a decision not to pay because the drug is not on the plan's formulary, because the drug is determined not to be medically necessary, because the drug is furnished by an out-of-network pharmacy, or because the Part D plan sponsor determines that the drug is otherwise excludable under section 1862(a) of the Act if applied to Medicare Part D) that the enrollee believes may be covered by the plan;

(2) Failure to provide a coverage determination in a timely manner, when a delay would adversely affect the health of the enrollee;

(3) A decision concerning an exceptions request under § 423.578(a);

(4) A decision concerning an exceptions request under § 423.578(b); or

(5) A decision on the amount of cost sharing for a drug.

(c) Who can request a coverage determination. Individuals who can request a standard or expedited coverage determination are—

(1) The enrollee;

(2) The enrollee's appointed representative, on behalf of the enrollee; or

(3) The prescribing physician, on behalf of the enrollee.

§ 423.568 Standard timeframe and notice requirements for coverage determinations.

(a) *Timeframe for requests for drug benefits.* When a party makes a request for a drug benefit, the Part D plan sponsor must notify the enrollee (and the prescribing physician involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request, or, for an exceptions request, the physician's supporting statement.

(b) *Timeframe for requests for payment.* When a party makes a request

for payment, the Part D plan sponsor must notify the enrollee of its determination no later than 72 hours after receipt of the request.

(c) *Written notice for denials by a Part D plan sponsor.* If a Part D plan sponsor decides to deny a drug benefit, in whole or in part, it must give the enrollee written notice of the determination.

(d) *Form and content of the denial notice.* The notice of any denial under paragraph (c) of this section must—

Use approved notice language in a readable and understandable form;

State the specific reasons for the denial;

Inform the enrollee of his or her right to a redetermination;

(i) For drug coverage denials, describe both the standard and expedited redetermination processes, including the enrollee's right to, and conditions for, obtaining an expedited redetermination and the rest of the appeals process;

(ii) For payment denials, describe the standard redetermination process and the rest of the appeals process; and

Comply with any other notice requirements specified by CMS.

(e) *Effect of failure to meet the adjudicatory timeframes.* If the Part D plan sponsor fails to notify the enrollee of its determination in the appropriate timeframe under paragraphs (a) or (b) of this section, the failure constitutes an adverse coverage determination, and the plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

§ 423.570 Expediting certain coverage determinations.

(a) *Request for expedited determination.* An enrollee or an enrollee's prescribing physician may request that a Part D plan sponsor expedite a coverage determination involving issues described in § 423.566(b). This does not include requests for payment of Part D drugs already furnished.

(b) *How to make a request.* (1) To ask for an expedited determination, an enrollee or an enrollee's prescribing physician on behalf of the enrollee must submit an oral or written request directly to the Part D plan sponsor, or if applicable, to the entity responsible for making the determination, as directed by the Part D plan sponsor.

(2) A prescribing physician may provide oral or written support for an enrollee's request for an expedited determination.

(c) *How the Part D plan sponsor must process requests.* The Part D plan sponsor must establish and maintain the following procedures for processing requests for expedited determinations:

(1) An efficient and convenient means for accepting oral or written requests submitted by enrollees or prescribing physicians.

(2) A method for documenting all oral requests and maintaining the documentation in the case file; and

(3) A means for issuing prompt decisions on expediting a determination, based on the following requirements:

(i) For a request made by an enrollee, provide an expedited determination if it determines that applying the standard timeframe for making a determination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by an enrollee's prescribing physician, provide an expedited determination if the physician indicates that applying the standard timeframe for making a determination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial.* If a Part D plan sponsor denies a request for expedited determination, it must take the following actions:

(1) Make the determination within the 72 hour timeframe established in § 423.568(a) for a standard determination. The 72 hour period begins on the day the Part D plan sponsor receives the request for expedited determination, or, for an exceptions request, the physician's supporting statement.

(2) Give the enrollee and prescribing physician prompt oral notice of the denial that—

(i) Explains that the Part D plan sponsor must process the request using the 72 hour timeframe for standard determinations;

(ii) Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the decision by the Part D plan sponsor not to expedite;

(iii) Informs the enrollee of the right to resubmit a request for an expedited determination with the prescribing physician's support; and

(iv) Provides instructions about the plan's grievance process and its timeframes.

(3) Subsequently deliver, within 3 calendar days, equivalent written notice.

(e) *Actions on accepted requests for expedited determination.* If a Part D plan sponsor grants a request for expedited determination, it must make the determination and give notice in accordance with § 423.572.

§ 423.572 Timeframes and notice requirements for expedited coverage determinations.

(a) *Timeframe for determinations and notification.* Except as provided in paragraph (b) of this section, a Part D plan sponsor that approves a request for expedited determination must make its determination and notify the enrollee (and the prescribing physician involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request, or, for an exceptions request, the physician's supporting statement.

(b) *Confirmation of oral notice.* If the Part D plan sponsor first notifies an enrollee of an adverse expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

(c) Content of the notice of expedited determination.

(1) The notice of any expedited determination must state the specific reasons for the determination in understandable language.

(2) If the determination is not completely favorable to the enrollee, the notice must—

(i) Inform the enrollee of his or her right to a redetermination;

(ii) Describe both the standard and expedited redetermination processes, including the enrollee's right to request, and conditions for obtaining, an expedited redetermination, and the rest of the appeal process; and

(iii) Comply with any other requirements specified by CMS.

(d) *Effect of failure to meet the adjudicatory timeframes.* If the Part D plan sponsor fails to notify the enrollee of its determination in the timeframe specified in paragraph (a) of this section, the failure constitutes an adverse coverage determination, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

§ 423.576 Effect of a coverage determination.

The coverage determination is binding on the Part D plan sponsor and the enrollee unless it is reviewed and revised under § 423.580 through § 423.630 or is reopened and revised under § 423.634.

§ 423.578 Exceptions process.

(a) *Requests for exceptions to a plan's tiered cost-sharing structure.* Each Part D plan sponsor that provides prescription drug benefits for Part D

drugs and manages this benefit through the use of a tiered formulary must establish and maintain reasonable and complete exceptions procedures subject to CMS' approval for this type of coverage determination. The Part D plan sponsor grants an exception whenever it determines that the non-preferred drug for treatment of the enrollee's condition is medically necessary, consistent with the physician's statement under paragraph (a)(4) of this section.

(1) The exceptions procedures must address situations where a formulary's tiering structure changes during the year and an enrollee is using a drug affected by the change.

(2) The exceptions criteria of a Part D plan sponsor must include, but are not limited to—

(i) A description of the criteria a Part D plan sponsor uses to evaluate a determination made by the enrollee's prescribing physician under paragraph (a)(4) of this section.

(ii) Consideration of whether the requested Part D drug that is the subject of the exceptions request is the therapeutic equivalent, as defined in § 423.100, of any other drug on the plan's formulary.

(iii) Consideration of the number of drugs on the plan's formulary that are in the same class and category as the requested prescription drug that is the subject of the exceptions request.

(3) An enrollee or the enrollee's prescribing physician may file a request for an exception.

(4) A prescribing physician must provide an oral or written supporting statement that the preferred drug for the treatment of the enrollee's condition—

(i) Would not be as effective for the enrollee as the requested drug;

(ii) Would have adverse effects for the enrollee; or

(iii) Both paragraphs (a)(4)(i) and (a)(4)(ii) of this section apply.

(5) If the physician provides an oral supporting statement, the Part D plan sponsor may require the physician to subsequently provide a written supporting statement to demonstrate the medical necessity of the drug. The Part D plan sponsor may require the prescribing physician to provide additional supporting medical documentation as part of the written follow-up.

(6) In no case is a Part D plan sponsor required to cover a non-preferred drug at the generic drug cost-sharing level if the plan maintains a separate tier dedicated to generic drugs.

(7) If a Part D plan sponsor maintains a formulary tier in which it places very high cost and unique items, such as genomic and biotech products, the sponsor may design its exception process so that very high cost or unique drugs are not eligible for a tiering exception.

(b) *Request for exceptions involving a non-formulary Part D drug.* Each Part D plan sponsor that provides prescription drug benefits for Part D drugs and manages this benefit through the use of a formulary must establish and maintain exceptions procedures subject to CMS' approval for receipt of an off-formulary drug. The Part D plan sponsor must grant an exception whenever it determines that the drug is medically necessary, consistent with the physician's statement under paragraph (b)(5) of this section, and that the drug would be covered but for the fact that it is an off-formulary drug. Formulary use includes the application of cost utilization tools, such as a dose restriction, including the dosage form, that causes a particular Part D drug not to be covered for the number of doses prescribed or a step therapy requirement that causes a particular Part D drug not to be covered until the requirements of the plan's coverage policy are met, or a therapeutic substitution requirement.

(1) The plan's formulary exceptions process must address each of the following circumstances:

(i) Situations where a formulary changes during the year, and situations where an enrollee is already using a given drug.

(ii) Continued coverage of a particular Part D prescription drug that the Part D plan sponsor is discontinuing coverage on the formulary for reasons other than safety or because the Part D prescription drug cannot be supplied by or was withdrawn from the market by the drug's manufacturer.

(iii) An exception to a plan's coverage policy that causes a Part D prescription drug not to be covered because of cost utilization tools, such as a requirement for step therapy, dosage limitations, or therapeutic substitution.

(2) The exception criteria of a Part D plan sponsor must include, but are not limited to—

(i) A description of the criteria a Part D plan sponsor uses to evaluate a prescribing physician's determination made under paragraph (b)(5) of this section;

(ii) A process for gathering and comparing applicable medical and scientific evidence on the safety and effectiveness of the requested non-formulary drug with the formulary drug for the enrollee, including safety information generated by an authoritative government body; and

(iii) A description of the cost-sharing scheme that will be applied when coverage is provided for a non-formulary drug.

(3) If the Part D plan sponsor covers a non-formulary drug, the cost(s) incurred by the enrollee for that drug are treated as being included for purposes of calculating and meeting the annual out-of-pocket threshold.

(4) An enrollee, the enrollee's appointed representative, or the prescribing physician (on behalf of the enrollee) may file a request for an exception.

(5) A prescribing physician must provide an oral or written supporting statement that the requested prescription drug is medically necessary to treat the enrollee's disease or medical condition because—

(i) All of the covered Part D drugs on any tier of a plan's formulary for treatment for the same condition would not be as effective for the enrollee as the non-formulary drug, would have adverse effects for the enrollee, or both;

(ii) The prescription drug alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements—

(A) Has been ineffective in the treatment of the enrollee's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the enrollee and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or

(B) Has caused or based on sound clinical evidence and medical and scientific evidence, is likely to cause an adverse reaction or other harm to the enrollee; or

(iii) The number of doses that is available under a dose restriction for the prescription drug has been ineffective in the treatment of the enrollee's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the enrollee and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance.

(6) If the physician provides an oral supporting statement, the Part D plan sponsor may require the physician to subsequently provide a written supporting statement. The Part D plan sponsor may require the prescribing physician to provide additional supporting medical documentation as part of the written follow-up.

(c) *Requirements for exceptions.* (1) *General rule.* A decision by a Part D

plan sponsor concerning an exceptions request under this section constitutes a coverage determination as specified at § 423.566.

(2) When a Part D plan sponsor does not make a timely decision. If the Part D plan sponsor fails to make a decision on an exceptions request and provide notice of the decision within the timeframe required under § 423.568(a) or § 423.572(a), as applicable, the failure constitutes an adverse coverage determination, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

(3) *When a tiering exceptions request is approved.* Whenever an exceptions request made under § 423.578(a) is approved, the Part D plan sponsor must provide coverage for the approved prescription drug at the cost-sharing level that applies for preferred drugs, and may not require the enrollee to request approval for a refill, or a new prescription to continue using the Part D prescription drug after the refills for the initial prescription are exhausted, as long as—

(i) The enrollee's prescribing physician continues to prescribe the drug;

(ii) The drug continues to be considered safe for treating the enrollee's disease or medical condition; and

(iii) The enrollment period has not expired. If an enrollee renews his or her membership after the plan year, the plan may choose to continue coverage into the subsequent plan year.

(4) *When a non-formulary exceptions request is approved.* Whenever an exceptions request made under § 423.578(b) is approved—

(i) The Part D plan sponsor may not require the enrollee to request approval for a refill, or a new prescription to continue using the Part D prescription drug after the refills for the initial prescription are exhausted, as long as—

(A) The enrollee's prescribing physician continues to prescribe the drug;

(B) The drug continues to be considered safe for treating the enrollee's disease or medical condition; and

(C) The enrollment period has not expired. If an enrollee renews his or her membership after the plan year, the plan may choose to continue coverage into the subsequent plan year.

(ii) The Part D plan sponsor must not establish a special formulary tier or co-payment or other cost-sharing requirement that is applicable only to prescription drugs approved for coverage under this section.

(iii) An enrollee may not request a tiering exception for a non-formulary prescription drug approved under § 423.578(b).

(d) *Notice regarding formulary changes.* Whenever a Part D plan sponsor removes a covered part D drug from its formulary or makes any changes in the preferred or tiered cost-sharing status of such a drug, the Part D plan sponsor must provide notice in accordance with § 423.120(b)(5).

(e) *Limitation of the exceptions procedures to Part D drugs.* Nothing in this section may be construed to allow an enrollee to use the exceptions processes set out in this section to request or be granted coverage for a prescription drug that does not meet the definition of a Part D drug.

(f) *Implication of the physician's supporting statement.* Nothing in this section should be construed to mean that the physician's supporting statement required for an exceptions request will result in an automatic favorable determination.

§ 423.580 Right to a redetermination.

An enrollee who has received a coverage determination (including one that is reopened and revised as described in § 423.634) may request that it be redetermined under the procedures described in § 423.582, which address requests for a standard redetermination. An enrollee or an enrollee's prescribing physician (acting on behalf of an enrollee) may request an expedited redetermination specified in § 423.584.

§ 423.582 Request for a standard redetermination.

(a) *Method and place for filing a request.* An enrollee must ask for a redetermination by making a written request with the Part D plan sponsor that made the coverage determination. The Part D plan sponsor may adopt a policy for accepting oral requests.

(b) *Timeframe for filing a request.* Except as provided in paragraph (c) of this section, an enrollee must file a request for a redetermination within 60 calendar days from the date of the notice of the coverage determination.

(c) *Extending the time for filing a request.* (1) *General rule.* If an enrollee shows good cause, the Part D plan sponsor may extend the timeframe for filing a request for redetermination.

(2) *How to request an extension of timeframe.* If the 60-day period in which to file a request for a redetermination has expired, an enrollee may file a request for redetermination and extension of time frame with the Part D plan sponsor. The request for redetermination and to extend the timeframe must—

(i) Be in writing; and

(ii) State why the request for redetermination was not filed on time.

(d) *Withdrawing a request.* The person who files a request for redetermination may withdraw it by filing a written request with the Part D sponsor.

§ 423.584 Expediting certain redeterminations.

(a) *Who may request an expedited redetermination.* An enrollee or an enrollee's prescribing physician may request that a Part D plan sponsor expedite a redetermination that involves the issues specified in § 423.566(b). (This does not include requests for payment of drugs already furnished.)

(b) *How to make a request.* (1) To ask for an expedited redetermination, an enrollee or a prescribing physician acting on behalf of an enrollee must submit an oral or written request directly to the Part D plan sponsor or, if applicable, to the entity responsible for making the redetermination, as directed by the Part D plan sponsor.

(2) A prescribing physician may provide oral or written support for an enrollee's request for an expedited redetermination.

(c) *How the Part D plan sponsor must process requests.* The Part D plan sponsor must establish and maintain the following procedures for processing requests for expedited redetermination:

(1) *Handling of requests.* The Part D plan sponsor must establish an efficient and convenient means for individuals to submit oral or written requests, document all oral requests in writing, and maintain the documentation in the case file.

(2) *Prompt decision making.* The Part D plan sponsor must promptly decide whether to expedite the redetermination or follow the timeframe for standard redetermination based on the following requirements:

(i) For a request made by an enrollee, the Part D plan sponsor must provide an expedited redetermination if it determines that applying the standard timeframe for making a redetermination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by a prescribing physician, the Part D plan sponsor must provide an expedited redetermination if the physician indicates that applying the standard timeframe for conducting a redetermination may seriously jeopardize the life or health of the

enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial of a request.* If a Part D plan sponsor denies a request for expedited redetermination, it must take the following actions:

(1) Make the determination within the 7-day timeframe established in § 423.590(a). The 7-day period begins the day the Part D plan sponsor receives the request for expedited redetermination.

(2) Give the enrollee prompt oral notice of the denial that—

(i) Explains that the Part D plan sponsor processes the enrollee's request using the 7-day timeframe for standard redetermination;

(ii) Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the decision by the Part D plan sponsor not to expedite;

(iii) Informs the enrollee of the right to resubmit a request for an expedited redetermination with the prescribing physician's support; and

(iv) Provides instructions about the expedited grievance process and its timeframes.

(3) Subsequently deliver, within three calendar days, equivalent written notice.

(e) *Action following acceptance of a request.* If a Part D plan sponsor grants a request for expedited redetermination, it must conduct the redetermination and give notice in accordance with § 423.590(d).

§ 423.586 Opportunity to submit evidence.

The Part D plan sponsor must provide the enrollee or the prescribing physician, as appropriate, with a reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing. In the case of an expedited redetermination, the opportunity to present evidence is limited by the short timeframe for making a decision. Therefore, the Part D plan sponsor must inform the enrollee or the prescribing physician of the conditions for submitting the evidence.

§ 423.590 Timeframes and responsibility for making redeterminations.

(a) *Standard redetermination—request for covered drug benefits.* (1) If the Part D plan sponsor makes a redetermination that is completely favorable to the enrollee, the Part D plan sponsor must notify the enrollee in writing of its redetermination (and effectuate it in accordance with § 423.636(a)(1)) as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for a standard redetermination.

(2) If the Part D plan sponsor makes a redetermination that affirms, in whole or in part, its adverse coverage determination, it must notify the enrollee in writing of its redetermination as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for a standard redetermination.

(b) *Standard redetermination—request for payment.* (1) If the Part D plan sponsor makes a redetermination that is completely favorable to the enrollee, the Part D plan sponsor must issue its redetermination (and effectuate it in accordance with § 423.636(a)(2)) no later than 7 calendar days from the date it receives the request for redetermination.

(2) If the Part D plan sponsor affirms, in whole or in part, its adverse coverage determination, it must notify the enrollee in writing of its redetermination no later than 7 calendar days from the date it receives the request for redetermination.

(c) *Effect of failure to meet timeframe for standard redeterminations.* If the Part D plan sponsor fails to provide the enrollee with a redetermination within the timeframes specified in paragraphs (a) or (b) of this section, the failure constitutes an adverse redetermination decision, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

(d) *Expedited redetermination.* (1) *Timeframe.* A Part D plan sponsor that approves a request for expedited redetermination must complete its redetermination and give the enrollee (and the prescribing physician involved, as appropriate), notice of its decision as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request.

(2) How the Part D plan sponsor must request additional information. If the Part D plan sponsor must receive medical information, the Part D plan sponsor must request the necessary information within 24 hours of the initial request for an expedited redetermination. Regardless of whether the Part D plan sponsor requests additional information, the Part D plan sponsor is responsible for meeting the timeframe and notice requirements.

(e) *Failure to meet timeframe for expedited redetermination.* If the Part D plan sponsor fails to provide the enrollee or the prescribing physician, as appropriate, with the results of its expedited redetermination within the timeframe described in paragraph (d) of this section, the failure constitutes an adverse redetermination decision, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

(f) *Who must conduct the review of an adverse coverage determination.* (1) A person or persons who were not involved in making the coverage determination must conduct the redetermination.

(2) When the issue is the denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the redetermination must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the redetermination need not, in all cases, be of the same specialty or subspecialty as the prescribing physician.

(g) *Form and content of an adverse redetermination notice.* The notice of any adverse determination under paragraphs (a)(2) or (b)(2) of this section must—

(1) Use approved notice language in a readable and understandable form;

(2) State the specific reasons for the denial;

(3) Inform the enrollee of his or her right to a reconsideration;

(i) For adverse drug coverage redeterminations, describe both the standard and expedited reconsideration processes, including the enrollee's right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeals process;

(ii) For adverse payment redeterminations, describe the standard reconsideration process and the rest of the appeals process; and

(4) Comply with any other notice requirements specified by CMS.

§ 423.600 Reconsideration by an independent review entity (IRE).

(a) An enrollee who is dissatisfied with the redetermination of a Part D plan sponsor has a right to a reconsideration by an independent review entity that contracts with CMS. An enrollee must file a written request for reconsideration with the IRE within 60 days of the date of the redetermination by the Part D plan sponsor.

(b) When an enrollee files an appeal, the IRE is required to solicit the views of the prescribing physician. The IRE may solicit the views of the prescribing physician orally or in writing. A written account of the prescribing physician's views (prepared by either the prescribing physician or IRE, as

appropriate) must be contained in the IRE's record.

(c) In order for an enrollee to request an IRE reconsideration of a determination by a Part D plan sponsor not to provide for a Part D drug that is not on the formulary, the prescribing physician must determine that all covered Part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual as the non-formulary drug, would have adverse effects for the individual, or both.

(d) The independent review entity must conduct the reconsideration as expeditiously as the enrollee's health condition requires but must not exceed the deadlines applicable in § 423.590, including those deadlines that are applicable when a request for an expedited reconsideration is received and granted.

(e) When the issue is the denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the reconsideration must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the reconsideration need not, in all cases, be of the same specialty or subspecialty as the prescribing physician.

§ 423.602 Notice of reconsideration determination by the independent review entity.

(a) *Responsibility for the notice.* When the IRE makes its reconsideration determination, it is responsible for mailing a notice of its determination to the enrollee and the Part D plan sponsor, and for sending a copy to CMS.

(b) *Content of the notice.* The notice must—

(1) State the specific reasons for the IRE's decision in understandable language;

(2) If the reconsideration determination is adverse (that is, does not completely reverse the adverse coverage determination by the Part D plan sponsor), inform the enrollee of his or her right to an ALJ hearing if the amount in controversy meets the threshold requirement under § 423.610;

(3) Describe the procedures that must be followed to obtain an ALJ hearing; and

(4) Comply with any other requirements specified by CMS.

§ 423.604 Effect of a reconsideration determination.

A reconsideration determination is final and binding on the enrollee and the Part D plan sponsor, unless the enrollee files a request for a hearing under the provisions of § 423.612.

§ 423.610 Right to an ALJ hearing.

(a) If the amount remaining in controversy after the IRE reconsideration meets the threshold requirement established annually by the Secretary, an enrollee who is dissatisfied with the IRE reconsideration determination has a right to a hearing before an ALJ.

(b) If the basis for the appeal is the refusal by the Part D plan sponsor to provide drug benefits, CMS uses the projected value of those benefits to compute the amount remaining in controversy. The projected value of a Part D drug or drugs shall include any costs the enrollee could incur based on the number of refills prescribed for the drug(s) in dispute during the plan year.

(c) *Aggregating appeals to meet the amount in controversy.* (1) *Enrollee.* Two or more appeals may be aggregated by an enrollee to meet the amount in controversy for an ALJ hearing if—

(i) The appeals have previously been reconsidered by an IRE;

(ii) The request for ALJ hearing lists all of the appeals to be aggregated and each aggregated appeal meets the filing requirement specified in § 423.612(b); and

(iii) The ALJ determines that the appeals the enrollee seeks to aggregate involve the delivery of prescription drugs to a single enrollee.

(2) *Multiple enrollees.* Two or more appeals may be aggregated by multiple enrollees to meet the amount in controversy for an ALJ hearing if—

The appeals have previously been reconsidered by an IRE;

The request for ALJ hearing lists all of the appeals to be aggregated and each aggregated appeal meets the filing requirement specified in § 423.612(b); and

The ALJ determines that the appeals the enrollees seek to aggregate involve the same prescription drug.

§ 423.612 Request for an ALJ hearing.

(a) *How and where to file a request.* The enrollee must file a written request for a hearing with the entity specified in the IRE's reconsideration notice.

(b) *When to file a request.* Except when an ALJ extends the timeframe as provided in part 422, subpart M of this chapter, the enrollee must file a request for a hearing within 60 days of the date of the notice of an IRE reconsideration determination. The time and place for a hearing before an ALJ will be set in accordance with § 405.1020 of this chapter.

(c) *Insufficient amount in controversy.* (1) If a request for a hearing clearly shows that the amount in controversy is less than that required under § 423.610, the ALJ dismisses the request.

(2) If, after a hearing is initiated, the ALJ finds that the amount in controversy is less than the amount required under § 423.610, the ALJ discontinues the hearing and does not rule on the substantive issues raised in the appeal.

§ 423.620 Medicare Appeals Council (MAC) review.

An enrollee who is dissatisfied with an ALJ hearing decision may request that the MAC review the ALJ's decision or dismissal. The regulations under part 422, subpart M of this chapter regarding MAC review apply to matters addressed by this subpart, to the extent applicable.

§ 423.630 Judicial review.

(a) *Review of ALJ's decision.* The enrollee may request judicial review of an ALJ's decision if—

(1) The MAC denied the enrollee's request for review; and

(2) The amount in controversy meets the threshold requirement established annually by the Secretary.

(b) *Review of MAC decision.* The enrollee may request judicial review of the MAC decision if it is the final decision of CMS and the amount in controversy meets the threshold established in paragraph (a)(2) of this section.

(c) How to request judicial review. In order to request judicial review, an enrollee must file a civil action in a district court of the United States in accordance with section 205(g) of the Act. (See part 422, subpart M of this chapter, for a description of the procedures to follow in requesting judicial review.)

§ 423.634 Reopening and revising determinations and decisions.

(a) A coverage determination or redetermination made by a Part D plan sponsor, a reconsideration made by the independent review entity specified in § 423.600, or the decision of an ALJ or the MAC that is otherwise final and binding may be reopened and revised by the entity that made the determination or decision, under the rules in part 422, subpart M of this chapter.

(b) The filing of a request for reopening does not relieve the Part D plan sponsor of its obligation to make payment or provide benefits as specified in § 423.636 or § 423.638.

(c) Once an entity issues a revised determination or decision, the revisions made by the decision may be appealed.

(d) A decision not to reopen by the Part D plan sponsor or any other entity is not subject to review.

§ 423.636 How a Part D plan sponsor must effectuate standard redeterminations, reconsiderations, or decisions.

(a) *Reversals by the Part D plan sponsor.* (1) *Requests for benefits.* If, on redetermination of a request for benefit, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for redetermination.

(2) *Requests for payment.* If, on redetermination of a request for payment, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize payment for the benefit within 7 calendar days from the date it receives the request for redetermination, and make payment no later than 30 calendar days after the date the plan sponsor receives the request for redetermination.

(b) *Reversals other than by the Part D plan sponsor.* (1) *Requests for benefits.* If, on appeal of a request for benefit, the determination by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must authorize or provide the benefit under dispute within 72 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

(2) *Requests for payment.* If, on appeal of a request for payment, the determination by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must authorize payment for the benefit within 72 hours, but make payment no later than 30 calendar days from the date it receives notice reversing the coverage determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

§ 423.638 How a Part D plan sponsor must effectuate expedited redeterminations or reconsiderations.

(a) *Reversals by the Part D plan sponsor.* If, on an expedited redetermination of a request for benefits, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 72 hours after the date the Part D plan sponsor receives the request for redetermination.

(b) *Reversals other than by the Part D plan sponsor.* If the expedited determination or expedited redetermination for benefits by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires but no later than 24 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

Subpart N—Medicare Contract Determinations and Appeals

§ 423.641 Contract determinations.

This subpart establishes the procedures for reviewing the following contract determinations:

(a) A determination that an entity is not qualified to enter into a contract with CMS under Part D of title XVIII of the Act.

(b) A determination not to authorize a renewal of a contract with a PDP sponsor in accordance with § 423.507(b).

(c) A determination to terminate a contract with a PDP sponsor in accordance with § 423.509.

(d) Fallback entities are governed under subpart Q of this part, and are not subject to this subpart, except to the extent a fallback prescription drug plan contract is terminated by CMS.

§ 423.642 Notice of contract determination.

(a) When CMS makes a contract determination under § 423.641, it gives the PDP sponsor written notice.

(b) The notice specifies the—

(1) Reasons for the determination; and

(2) PDP sponsor's right to request reconsideration.

(c) For CMS-initiated terminations, CMS mails notice 90 days before the anticipated effective date of the termination. For terminations based on initial determinations described at § 423.509(a)(4) or (a)(5), CMS immediately notifies the PDP sponsor of its decision to terminate the organization's PDP contract.

(d) When CMS determines that it is not going to authorize a contract renewal, CMS mails the notice to the PDP sponsor by May 1 of the current contract year.

§ 423.643 Effect of contract determination.

The contract determination is final and binding unless—

(a) The determination is reconsidered in accordance with § 423.644 through § 423.649;

(b) A timely request for a hearing is filed under § 423.651; or

(c) The reconsideration decision is revised as a result of a reopening under § 423.668.

§ 423.644 Reconsideration: Applicability.

(a) Reconsideration is the first step for appealing a contract determination specified in § 423.641.

(b) CMS reconsiders the specified determinations if the contract applicant or the PDP sponsor files a written request in accordance with § 423.645.

§ 423.645 Request for reconsideration.

(a) *Method and place for filing a request.* A request for reconsideration must be made in writing and filed with any CMS office.

(b) *Time for filing a request.* The request for reconsideration must be filed within 15 days from the date of the notice of the initial determination.

(c) *Proper party to file a request.* Only an authorized official of the contract applicant or PDP sponsor that was the subject of a contract determination may file the request for reconsideration.

(d) *Withdrawal of a request.* The PDP sponsor or contract applicant who filed the request for a reconsideration may withdraw it at any time before the notice of the reconsidered determination is mailed. The request for withdrawal must be in writing and filed with CMS.

§ 423.646 Opportunity to submit evidence.

CMS provides the PDP sponsor or contract applicant and the CMS official or officials who made the contract determination reasonable opportunity, not to exceed the timeframe in which a PDP sponsor chooses to request a hearing as described at § 423.651, to present as evidence any documents or written statements that are relevant and material to the matters at issue.

§ 423.647 Reconsidered determination.

A reconsidered determination is a new determination that—

(a) Is based on a review of the contract determination, the evidence and findings upon which that was based, and any other written evidence submitted before notice of the reconsidered determination is mailed, including facts relating to the status of the PDP sponsor subsequent to the contract determination; and

(b) Affirms, reverses, or modifies the initial determination.

(c) Any favorable redetermination, including those resulting from a hearing or Administrator review, must be made by July 15 for the contract in question to be effective on January of the following year.

§ 423.648 Notice of reconsidered determination.

(a) CMS gives the PDP sponsor or contract applicant written notice of the reconsidered determination.

(b) The notice—

(1) Contains findings for the contract applicant's qualifications to enter into, or the PDP sponsor's qualifications to remain under, a contract with CMS under Part D of the Act;

(2) States the specific reasons for the reconsidered determination; and

(3) Informs the PDP sponsor or contract applicant of its right to a hearing if it is dissatisfied with the determination.

§ 423.649 Effect of reconsidered determination.

A reconsidered determination is final and binding unless a request for a hearing is filed in accordance with § 423.651 or it is revised in accordance with § 423.668.

§ 423.650 Right to a hearing.

The following parties are entitled to a hearing:

(a) A contract applicant that is determined in a reconsidered determination to be unqualified to enter into a contract with CMS under Part D of title XVIII of the Act.

(b) A PDP sponsor whose contract with CMS is terminated or is not renewed as a result of a contract determination as provided in § 423.641.

§ 423.651 Request for hearing.

(a) *Method and place for filing a request.* A request for a hearing must be made in writing and filed by an authorized official of the contract applicant or PDP sponsor that was the party to the determination under appeal. The request for a hearing must be filed with any CMS office.

(b) *Time for filing a request.* A request for a hearing must be filed within 15 days after the date of the reconsidered determination.

(c) *Parties to a hearing.* The parties to a hearing must be—

(1) The parties described in § 423.650;

(2) At the discretion of the hearing officer, any interested parties who make a showing that their rights may be prejudiced by the decision to be rendered at the hearing; and

(3) CMS.

§ 423.652 Postponement of effective date of a contract determination when a request for a hearing for a contract determination is filed timely.

(a) CMS postpones the proposed effective date of the contract determination to terminate a contract with a PDP sponsor until a hearing decision is reached and affirmed by the Administrator following review under § 423.666 in instances where a PDP sponsor requests review by the Administrator; and

(b) CMS extends the current contract at the end of the contract period (in the case of a determination not to renew) only—

(1) If CMS finds that an extension of the contract is consistent with the purpose of this part; and

(2) For the period as CMS and the PDP sponsor agree.

(c) Exception: A contract terminated in accordance with § 423.509(a)(4) or (a)(5) is immediately terminated and is not postponed if a hearing is requested.

§ 423.653 Designation of hearing officer.

CMS designates a hearing officer to conduct the hearing. The hearing officer need not be an ALJ.

§ 423.654 Disqualification of hearing officer.

(a) A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(b) A party to the hearing who objects to the designated hearing officer must notify that officer in writing at the earliest opportunity.

(c) The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw.

(1) If the hearing officer withdraws, CMS designates another hearing officer to conduct the hearing.

(2) If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted in writing to CMS.

§ 423.655 Time and place of hearing.

(a) The hearing officer fixes a time and place for the hearing, which is not to exceed 30 days from the receipt of the request for the hearing, and sends written notice to the parties. The notice also informs the parties of the general and specific issues to be resolved and information about the hearing procedure.

(b) The hearing officer may, on his or her own motion, or at the request of a party, change the time and place for the hearing. The hearing officer may adjourn or postpone the hearing.

(c) The hearing officer gives the parties reasonable notice of any change in time or place of hearing, or of adjournment or postponement.

§ 423.656 Appointment of representatives.

A party may appoint as its representative at the hearing anyone not disqualified or suspended from acting as a representative before the Secretary or otherwise prohibited by law.

§ 423.657 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 423.656, on behalf of the represented party—

(1) Gives or accepts any notice or request pertinent to the proceedings set forth in this subpart;

(2) Presents evidence and allegations as to facts and law in any proceedings affecting that party; and

(3) Obtains information to the same extent as the party.

(b) A notice or request sent to the representative has the same force and effect as if it is sent to the party.

§ 423.658 Conduct of hearing.

(a) The hearing is open to the parties and to the public.

(b) The hearing officer inquires fully into all the matters at issue and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(c) The hearing officer provides the parties an opportunity to enter any objection to the inclusion of any document.

(d) The hearing officer decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

§ 423.659 Evidence.

The hearing officer rules on the admissibility of evidence and may admit evidence that is inadmissible under rules applicable to court procedures.

§ 423.660 Witnesses.

(a) The hearing officer may examine the witnesses.

(b) The parties or their representatives are permitted to examine their witnesses and cross-examine witnesses of other parties.

§ 423.661 Discovery.

(a) Prehearing discovery is permitted upon timely request of a party.

(b) A request is timely if it is made before the beginning of the hearing.

(c) A reasonable time for inspection and reproduction of documents is provided by order of the hearing officer.

(d) The hearing officer's order on all discovery matters is final.

§ 423.662 Prehearing.

The hearing officer may schedule a prehearing conference if he or she believes that a conference may more clearly define the issues.

§ 423.663 Record of hearing.

(a) A complete record of the proceedings at the hearing is made and transcribed and made available to all parties upon request.

(b) The record may not be closed until a hearing decision is issued.

§ 423.664 Authority of hearing officer.

In exercising his or her authority, the hearing officer must comply with the provisions of title XVIII and related provisions of the Act, the regulations issued by the Secretary, and general instructions issued by CMS in implementing the Act.

§ 423.665 Notice and effect of hearing decision.

(a) As soon as practical after the close of the hearing, the hearing officer issues a written decision that—

(1) Is based upon the evidence of record; and

(2) Contains separately numbered findings of fact and conclusions of law.

(b) The hearing officer provides a copy of the hearing decision to each party.

(c) The hearing decision is final and binding unless it is reversed or modified by the Administrator following review under § 423.666, or reopened and revised in accordance with § 423.668.

§ 423.666 Review by the Administrator.

(a) *Request for review by the Administrator.* A PDP sponsor that receives a hearing decision upholding a contract termination determination may request review by the Administrator within 15 days of receiving the hearing decision as provided under § 423.665(b).

(b) *Review by the Administrator.* The Administrator must review the hearing officer's decision, and determine, based upon this decision, the hearing record, and any written arguments submitted by the PDP sponsor, whether the termination decision must be upheld, reversed, or modified.

(c) *Decision by the Administrator.* The Administrator issues a written decision, and furnishes the decision to the PDP sponsor requesting review.

§ 423.667 Effect of Administrator's decision.

A decision by the Administrator under section § 423.666(c) is final and binding unless it is reopened and revised in accordance with § 423.668.

§ 423.668 Reopening of contract or reconsidered determination or decision of a hearing officer or the Administrator.

(a) *Initial or reconsidered determination.* CMS may reopen and revise an initial or reconsidered determination upon its own motion within 1 year of the date of the notice of determination.

(b) *Decision of hearing officer.* A decision of a hearing officer that is unfavorable to any party and is otherwise final may be reopened and revised by the hearing officer upon the officer's own motion within 1 year of the notice of the hearing decision. Another hearing officer designated by CMS may reopen and revise the decision if the hearing officer who issued the decision is unavailable.

(c) *Decision of Administrator.* A decision by the Administrator that is otherwise final may be reopened and revised by the Administrator upon the Administrator's own motion within 1 year of the notice of the Administrator's decision.

(d) *Notices.* (1) The notice of reopening and of any revisions following the reopening is mailed to the parties.

(2) The notice of revision specifies the reasons for revisions.

§ 423.669 Effect of revised determination.

The revision of a contract or reconsidered determination is binding unless a party files a written request for hearing of the revised determination in accordance with § 423.651.

Subpart O—Intermediate Sanctions

§ 423.750 Kinds of sanctions.

(a) The following intermediate sanctions and civil money penalties may be imposed:

(1) Civil money penalties ranging from $10,000 to $100,000 depending upon the violation.

(2) Suspension of enrollment of Medicare beneficiaries.

(3) Suspension of payment to the Part D sponsor for Medicare beneficiaries who enroll.

(4) Suspension of all Part D plan marketing activities to Medicare beneficiaries for the Part D plan subject to the intermediate sanctions.

(b) The enrollment, payment, and marketing sanctions continue in effect until CMS is satisfied that the deficiency on which the determination was based is corrected and is not likely to recur.

§ 423.752 Basis for imposing sanctions.

(a) *All intermediate sanctions.* For the violations listed below, we may impose one, or more, of the sanctions specified in § 423.750(a)(2), (a)(3) or (a)(4) on any Part D sponsor that has a contract in effect. The Part D sponsor may also be subject to other applicable remedies available under law.

(1) Fails substantially to provide, to a Part D plan enrollee, medically necessary services that the organization is required to provide (under law or under the contract) to a Part D plan enrollee, and that failure adversely affects (or is substantially likely to adversely affect) the enrollee.

(2) Imposes on Part D plan enrollees premiums in excess of the monthly basic and supplemental beneficiary premiums permitted under section 1860D–1 *et seq.* of the Act and subpart F of this part.

(3) Acts to expel or refuses to reenroll a beneficiary in violation of the provisions of this part.

(4) Engages in any practice that may reasonably be expected to have the effect of denying or discouraging enrollment of individuals whose medical condition or history indicates a need for substantial future medical services.

(5) Misrepresents or falsifies information that it furnishes—

(i) To CMS; or

(ii) To an individual or to any other entity under the Part D drug benefit program.

(6) Employs or contracts with an individual or entity who is excluded from participation in Medicare under section 1128 or 1128A of the Act (or with an entity that employs or contracts with an excluded individual or entity) for the provision of any of the following:

(i) Health care.

(ii) Utilization review.

(iii) Medical social work.

(iv) Administrative services.

(b) *Suspension of enrollment and marketing.* If CMS makes a determination that could lead to a contract termination under § 423.509(a), CMS may instead impose the intermediate sanctions in § 423.750(a)(2) and (a)(4).

§ 423.756 Procedures for imposing sanctions.

(a) *Notice of sanction and opportunity to respond.*

(1) Notice of sanction. Before imposing the intermediate sanctions specified in paragraph (c) of this section, CMS—

(i) Sends a written notice to the Part D sponsor stating the nature and basis of the proposed sanction; and

(ii)Sends the Office of the Inspector General a copy of the notice.

(2) *Opportunity to respond.* CMS allows the Part D sponsor 15 days from

receipt of the notice to provide evidence that it has not committed an act or failed to comply with the requirements described in § 423.752, as applicable. CMS may allow a 15-day addition to the original 15 days upon receipt of a written request from the Part D sponsor. To be approved, the request must provide a credible explanation of why additional time is necessary and be received by CMS before the end of the 15-day period following the date of receipt of the sanction notice. CMS does not grant an extension if it determines that the Part D sponsor's conduct poses a threat to an enrollee's health and safety.

(b) *Informal reconsideration.* If, consistent with paragraph (a)(2) of this section, the Part D sponsor submits a timely response to CMS' notice of sanction, CMS conducts an informal reconsideration that—

(1) Consists of a review of the evidence by an CMS official who did not participate in the initial decision to impose a sanction; and

(2) Gives the Part D sponsor a concise written decision setting forth the factual and legal basis for the decision that affirms or rescinds the original determination.

(c) *Specific sanctions.* If CMS determines that a Part D sponsor has acted or failed to act as specified in § 423.752 and affirms this determination in accordance with paragraph (b) of this section, CMS may—

(1) Require the Part D sponsor to suspend acceptance of applications made by Medicare beneficiaries for enrollment in the sanctioned plan during the sanction period;

(2) In the case of a violation under § 423.752(a), suspend payments to the Part D sponsor for Medicare beneficiaries enrolled in the sanctioned plan during the sanction period; and

(3) Require the Part D sponsor to suspend all marketing activities for the sanctioned plan to Medicare enrollees.

(d) *Effective date and duration of sanctions.* (1) *Effective date.* Except as provided in paragraph (d)(2) of this section, a sanction is effective 15 days after the date that the organization is notified of the decision to impose the sanction or, if the Part D sponsor seeks reconsideration in a timely manner under paragraph (b) of this section, on the date specified in the notice of CMS' reconsidered determination.

(2) *Exception.* If CMS determines that the Part D sponsor's conduct poses a serious threat to an enrollee's health and safety, CMS may make the sanction effective on a date before issuance of CMS' reconsidered determination.

(3) *Duration of sanction.* The sanction remains in effect until CMS notifies the Part D sponsor that CMS is satisfied that the basis for imposing the sanction is corrected and is not likely to recur.

(e) *Termination by CMS.* In addition to or as an alternative to the sanctions described in paragraph (c) of this section, CMS may decline to authorize the renewal of an organization's contract in accordance with § 423.507(b)(2) and (b)(3), or terminate the contract in accordance with § 423.509.

(f) *Civil money penalties.* (1) If CMS determines that a Part D sponsor has committed an act or failed to comply with a requirement described in § 423.752, CMS notifies the OIG of this determination, and also notifies OIG when CMS reverses or terminates a sanction imposed under this part.

(2) In the case of a violation described in § 423.752(a), or a determination under § 423.752(b) based upon a violation under § 423.509(a)(4) (involving fraudulent or abusive activities), in accordance with the provisions of part 1003 of this chapter, the OIG may impose civil money penalties on the Part D sponsor in accordance with part 1003 of this chapter in addition to, or in place of, the sanctions that CMS may impose under paragraph (c) of this section.

(3) In the case of a determination under § 423.752(b) other than a determination based upon a violation under § 423.509(a)(4), CMS may impose civil money penalties on the Part D sponsor in the amounts specified in § 423.758 in addition to, or in place of, the sanctions that CMS may impose under paragraph (c) of this section.

§ 423.758 Maximum amount of civil money penalties imposed by CMS.

If CMS makes a determination under § 423.509(a), as described in § 423.752(b), excepting those determinations under § 423.509(a)(4), CMS may impose civil money penalties, in addition to, or in place of, the sanctions that CMS may impose under § 423.756(c), in the following amounts:

(a) If the deficiency on which the determination is based has directly adversely affected (or has the substantial likelihood of adversely affecting) one or more Part D plan enrollees—up to $25,000 for each determination.

(b)For each week that a deficiency remains uncorrected after the week in which the Part D sponsor receives CMS' notice of the determination—up to $10,000 per week.

(c)If CMS makes a determination that a Part D sponsor has terminated its contract with CMS other than in a manner described in § 423.510 and that the sponsor has therefore failed to substantially carry of the terms of the contract, $250 per Medicare enrollee from the terminated Part D plan or plans at the time the Part D sponsor terminated its contract, or $100,000, whichever is greater.

§ 423.760 Other applicable provisions.

The provisions of section 1128A of the Act (except paragraphs (a) and (b)) apply to civil money penalties under this subpart to the same extent that they apply to a civil money penalty or procedure under section 1128A of the Act.

Subpart P—Premiums and Cost-Sharing Subsidies for Low-Income Individuals

§ 423.771 Basis and scope.

(a) *Basis.* This subpart is based on section 1860D–14 of the Act.

(b) *Scope.* This subpart sets forth the requirements and limitations for payments by and on behalf of low-income Medicare beneficiaries who enroll in a Part D plan.

§ 423.772 Definitions.

For purposes of this subpart, the following definitions apply:

Applicant means the Part D eligible individual applying for the subsidies available to subsidy eligible individuals under this subpart.

Family size means the applicant, the spouse who is living in the same household, if any and the number of individuals who are related to the applicant or applicants, who are living in the same household and who are dependent on the applicant or the applicant's spouse for at least one-half of their financial support.

Federal poverty line (FPL) has the meaning given that term in section 673(2) of the Community Services Block Grant Act (42 USC 9902(2)), including any revision required by that section.

Full-benefit dual eligible individual means an individual who, for any month—

(1) Has coverage for the month under a prescription drug plan under Part D of title XVIII, or under an MA-PD plan under Part C of title XVIII; and

(2) Is determined eligible by the State for medical assistance for full benefits under title XIX for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act. (This does not include individuals under Pharmacy Plus program demonstrations or under a section 1115 demonstration that provides pharmacy-only benefits to

these individuals.). It also includes any individual who is determined by the State to be eligible for medical assistance under section 1902(a)(10)(C) of the Act (medically needy) or section 1902(f) of the Act (States that use more restrictive eligibility criteria than are used by the SSI program) of the Act for any month if the individual was eligible for medical assistance in any part of the month.

Full subsidy means the subsidies available to full subsidy eligible individuals under § 423.780(a) and § 423.782(a).

Full subsidy eligible individuals means individuals meeting the eligibility requirements under § 423.773(b).

Income means income as described under section 1905(p)(1) of the Act without use of any more liberal disregards under section 1902(r)(2) of the Act (that is, as defined by section 1612 of the Act). This definition includes the income of the applicant and spouse who is living in the same household, if any, regardless of whether the spouse is also an applicant.

Institutionalized individual means a full-benefit dual eligible individual who is an inpatient in a medical institution or nursing facility for which payment is made under Medicaid throughout a month, as defined under section 1902(q)(1)(B) of the Act.

Other subsidy eligible individuals means those individuals meeting the eligibility requirements under § 423.773(d).

Personal representative for purposes of this subpart means —

(1) An individual who is authorized to act on behalf of the applicant;

(2) If the applicant is incapacitated; or incompetent, someone acting responsibly on their behalf, or

(3)An individual of the applicant's choice who is requested by the applicant to act as his or her representative in the application process.

Resources means liquid resources of the applicant (and, if married, his or her spouse who is living in the same household), such as checking and savings accounts, stocks, bonds, and other resources that can be readily converted to cash within 20 days, that are not excluded from resources in section 1613 of the Act, and real estate that is not the applicant's primary residence or the land on which the primary residence is located.

State means for purposes of this subpart each of the 50 States and the District of Columbia.

§ 423.773 Requirements for eligibility

(a) *Subsidy eligible individual.* A subsidy eligible individual is a Part D eligible individual residing in a State who is enrolled in, or seeking to enroll in a Part D plan and meets the following requirements:

(1) Has income below 150 percent of the FPL applicable to the individual's family size.

(2) Has resources at or below the resource thresholds set forth in § 423.773(b)(2) or (d)(2).

(b) *Full subsidy eligible individual.* A full subsidy eligible individual is a subsidy eligible individual who—

(1) Has income below 135 percent of the FPL applicable to the individual's family size; and

(2)Has resources that do not exceed—

(i) For 2006, 3 times the amount of resources an individual may have and still be eligible for benefits under the Supplemental Security Income (SSI) program under title XVI of the Act (including the assets or resources of the individual's spouse).

(ii) For subsequent years, the amount of resources allowable for the previous year under this paragraph (b)(2) increased by the annual percentage increase in the consumer price index (all items, U.S. city average) as of September of that previous year, rounded to the nearest multiple of $10. The nearest multiple are rounded up if it is equal to or greater than $5 and down if it is less than $5.

(c)(1) *Individuals treated as full subsidy eligible.* An individual must be treated as meeting the eligibility requirements for full subsidy eligible individuals under paragraph (b) of this section if the individual is a—

(i) Full-benefit dual eligible individual;

(ii) Recipient of SSI benefits under title XVI of the Act; or

(iii) Eligible for Medicaid as a Qualified Medicare Beneficiary (QMB), Specified Low Income Medicare Beneficiary (SLMB), or a Qualifying Individual (QI) under a State's plan.

(2) CMS notifies an individual treated as a full subsidy eligible under this paragraph (c) of this section that he or she does not need to apply for the subsidies available under this subpart, and is deemed eligible for a full subsidy for a period up to one year.

(d) *Other low-income subsidy individuals.* Other low-income subsidy individuals are subsidy eligible individuals who—

(1) Have income less than 150 percent of the FPL applicable to the individual's family size; and

(2) Have resources that do not exceed—

(i) For 2006, $10,000 if single or $20,000 if married (including the assets or resources of the individual's spouse).

(ii) For subsequent years, the resource amount

allowable for the previous year under this paragraph (d)(2), increased by the annual percentage increase in the consumer price index (all items, U.S. city average) as of September of the previous year, rounded to the nearest multiple of $10. The nearest multiple will be rounded up if it is equal to or greater than $5 and down if it is less than $5.

§ 423.774 Eligibility determinations, redeterminations, and applications.

(a) *Determinations of whether an individual is a subsidy eligible individual.* Determinations of eligibility for subsidies under this subpart are made by the State under its State plan under title XIX of the Act if the individual applies with the Medicaid agency, or if the individual applies with the Social Security Administration (SSA), the Commissioner of Social Security in accordance with the requirements of section 1860D–14(a)(3) of the Act.

(b) *Effective date of initial eligibility determinations.* Initial eligibility determinations are effective beginning with the first day of the month in which the individual applies, but no earlier than January 1, 2006 and remain in effect for a period not to exceed 1 year.

(c) *Redeterminations and appeals of low-income subsidy eligibility.*

(1) *Redeterminations and appeals of low-income subsidy eligibility determinations—eligibility determinations made by States.* Redeterminations and appeals of low-income subsidy eligibility determinations by States must be made in the same manner and frequency as the redeterminations and appeals are made under the State's plan.

(2) *Redeterminations and appeals of low-income subsidy eligibility—eligibility determinations made by Commissioner of Social Security.* Redeterminations and appeals of eligibility determinations made by the Commissioner will be made in the manner specified by the Commissioner of Social Security.

(d) *Application requirements.* (1) In order for applications for the subsidies under this subpart to be considered complete, applicants or personal representatives applying on the individual's behalf, must—

(i) Complete all required elements of the application; (ii) Provide any statements from financial institutions,

as requested, to support information in the application; and

(iii) Certify, under penalty of perjury or similar sanction for false statements, as to the accuracy of the information provided on the application form.

(2) Multiple applications. If the individual or his or her personal representative has previously filed an application with the State or SSA which seeks subsidy eligibility for any portion of the eligibility period covered by a subsequent application, the later application is void if the individual has received a positive subsidy determination on that earlier application from the State or SSA.

§ 423.780 Premium subsidy.

(a) *Full subsidy eligible individuals.* Full subsidy eligible individuals are entitled to a premium subsidy equal to 100 percent of the premium subsidy amount.

(b) *Premium subsidy amount.*

(1) The premium subsidy amount is equal to an amount which is the lesser of:

(i) Under the Part D plan selected by the beneficiary, the monthly beneficiary premium for a Part D plan other than a MA-PD plan that is basic prescription drug coverage, the portion of the monthly beneficiary premium attributable to basic prescription drug coverage for a Part D plan other than a MA-PD plan that is enhanced alternative coverage, or the MA monthly prescription drug beneficiary premium as defined under section 1854(b)(2)(B) of the Act, or

(ii) The greater of the low-income benchmark premium amount for a PDP region as determined under paragraph (b)(2) of this section or the lowest monthly beneficiary premium for a prescription drug plan that offers basic prescription drug coverage in the PDP region.

(2) *Calculation of the low-income benchmark premium amount.* (i) The low-income benchmark premium amount for a PDP region is a weighted average of the premium amounts described in this paragraph (b)(2)(ii) of this section , with the weight for each PDP and MA-PD plan equal to a percentage, the numerator being equal to the number of Part D eligible individuals enrolled in the plan in the reference month (as defined in § 422.258(c)(1) of this chapter) and the denominator equal to the total number of Part D eligible individuals enrolled in all PDP and MA-PD plans (but not including PACE, private fee-for-service plans or 1876 cost plans)in a PDP region in the reference month.

(ii) Premium amounts: The premium amounts used to calculate the low-income benchmark premium amount are as follows:

(A) The monthly beneficiary premium for a PDP that is basic prescription drug coverage;

(B) The portion of the monthly beneficiary premium attributable to basic prescription drug coverage for a PDP that is enhanced alternative coverage; or,

(C)The MA monthly prescription drug beneficiary premium (as defined under section 1854(b)(2)(B) of the Act) for a MA-PD plan.

(c) *Special rule for 2006 to weight the low-income benchmark premium.* For purposes of calculating the low-income benchmark premium amount for 2006, CMS assigns equal weighting to PDP sponsors (including fallback entities) and assigns MA-PD plans a weight based on prior enrollment. New MA-PD plans are assigned a zero weight. PACE, private fee-for-service plans and 1876 cost plans are not included.

(d) *Other low-income subsidy eligible individuals—sliding scale premium.* Other low-income subsidy eligible individuals are entitled to a premium subsidy based on a linear sliding scale ranging from 100 percent of the premium subsidy amount described in paragraph (b) of this section as follows:

(1) For individuals with income at or below 135 percent of the FPL applicable to their family size, the full premium subsidy amount.

(2) For individuals with income greater than 135 percent but at or below 140 percent of the FPL applicable to the family size, a premium subsidy equal to 75 percent of the premium subsidy amount.

(3) For individual with income greater than 140 percent but at or below 145 percent of the FPL applicable to the family size a premium subsidy equal to 50 percent of the premium subsidy amount.

(4) For individuals with income greater than 145 percent but below 150 percent of FPL applicable to the family size a premium subsidy equal to 25 percent of the premium subsidy amount.

(e) *Premium subsidy for late enrollment penalty.* Full subsidy eligible individuals who are subject to late enrollment penalties under § 423.46 are entitled to an additional premium subsidy equal to 80 percent of the late enrollment penalty for the first 60 months during which the penalty is imposed and 100 percent of their late enrollment penalty thereafter.

§ 423.782 Cost-sharing subsidy.

(a) *Full subsidy eligible individuals.* Full subsidy eligible individuals are entitled to the following:

(1) Elimination of the annual deductible under § 423.104(d)(1).

(2) Reduction in cost-sharing for all covered Part D drugs covered under the PDP or MA-PD plan below the out-of-pocket limit (under § 423.104), including Part D drugs covered under the PDP or MA-PD plan obtained after the initial coverage limit (under § 423.104(d)(4)), as follows:

(i) Except as provided under paragraphs (a)(2)(ii) and (a)(2)(iii) of this section, copayment amounts not to exceed the copayment amounts specified in § 423.104(d)(5)(A). This applies to both:

(A) those full-benefit dual eligible individuals who are not institutionalized and who have income above 100 percent of the Federal poverty line applicable to the individual's family size and

(B) those individuals who have income under 135 percent of the Federal poverty line applicable to the individual's family size who meet the resources test described at § 423.773(b)(2).

(ii) Full-benefit dual eligible individuals who are institutionalized have no cost-sharing for covered Part D drugs covered under their PDP or MA-PD plans.

(iii) Full-benefit dual eligible individuals with incomes that do not exceed 100 percent of the Federal poverty line applicable to the individual's family size are subject to cost-sharing for covered Part D drugs equal to the lesser of:

(A) A copayment amount of not more than $1 for a generic drug or preferred drugs that are multiple source (as defined under section 1927(k)(7)(A)(i) of the Act) or $3 for any other drug in 2006, or for years after 2006 the amounts specified in this paragraph (a)(2)(iii)(A) for the percentage increase in the Consumer Price Index, rounded to the nearest multiple of 5 cents or 10 cents, respectively; or

(B) The copayment amount charged to other individuals under this paragraph (a)(2)(i) of this section.

(3) Elimination of all cost-sharing for covered Part D drugs covered under the PDP or MA-PD plan above the out-of-pocket limit (under § 423.104(d)(5)).

(b) *Other low-income subsidy eligible individuals.* Other low-income subsidy eligible individuals are entitled to the following:

(1) In 2006, reduction in the annual deductible to $50. This amount is increased each year beginning in 2007

by the annual percentage increase in average per capita aggregate expenditures for Part D drugs, rounded to the nearest multiple of $1.

(2) Fifteen percent coinsurance for all covered Part D drugs obtained after the annual deductible under the plan up to the out-of-pocket limit (under § 423.104(d)(5)(iii)).

(3) For covered Part D drugs above the out-of-pocket limit (under § 423.104(d)(5)(iii)), in 2006, copayments not to exceed $2 for a generic drug or preferred drugs that are multiple source drugs (as defined under section 1927(k)(7)(A)(i) of the Act) and $5 for any other drug. For years beginning in 2007, the amounts specified in section paragraph (b)(3) for the previous year increased by the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs, rounded to the nearest multiple of 5 cents.

§ 423.800 Administration of subsidy program.

(a) *Notification of eligibility for low-income subsidy.* CMS notifies the Part D sponsor offering the Part D plan, in which a subsidy eligible individual is enrolled, of the individual's eligibility for a subsidy under this section and the amount of the subsidy.

(b) *Reduction of premium or cost-sharing by PDP sponsor or organization.* The Part D sponsor offering the Part D plan, in which a subsidy eligible individual is enrolled must reduce the individual's premiums and cost-sharing as applicable, and provide information to CMS on the amount of those reductions, in a manner determined by CMS. The Part D sponsor must track the application of the subsidies under this subpart to be applied to the out-of-pocket threshold.

(c) *Reimbursement for cost-sharing paid before notification of eligibility for low-income subsidy.* The Part D sponsor offering the Part D plan must reimburse subsidy eligible individuals, and organizations paying cost-sharing on behalf of such individuals, any excess premiums and cost-sharing paid by such individual or organization after the effective date of the individual's eligibility for a subsidy under this subpart.

Subpart Q—Guaranteeing Access to a Choice of Coverage (Fallback Prescription Drug Plans)

§ 423.851 Scope.

This subpart sets forth—the rights of beneficiaries to a choice of at least two sources of qualified prescription drug coverage; requirements and limitations on the bid submission, review and approval of fallback prescription drug plans, and the determination of enrollee premium and plan payments for these plans.

§ 423.855 Definitions.

As used in this subpart, unless specified otherwise-

Actual costs means the subset of prescription drug costs (not including administrative costs or return on investment, but including costs directly related to the dispensing of covered Part D drugs during the year) that are attributable to standard benefits only and that are incurred and actually paid by the sponsor or organization under the plan.

Actually paid has the same meaning described in § 423.308.

Eligible fallback entity or *fallback entity* means an entity that, for a particular contract period-

(1) Is a PDP sponsor that does not have to be a risk-bearing entity (or, if applying to become a fallback entity, an entity that meets all the requirements to become a Part D plan sponsor except that it does not have to be a risk-bearing entity); and

(2) Does not submit a risk bid under § 423.265 for offering a prescription drug plan for any PDP region for the first year of that contract period. An entity is treated as submitting a risk bid if the entity is acting as a subcontractor for an integral part of the drug benefit management activities of an entity that is or applies to become a non-fallback PDP sponsor. An entity is not treated as submitting a bid if it is a subcontractor of an MA organization, unless that organization is acting as or applies to become a non-fallback PDP sponsor for a prescription drug plan.

Fallback prescription drug plan means a prescription drug plan (PDP) offered by a fallback entity that--

(1) Offers only defined standard or actuarially equivalent standard prescription drug coverage as defined in § 423.100;

(2) Provides access to negotiated prices, including discounts from manufacturers; and

(3) Meets all other requirements established for prescription drug plans, except as otherwise specified by CMS in this subpart or in separate guidance.

Qualifying plan means a full-risk or limited-risk prescription drug plan, as defined in § 423.258, or an MA-PD plan described in section 1851(a)(2)(A)(i) of the Act, that provides required prescription drug coverage, as defined in § 423.100 An MA-PD plan must be open for enrollment and not operating under a capacity waiver to be counted as a qualifying plan. A PDP must not be operating under a restricted enrollment waiver, such as those that may be granted to special needs plans or employer group plans, in order to be counted as a qualifying plan in an area.

§ 423.859 Assuring access to a choice of coverage.

(a) *Choice of at least 2 qualifying plans in each area.* Each Part D eligible individual must have available a choice of enrollment in at least 2 qualifying plans (as defined in § 423.855) in the area in which the individual resides. This requirement is not satisfied if only one entity offers all the qualifying plans in the area. At least 1 of the 2 qualifying plans must be a prescription drug plan.

(b) *Fallback service area.* (1) *For coverage year.* Before the start of each coverage year CMS determines if Part D eligible individuals residing in a PDP region have access to a choice of enrollment in a minimum of 2 qualifying plans, as described in paragraph (a) of this section. If CMS determines that Part D eligible individuals in a PDP region, or some portion of the region, do not have available a choice of enrollment in a minimum of two qualified plans, CMS designates the region or portion of a region as a fallback service area. Each Part D eligible individual in a fallback service area is given the opportunity to enroll in a fallback prescription drug plan.

(2) *For mid-year changes.* If a contract with a qualifying plan is terminated in the middle of a contract year (as provided for in § 423.508, § 423.509, or § 423.510), CMS determines if Part D eligible individuals residing in the affected PDP region still have access to a choice of enrollment in a minimum of 2 qualifying plans, as described in paragraph (a) of this section. If CMS determines that Part D eligible individuals in a PDP region, or some portion of the region, no longer have available a choice of enrollment in a minimum of two qualifying plans, CMS designates the region or portion of a region as a fallback service area.

(c) *Access to coverage in the territories.* CMS may waive or modify the requirements of this part if--

(1) CMS determines that waiver or modification is necessary to secure access to qualified prescription drug coverage for Part D eligible individuals residing in a State other than the 50 States or the District of Columbia; or

(2) An entity seeking to become a prescription drug plan in an area such as a territory, other than the 50 States or the District of Columbia requests waiver or modification of any Part D

requirement in order to provide qualified prescription drug coverage.

§ 423.863 Submission and approval of bids.

(a) *Submission of Bids.* (1) *Solicitation of bids.* Separate from the risk bidding process under § 423.265, CMS solicits bids from eligible fallback entities for the offering in all fallback service areas in one or more PDP regions of a fallback prescription drug plan during the contract period specified in § 423.871(b).

(2) *Timing of bids.* CMS determines when to solicit bids for 2006 so that potential fallback prescription drug plans have enough time to prepare a bid. After that, bids are solicited on 3 year cycles, or annually thereafter as needed to replace contractors between contracting cycles.

(3) *Format of bid.* CMS specifies the form and manner in which fallback bids are submitted in separate guidance to bidders.

(b) *Negotiation and acceptance of bids.*

(1) *General rule.* Except as provided in this section, the provisions of § 423.272 apply for the approval or disapproval of fallback prescription drug plans. CMS enters into contracts under this paragraph with eligible fallback entities for the offering of approved fallback prescription drug plans in potential fallback service areas.

(2) *Flexibility in risk assumed and application of fallback prescription drug plan.* In order to ensure access in an area in accordance with § 423.859(a), CMS may approve limited risk plans under § 423.272(c) for that area. If the access requirement is still not met after applying § 423.272(c), CMS provides for the offering of a fallback prescription drug plan in that area.

(3) *Limitation of 1 Plan for all fallback service areas in a PDP region.* All fallback service areas in any PDP region for a contract period must be served by the same fallback prescription drug plan.

(4) *Competitive procedures.* CMS uses competitive procedures (as defined in section 4(5) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(5)) to enter into a contract under this paragraph. The provisions of section 1874A(d) of the Act apply to a contract under this section in the same manner as they apply to a contract under that section.

(5) *Timing of contracts.* CMS approves a fallback prescription drug plan for a PDP region in a manner so that, if there are any fallback service areas in the region for a year, the fallback prescription drug plan is offered at the same time as prescription drug plans are otherwise offered. In the event of mid-year changes and as required by § 423.859(b)(2), CMS approves a fallback prescription drug plan for a PDP region in a manner so that the fallback prescription drug plan is offered within 90 days of notice.

(6) *No national fallback prescription drug plan.* CMS may not enter into a contract with a single fallback entity for the offering of fallback prescription drug plans throughout the United States.

§ 423.867 Rules regarding premiums.

(a) *Monthly beneficiary premium.* Except as provided in § 423.286(d)(3) (relating to late enrollment penalty) and subject to subpart P (relating to low-income assistance), the monthly beneficiary premium under a fallback prescription drug plan must be uniform for all fallback service areas in a PDP region. It must equal 25.5 percent of CMS's estimate of the average monthly per capita actuarial cost, including administrative expenses, of providing coverage in the PDP region based on similar expenses of prescription drug plans that are not fallback prescription drug plans.

(b) *Special rule for collection of premiums in fallback prescription drug plans.* In the case of a fallback prescription drug plan, the provisions of § 423.293 (b) concerning payments of the late enrollment penalty to the PDP sponsor do not apply and the monthly beneficiary premium is collected in the manner specified in § 422.262(f)(1) of this chapter, or paid directly to the fallback entity by the beneficiary if there are either no benefits, or insufficient benefits available to be collected in the manner specified under § 422.262(f)(1) of this chapter. The amount of any premiums collected by the fallback entity is deducted from management fees due from CMS.

§ 423.871 Contract terms and conditions.

(a) *General.* Except as may be appropriate to carry out the requirements of this section, the terms and conditions of contracts with eligible fallback entities offering fallback prescription drug plans are the same as the terms and conditions of contracts at § 423.504 and § 423.505 for Part D plans.

(b) *Period of contract.* A contract with a fallback entity for fallback service areas for a PDP region is in effect for a period of 3 years. However, a fallback prescription drug plan may be offered for any year within the contract period for a particular area only if the area is a fallback service area for that year.

(c) *Entity not permitted to market or brand fallback prescription drug plans.* Notwithstanding any other provisions of this part, an eligible fallback entity with a contract under this part may not engage in any marketing or branding of a fallback prescription drug plan.

(d) *Performance measures.* CMS issues guidance establishing performance measures for fallback prescription drug plans based on the following:

(1) *Types of performance measures.* Performance measures include at least measures for each of the following:

(i) *Costs.* The entity contains costs to the Medicare Prescription Drug Account and to Part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity through mechanisms such as generic substitution and price discounts.

(ii) *Quality programs.* The entity provides the enrollees in its fallback prescription drug plan with quality programs that avoid adverse drug reactions, monitor for appropriate utilization, and reduce medical errors.

(iii) *Customer service.* The entity provides timely and accurate delivery of services and pharmacy and beneficiary support services.

(iv) *Benefit administration and claims adjudication.* The entity provides efficient and effective benefit administration and claims adjudication.

(2) *Development of performance measures.* CMS establishes detailed performance measures for use in evaluating fallback entity performance and determination of certain management fees based on criteria from historical performance, application of acceptable statistical measures of variation to fallback entity and PDP sponsor (other than fallback entities) experience nationwide during a base period, or changing program emphases or requirements.

(e) *Payment terms.* A contract approved with a fallback entity includes terms for payment for--

(1) The actual costs of covered Part D drugs provided to Part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity; and

(2) Management fees that consist of administrative costs and return on investment and are tied to the performance measures established by CMS for the management, administration, and delivery of the benefits under the contract as provided under paragraph (d) of this section.

(f) *Requirement for the submission of information.* Each contract for a fallback prescription drug plan requires an eligible fallback entity offering a fallback prescription drug plan to provide CMS with the information CMS

determines is necessary to carry out the payment provisions under subpart G or under this subpart, or as required by law. Information disclosed to determine Medicare payment or reimbursement to the fallback entity may be used by the officers, employees and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, determining such payment or reimbursement. This restriction does not limit CMS or OIG authority to conduct audits and evaluations necessary to ensure accurate and correct payment and to otherwise oversee Medicare reimbursement

(g) *Amendment to reflect changes in service area.* The contract may be amended by CMS at any time as needed to reflect the exact regions or counties where the fallback plan are required to operate within the contracted service area(s).

§ 423.875 Payment to fallback plans.

The amount payable for a fallback prescription drug plan is the amount determined under the contract for the plan in accordance with § 423.871(e).

Subpart R—Payments to Sponsors of Retiree Prescription Drug Plans

§ 423.880 Basis and scope.

(a) Basis. This subpart is based on section 1860D–22 of the Act, as amended by section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

(b) Scope. This section implements the statutory requirement that a subsidy payment be made to sponsors of qualified retiree prescription drug plans.

§ 423.882 Definitions.

For the purposes of this subpart, the following definitions apply:

Allowable retiree costs, in accordance with section 1860D–22(a)(3)(C)(i) of the Act, means gross covered retiree plan-related prescription drug costs that are actually paid (net any manufacturer or pharmacy discounts, chargebacks, rebates, and similar price concessions) by either the qualified retiree prescription drug plan or the qualifying covered retiree (or on the qualifying covered retiree's behalf).

Benefit option means a particular benefit design, category of benefits, or cost-sharing arrangement offered within a group health plan.

Employment-based retiree health coverage means coverage of health care costs under a group health plan based on an individual's status as a retired participant in the plan, or as the spouse or dependent of a retired participant. The term includes coverage provided by voluntary insurance coverage, or coverage as a result of a statutory or contractual obligation.

Gross covered retiree plan-related prescription drug costs, or *gross retiree costs means*, for a qualifying covered retiree who is enrolled in a qualified retiree prescription drug plan during a plan year, non-administrative costs incurred under the plan for Part D drugs during the year, whether paid for by the plan or the retiree, including costs directly related to the dispensing of Part D drugs.

Group health plans include plans as defined in section 607(1) of ERISA, 29 U.S.C. § 1167(1). They also include the following plans:

(1) A Federal or State governmental plan, which is a plan providing medical care that is established or maintained for its employees by the Government of the United States, by the government of any State or political subdivision of a State (including a county or local government), or by any agency or instrumentality or any of the foregoing, including a health benefits plan offered under chapter 89 of Title 5, United States Code (the Federal Employee Health Benefit Plan (FEHBP)).

(2) A collectively bargained plan, which is a plan providing medical care that is established or maintained under or by one or more collective bargaining agreements.

(3) A church plan, which is a plan providing medical care that is established and maintained for its employees or their beneficiaries by a church or by a convention or association of churches that is exempt from tax under section 501 of the Internal Revenue Code of 1986 (26 U.S.C. 501).

(4) An account-based medical plan such as a Health Reimbursement Arrangement (HRA) as defined in Internal Revenue Service Notice 2002–45, 2002–28 I.R.B. 93, a health Flexible Spending Arrangement (FSA) as defined in Internal Revenue Code (Code) section 106(c)(2), a health savings account (HSA) as defined in Code section 223, or an Archer MSA as defined in Code section 220, to the extent they are subject to ERISA as employee welfare benefit plans providing medical care (or would be subject to ERISA but for the exclusion in ERISA section 4(b), 29 U.S.C.§ . § 1003(b), for governmental plans or church plans).

Part D drug is defined in § 423.100 of this part.

Part D eligible individual is defined in § 423.4 of this part.

Qualified retiree prescription drug plan means employment-based retiree health coverage that meets the requirements set forth in § 423.884 of this chapter for a Part D eligible individual who is a retired participant or the spouse or dependent of a retired participant under the coverage.

Qualifying covered retiree means a Part D eligible individual who is: a participant or the spouse or dependent of a participant; covered under employment-based retiree health coverage that qualifies as a qualified retiree prescription drug plan; and not enrolled in a Part D plan. For this purpose, the determination of whether an individual is covered under employment-based retiree health coverage is made by the sponsor in accordance with the rules of its plan. For purposes of this subpart, however, an individual is presumed not to be covered under employment-based retiree health coverage if, under the Medicare Secondary Payer rules in § 411.104 of this chapter and related CMS guidance, the person is considered to be receiving coverage by reason of current employment status. The presumption applies whether or not the Medicare Secondary Payer rules actually apply to the sponsor. For this purpose, a sponsor also may treat a person receiving coverage under its qualified retiree prescription drug plan as the dependent of a qualifying covered retiree in accordance with the rules of its plan, regardless of whether that person constitutes the qualifying covered retiree's dependent for Federal or State tax purposes.

Retiree drug subsidy amount, or subsidy payment, means the subsidy amount paid to sponsors of qualified retiree prescription drug coverage under § 423.886(a).

Standard prescription drug coverage is defined in § 423.100 of this part.

Sponsor is a plan sponsor as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1002(16)(B), except that, in the case of a plan maintained jointly by one employer and an employee organization and for which the employer is the primary source of financing, the term means the employer.

Sponsor agreement means an agreement by the sponsor to comply with the provisions of this subpart.

§ 423.884 Requirements for qualified retiree prescription drug plans.

(a) *General.* Employment-based retiree health coverage is considered to be a qualified retiree prescription drug plan if all of the following requirements are satisfied:

(1) An actuarial attestation is submitted in accordance with paragraph (d) of this section. The rules for submitting attestations as part of

subsidy applications are described in paragraph (c) of this section.

(2) Part D eligible individuals covered under the plan are provided with creditable coverage notices in accordance with § 423.56.

(3) Records are maintained and made available for audit in accordance with paragraph (f) of this section and § 423.888(d).

(b) *Disclosure of information.* The sponsor must have a written agreement with its health insurance issuer (as defined in 45 CFR 160.103), or group health plan (as applicable) regarding disclosure of information to CMS, and the issuer or plan must disclose to CMS, on behalf of the sponsor, the information necessary for the sponsor to comply with this subpart.

(c) *Application.* (1) *Submitting an application.* The sponsor (or its designee) must submit an application for the subsidy to CMS that is signed by an authorized representative of the sponsor. The application must be provided in a form and manner specified by CMS.

(2) *Required information.* In connection with each application the sponsor (either directly or through its designee) must submit the following:

(i) Employer Tax ID Number (if applicable).

(ii) Sponsor name and address.

(iii) Contact name and email address.

(iv) Actuarial attestation that satisfies the standards specified in paragraph (d) of this section and any other supporting documentation required by CMS for each qualified retiree prescription drug plan for which the sponsor seeks subsidy payments.

(v) A list of all individuals the sponsor believes (using information reasonably available to the sponsor when it submits the application) are qualifying covered retirees enrolled in each prescription drug plan (including spouses and dependents, if Medicare-eligible), along with the information about each person listed below in this paragraph:

(A) Full name.

(B) Health Insurance Claim (HIC) number or Social Security number.

(C) Date of birth.

(D) Gender.

(E) Relationship to the retired employee.

(vi) A sponsor may satisfy paragraph (c)(2)(v) of this section by entering into a voluntary data sharing agreement (VDSA) with CMS (or any other arrangement CMS may make available).

(vii) A signed sponsor agreement.

(viii) Any other information specified by CMS.

(3) *Terms and conditions.* To receive a subsidy payment, the sponsor (through the signed sponsor agreement or as otherwise specified by CMS) must specifically accept and agree to:

(i) Comply with the terms and conditions of eligibility for a subsidy payment set forth in this regulation and in any related CMS guidance;

(ii) Acknowledge that the information in the application is being provided to obtain Federal funds; and

(iii) Require that all subcontractors, including plan administrators, acknowledge that information provided in connection with the subcontract is used for purposes of obtaining Federal funds.

(4) *Signature by sponsor.* An authorized representative of the requesting sponsor must sign the completed application and certify that the information contained in the application is true and accurate to the best of the sponsor's knowledge and belief.

(5) *Timing.* (i) *General rule.* An application for a given plan year must be submitted by no later than 90 days prior to the beginning of the plan year, unless a request for an extension has been filed and approved under procedures established by CMS.

(ii) *Transition rule.* For plan years that end in 2006, an application must be submitted by September 30, 2005 unless a request for an extension has been filed and approved under procedures established by CMS.

(6) *Updates.* The sponsor (or the designee) must provide updates to CMS in a manner specified by CMS of the information required in paragraph (c)(2) of this section on a monthly basis or at a frequency specified by CMS.

(7) *Data match.* Once the full application for the subsidy payment is submitted, CMS—

(i) Matches the names and identifying information of the individuals submitted as qualifying covered retirees with the Medicare Beneficiary Database (MBD) to determine which retirees are Part D eligible individuals who are not enrolled in a Part D plan.

(ii) Provides information concerning the results of the search in paragraph (c)(7)(i) of this paragraph (such as names and other identifying information, if necessary) to the sponsor (or to a designee).

(d) *Actuarial attestation-general.* The sponsor of the plan must provide to CMS an attestation in a form and manner specified by CMS that the actuarial value of the retiree prescription drug coverage under the plan is at least equal to the actuarial value of the defined standard prescription drug coverage (as defined at § 423.100). The attestation must meet all of the following standards.

(1) Contents of the attestation include the following assurances:

(i) The actuarial gross value of the retiree prescription drug coverage under the plan for the plan year is at least equal to the actuarial gross value of the defined standard prescription drug coverage under Part D for the plan year in question.

(ii) The actuarial net value of the retiree prescription drug coverage under the plan for that plan year is at least equal to the actuarial net value of the defined standard prescription drug coverage under Part D for the plan year in question.

(iii) The actuarial values must be determined using the methodology in paragraph (d)(5) of this section.

(2) The attestation must be made by a qualified actuary who is a member of the American Academy of Actuaries. Applicants may use qualified outside actuaries, including (but not limited to) actuaries employed by the plan administrator or an insurer providing benefits under the plan. If an applicant uses an outside actuary, the attestation can be submitted directly by the outside actuary or by the plan sponsor.

(3)The attestation must be signed by a qualified actuary and must state that the attestation is true and accurate to the best of the attester's knowledge and belief.

(4) The attestation must contain an acknowledgement that the information being provided in the attestation is being used to obtain Federal funds.

(5) Methodology. (i) *Basis of the attestation.* The attestation must be based on generally accepted actuarial principles and any actuarial guidelines established by CMS in this section or in future guidance. To the extent CMS has not provided guidance on a specific aspect of the actuarial equivalence standard under this section, an actuary providing the attestation may rely on any reasonable interpretation of this section and section 1860D–22(a) of the Act consistent with generally accepted actuarial principles in determining actuarial values.

(ii) *Specific rules for determining the actuarial value of the sponsor's retiree prescription drug coverage.*

(A) The gross value of coverage under the sponsor's retiree prescription drug plan must be determined using the actual claims experience and demographic data for Part D eligible individuals who are participants and beneficiaries in the sponsor's plan, provided that sponsors without creditable data due to their size or other factors, may use normative databases as

specified by CMS. Sponsors may use other actuarial approaches specified by CMS as an alternative to the actuarial valuation specified by this paragraph (d)(5)(ii)(A).

(B) The net value of coverage provided under the sponsor's retiree prescription drug plan must be determined by reducing the gross value of such coverage as determined under paragraph (d)(5)(ii)(A) of this section by the expected premiums paid by Part D eligible individuals who are plan participants or their spouses and dependents. For sponsors of plans that charge a single, integrated premium or contribution to their retirees for both prescription drug coverage and other types of medical coverage, the attestation must allocate a portion of the premium/contribution to prescription drug coverage under the sponsor's plan, under any method determined by the sponsor or its actuary.

(iii) *Specific rules for calculating the actuarial value of defined standard prescription drug coverage under Part D.*

(A) The gross value of defined standard prescription drug coverage under Part D must be determined using the actual claims experience and demographic data for Part D eligible individuals in the sponsor's plan, provided that sponsors without credible data due to their size or other factors may use normative databases as specified by CMS. Sponsors may use other actuarial approaches specified by CMS as an alternative to the actuarial valuation specified by this paragraph (d)(5)(iii)(A).

(B) To calculate the net value of defined standard prescription drug coverage under Part D, the gross value of defined standard prescription drug coverage under Part D as determined by paragraph (d)(5)(iii)(A) of this section is reduced by the following amounts:

(1) The monthly beneficiary premiums (as defined in § 423.286) expected to be paid for standard prescription drug coverage; and

(2) An amount calculated to reflect the impact on the value of defined standard prescription drug coverage of supplemental coverage provided by the sponsor. Sponsors may use other actuarial approaches specified by CMS as an alternative to the actuarial valuation specified in this paragraph (d)(5)(iii)(B)(2).

(C) The valuation of defined standard prescription drug coverage for a given plan year is based on the initial coverage limit cost-sharing and out-of-pocket threshold for defined standard prescription drug coverage under Part D in effect at the start of such plan year. The attestation, however, must be submitted to CMS no later than 60 days after the publication of the Part D coverage limits for the upcoming calendar year otherwise, such valuation is based on the initial coverage limit, cost-sharing amounts, and out-of-pocket threshold for defined standard prescription drug coverage under Part D for the upcoming calendar year.

(D) Example. If a sponsor's retiree prescription drug plan operates under a plan year that ends March 30, the attestation for the year April 1, 2007–March 30, 2008 is based on the coverage limit, cost-sharing and out-of-pocket threshold that apply to defined standard prescription drug coverage under Part D in 2007 provided the attestation is submitted within 60 days after the publication of the Part D coverage limits for 2008. If the attestation is submitted more than 60 days after the 2008 coverage limits have been published, the 2008 coverage limits would apply.

(iv) Employment-based retiree health coverage with two or more benefit options. For the assurance required under paragraph (d)(1)(i) of this section, the assurance must be provided separately for each benefit option for which the sponsor requests a subsidy under this subpart. For the assurance required under paragraph (d)(1)(ii) of this section, the assurance may be provided either separately for each benefit option for which the sponsor provided assurances under paragraph (d)(1)(i) of this section, or in the aggregate for all benefit options for which the sponsor provided assurances under paragraph (d)(1)(i) of this section.

(6) Timing. (i) *Annual submission.* The attestation must be provided annually at the time the sponsor's subsidy application is submitted, or at such other times as specified by CMS in further guidance.

(ii) *Submission following material change.* The attestation must be provided no later than 90 days before the implementation of a material change to the drug coverage of the sponsor's plan that impacts the actuarial value of the coverage.

(e) *Disclosure of creditable prescription drug coverage status.* The sponsor must disclose to all of its retirees and their spouses and dependents eligible to participate in its plan who are Part D eligible individuals whether the coverage is creditable prescription drug coverage under § 423.56 in accordance with the notification requirements under that section.

(f) *Access to records for audit.* The sponsor (and where applicable, its designee) must meet the requirements of § 423.888(d). Failure to comply with § 423.888(d) may result in nonpayment or recoupment of all or part of a subsidy payment.

§ 423.886 Retiree drug subsidy amounts.

(a) *Amount of subsidy payment.* (1) For each qualifying covered retiree enrolled with the sponsor of a qualified retiree prescription drug plan in a plan year, the sponsor receives a subsidy payment in the amount of 28 percent of the allowable retiree costs (as defined in § 423.882) in the plan year for such retiree attributable to gross retiree costs between the cost threshold and the cost limit as defined in paragraph (b) of this section. The subsidy payment is calculated by first determining gross retiree costs between the cost threshold and cost limit, and then determining allowable retiree costs attributable to the gross retiree costs. For this purpose and where otherwise relevant in this subpart, plan year is the calendar, policy, or fiscal year on which the records of a plan are kept.

(2) *Transition provision.* For a qualified retiree prescription drug plan that has a plan year which begins in calendar year 2005 and ends in calendar year 2006, the subsidy for the plan year must be determined in the following manner. Claims incurred in all months of the plan year (including claims incurred in 2005) are taken into account in determining which claims fall within the cost threshold and cost limit for the plan year. The subsidy amount is determined based only on costs incurred on and after January 1, 2006.

(b) *Cost threshold and cost limit.* The following cost threshold and cost limits apply—

(1) Subject to paragraph (b)(3) of this section, the cost threshold under this section is equal to $250 for plan years that end in 2006.

(2) Subject to paragraph (b)(3) of this section, the cost limit under this section is equal to $5,000 for plan years that end in 2006.

(3) The cost threshold and cost limit specified in paragraphs (b)(1) and (b)(2) of this section, for plan years that end in years after 2006, are adjusted in the same manner as the annual Part D deductible and the annual Part D out-of-pocket threshold are adjusted annually under § 423.104(d)(1)(ii) and (d)(5)(iii)(B), respectively.

§ 423.888 Payment methods, including provision of necessary information.

(a) *Basis.* The provisions of § 423.301 through § 423.343, including requirements to provide information necessary to ensure accurate subsidy payments, govern payment under

§ 423.886 except to the extent the provisions in this section specify otherwise.

(b) *General payment rules.* Payment under § 423.886 is conditioned on provision of accurate information. The information must be submitted, in a form and manner and at the times provided in this paragraph and under other guidance specified by CMS, by the sponsor or its designee.

(1) *Timing.* Payment can be made on a monthly, quarterly or annual basis, as elected by the plansponsor under guidance specified by CMS, unless CMS determines that the options must be restricted because of operational limitations.

(i) *Monthly or quarterly payments.* If the plan sponsor elects for payment on a monthly or quarterly basis, it must provide information described in paragraph (b)(2)(i) of this section on the same monthly or quarterly basis, or at such time as CMS specifies.

(ii) *Annual payments.* If the sponsor elects an annual payment, it must submit to CMS actual rebate and other price concession data within 15 months after the end of the plan year.

(2) *Submission of cost data.* (i) *Monthly or quarterly payments.* If the plan sponsor elects to receive payment on a monthly or quarterly basis, it must submit to CMS, in a manner specified by CMS, the gross covered retiree plan-related prescription drug costs (as defined in § 423.882) incurred for its qualifying covered retirees during the payment period for which it is claiming a subsidy payment and any other data CMS may require. Except as otherwise provided by CMS in future guidance, the sponsor must also submit, using historical data and generally accepted actuarial principles, an estimate of the extent to which its expected allowable retiree costs differs from the gross covered retiree plan-related prescription drug costs, based on expected rebates and other price concessions for the upcoming plan year. The estimate must be used to reduce the periodic payments for the plan year. Final allocation of price concession data must occur after the end of the year under the reconciliation provisions of paragraph (b)(4) of this section

(ii) *Annual payments.* If the plan sponsor elects a one-time final annual payment, it must submit, in a manner specified by CMS, within 15 months, or within any other longer time limit specified by CMS, after the end of the plan year, the total gross covered retiree plan-related prescription drug costs (as defined in § 423.882) for the plan year for which it is claiming a subsidy payment, actual rebate and other price concession data described in paragraph (b)(1)(ii) of this section, and any other data CMS may require. The alternative is that the sponsor can elect an interim annual payment, in which case it must submit the following to CMS, at a time and in a manner specified by CMS: the gross covered retiree plan-related prescription drug costs (as defined in § 423.882) incurred for all of its qualifying covered retirees during the payment period for which it is claiming a subsidy payment; an estimate (using historical data and generally accepted actuarial principles) of the difference between such gross costs and allowable costs (based on expected rebates and other price concessions for the upcoming plan year); and any other data CMS may require.

(3) *Payment by CMS.* CMS makes payment after the sponsor's submission of the cost data at a time and in a manner to be specified by CMS.

(4) *Reconciliation.* (i) Sponsors who elect either monthly, quarterly or an interim annual payment must submit to CMS, within 15 months, or within any other longer time limit specified by CMS, after the end of its plan year, the total gross covered retiree plan-related prescription drug costs (as defined in § 423.882), in a manner specified by CMS; actual rebate and other price concession data for the plan year in question; and any other data CMS may require.

(ii) Upon receiving this data, CMS adjusts the payments made for the plan year in question in a manner to be specified by CMS.

(5) *Special rule for insured plans.* (i) *Interim payments.* Sponsors of group health plans that provide benefits through health insurance coverage (as defined in 45 CFR 144.103) and that choose either monthly payments, quarterly payments or an interim annual payment in paragraphs (b)(1) and (b)(2) of this section , may elect to determine gross covered plan-related retiree prescription drug costs for purposes of the monthly, quarterly or interim annual payments based on a portion of the premium costs paid by the sponsor (or by the qualifying covered retirees) for coverage of the covered retirees under the group health plan. Premium costs that are determined, using generally accepted actuarial principles, may be attributable to the gross prescription drug costs incurred by the health insurance issuer (as defined in 45 CFR § 144.103) for the sponsor's qualifying covered retirees, except that administrative costs and risk charges must be subtracted from the premium.

(ii) *Final payments.* At the end of the plan year, actual gross retiree plan-related prescription drug costs incurred by the insurer (or the retiree), and the allowable costs attributable to the gross costs, are determined for each of the sponsor's qualifying covered retirees and submitted for reconciliation after the end of the plan year as specified in paragraph (b)(4)of this section. The data for the reconciliation can be submitted directly to CMS by the insurer in a manner to be specified by CMS. Upon receiving this data, CMS adjusts the payments made for the relevant plan year in a manner to be specified by CMS.

(c) *Use of information provided.* Officers, employees and contractors of the Department of Health and Human Services, including the Office of Inspector General (OIG), may use information collected under this section only for the purposes of, and to the extent necessary in, carrying out this subpart including, but not limited to, determination of payments and payment-related oversight and program integrity activities, or as otherwise required by law. This restriction does not limit OIG authority to conduct audits and evaluations necessary for carrying out these regulations.

(d) *Maintenance of records.* (1) The sponsor of the qualified retiree prescription drug plan (or a designee), as applicable, must maintain, and furnish to CMS or the OIG upon request, the records enumerated in paragraph (d)(3) of this section. The records must be maintained for 6 years after the expiration of the plan year in which the costs were incurred for the purposes of audits and other oversight activities conducted by CMS to assure the accuracy of the actuarial attestation and the accuracy of payments.

(2) CMS or the OIG may extend the 6-year retention requirement for the records enumerated in paragraph (d)(3) of this section in the event of an ongoing investigation, litigation, or negotiation involving civil, administrative or criminal liability. In addition, the sponsor of the qualified retiree prescription drug plan (or a designee), as applicable, must maintain the records enumerated in paragraph (d)(3) of this section longer than 6 years if it knows or should know that the records are the subject of an ongoing investigation, litigation or negotiation involving civil, administrative or criminal liability.

(3) The records that must be retained are:

(i) Reports and working documents of the actuaries who wrote the attestation submitted in accordance with § 423.884(a).

(ii)All documentation of costs incurred and other relevant information

utilized for calculating the amount of the subsidy payment made in accordance with § 423.886, including the underlying claims data.

(iii) Any other records specified by CMS.

(4) CMS may issue additional guidance addressing recordkeeping requirements, including (but not limited to) the use of electronic media.

§ 423.890 Appeals.

(a) *Informal written reconsideration.* (1) *Initial determinations.* A sponsor is entitled to an informal written reconsideration of an adverse initial determination. An initial determination is a determination regarding the following:

(i) The amount of the subsidy payment.

(ii) The actuarial equivalence of the sponsor's retiree prescription drug plan.

(iii) If an enrollee in a retiree prescription drug plan is a qualifying covered retiree; or

(iv) Any other similar determination (as determined by CMS) that affects eligibility for, or the amount of, a subsidy payment.

(2) *Effect of an initial determination regarding the retiree drug subsidy.* An initial determination is final and binding unless reconsidered in accordance with this paragraph (a) of this section.

(3) *Manner and timing for request.* A request for reconsideration must be made in writing and filed with CMS within 15 days of the date on the notice of adverse determination.

(4) *Content of request.* The request for reconsideration must specify the findings or issues with which the sponsor disagrees and the reasons for the disagreements. The request for reconsideration may include additional documentary evidence the sponsor wishes CMS to consider.

(5) *Conduct of informal written reconsideration.* In conducting the reconsideration, CMS reviews the subsidy determination, the evidence and findings upon which it was based, and any other written evidence submitted by the sponsor or by CMS before notice of the reconsidered determination is made.

(6) *Decision of the informal written reconsideration.* CMS informs the sponsor of the decision orally or through electronic mail. CMS sends a written decision to the sponsor on the sponsor's request.

(7) *Effect of CMS informal written reconsideration.* A reconsideration decision, whether delivered orally or in writing, is final and binding unless a request for hearing is filed in accordance with paragraph (b) of this section, or it is revised in accordance paragraph (d) of this section.

(b) *Right to informal hearing.* A sponsor dissatisfied with the CMS reconsideration decision is entitled to an informal hearing as provided in this section.

(1) *Manner and timing for request.* A request for a hearing must be made in writing and filed with CMS within 15 days of the date the sponsor receives the CMS reconsideration decision.

(2) *Content of request.* The request for informal hearing must include a copy of the CMS reconsideration decision (if any) and must specify the findings or issues in the decision with which the sponsor disagrees and the reasons for the disagreements.

(3) *Informal hearing procedures.* (i)CMS provides written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The hearing is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence that was not presented with the reconsideration request. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made both its initial and reconsideration determinations.

(iii) If CMS did not issue a written reconsideration decision, the hearing officer may request, but not require, a written statement from CMS or its contractors explaining CMS' determination, or CMS or its contractors may, on their own, submit the written statement to the hearing officer. Failure of CMS to submit a written statement does not result in any adverse findings against CMS and may not in any way be taken into account by the hearing officer in reaching a decision.

(4) *Decision of the CMS hearing officer.* The CMS hearing officer decides the case and sends a written decision to the sponsor, explaining the basis for the decision.

(5) *Effect of hearing officer decision.* The hearing officer decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (c) of this section.

(c) *Review by the Administrator.* (1) A sponsor that has received a hearing officer decision upholding a CMS initial or reconsidered determination may request review by the Administrator within 15 days of receipt of the hearing officer's decision.

(2) The Administrator may review the hearing officer's decision, any written documents submitted to CMS or to the hearing officer, as well as any other information included in the record of the hearing officer's decision and determine whether to uphold, reverse or modify the hearing officer's decision.

(3) The Administrator's determination is final and binding.

(d) *Reopening.* (1) *Ability to reopen.* CMS may reopen and revise an initial or reconsidered determination upon its own motion or upon the request of a sponsor:

(i) Within 1 year of the date of the notice of determination for any reason.

(ii) Within 4 years for good cause.

(iii) At any time when the underlying decision was obtained through fraud or similar fault.

(2) *Notice of reopening.* (i) Notice of reopening and any revisions following the reopening are mailed to the sponsor.

(ii) Notice of reopening specifies the reasons for revision.

(3) *Effect of reopening.* The revision of an initial or reconsidered determination is final and binding unless-

(i) The sponsor requests reconsideration in accordance with paragraph (a) of this section;

(ii) A timely request for a hearing is filed under paragraph (b) of this section;

(iii) The determination is reviewed by the Administrator in accordance with paragraph (c) of this section; or

(iv) The determination is reopened and revised in accordance with paragraph (d) of this section.

(4) *Good cause.* For purposes of this section, CMS finds good cause if —

(i) New and material evidence exists that was not readily available at the time the initial determination was made;

(ii) A clerical error in the computation of payments was made; or

(iii) The evidence that was considered in making the determination clearly shows on its face that an error was made.

(5) For purposes of this section, CMS does not find good cause if the only reason for reopening is a change of legal interpretation or administrative ruling upon which the initial determination was made.

(6) A decision by CMS not to reopen an initial or reconsidered determination is final and binding and cannot be appealed.

§ 423.892 Change of ownership.

(a) *Change of ownership.* Any of the following constitutes a change of ownership:

(1) *Partnership.* The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law.

(2) *Asset sale.* Transfer of all or substantially all of the assets of the sponsor to another party.

(3) *Corporation.* The merger of the sponsor's corporation into another corporation or the consolidation of the sponsor's organization with one or more other corporations, resulting in a new corporate body.

(b) *Change of ownership, exception.* Transfer of corporate stock or the merger of another corporation into the sponsor's corporation, with the sponsor surviving, does not ordinarily constitute change of ownership.

(c) *Advance notice requirement.* A sponsor that has a sponsor agreement in effect under this part and is considering or negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change.

(d) *Assignment of agreement.* When there is a change of ownership as specified in paragraph (a) of this section, and this results in a transfer of the liability for prescription drug costs, the existing sponsor agreement is automatically assigned to the new owner.

(e) *Conditions that apply to assigned agreements.* The new owner to whom a sponsor agreement is assigned is subject to all applicable statutes and regulations and to the terms and conditions of the sponsor agreement.

§ 423.894 Construction.

Nothing in this part must be interpreted as prohibiting or restricting:

(a) A Part D eligible individual who is covered under employment-based retiree health coverage, including a qualified retiree prescription drug plan, from enrolling in a Part D plan;

(b) A sponsor or other person from paying all or any part of the monthly beneficiary premium (as defined in § 423.286) for a Part D plan on behalf of a retiree (or his or her spouse or dependents);

(c) A sponsor from providing coverage to Part D eligible individuals under employment-based retiree health coverage that is—

(1) Supplemental to the benefits provided under a Part D plan; or

(2) Of higher actuarial value than the actuarial value of standard prescription drug coverage (as defined in § 423.104(d)); or

(d) Sponsors from providing for flexibility in the benefit design and pharmacy network for their qualified retiree prescription drug coverage, without regard to the requirements applicable to Part D plans under § 423.104, as long as the requirements under § 423.884 are met.

Subpart S—Special Rules for States-Eligibility Determinations for Subsidies and General Payment Provisions.

§ 423.900 Basis and scope.

(a) *Basis.* This subpart is based on sections 1935(a) through (d) of the Act as amended by section 103 of the MMA.

(b) *Scope.* This subpart specifies State agency obligations for the Part D prescription drug benefit.

§ 423.902 Definitions.

The following definitions apply to this subpart:

Actuarial value of capitated prescription drug benefits is the estimated actuarial value of prescription drug benefits provided under a comprehensive Medicaid managed care plan per full-benefit dual eligible individual for 2003, as determined using data as the Secretary determines appropriate. This value will be established using data determined by the Secretary to be the best available among the following options:

(1) State rate setting documentation for drug costs to the full dual eligible population;

(2) State encounter and enrollment record databases including cost data; and

(3) State managed care plan-specific financial cost data; and

(4) Other appropriate data.

Applicable growth factor for each of 2004, 2005, and 2006, is the average annual percent change (to that year from the previous year) of the per capita amount of prescription drug expenditures (as determined based on the most recent National Total Drug National Health Expenditure projections for the years involved). The growth factor for 2007 and succeeding years will equal the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals for the 12-month period ending in July of the previous year, as described in § 423.104(d)(5)(iv). CMS provides further detail regarding the sources of data to be used and how the annual percentage increase will be determined via operational guidance to States.

Base year Medicaid per capita expenditures are equal to the weighted average of:

(1) The gross base year (calendar year 2003) per capita Medicaid expenditures for prescription drugs, reduced by the rebate adjustment factor; and

(2) The estimated actuarial value of prescription drug benefits provided under a comprehensive capitated Medicaid managed care plan per full-benefit dual eligible for 2003. The per capita payments for full-benefit dual eligibles with comprehensive managed care and non-managed care are weighted by the respective average monthly full dual eligible enrollment populations reported through the Medicaid Statistical Information System (MSIS).

Full-benefit dual eligible individual means an individual who, for any month-

(1) Has coverage for the month under a prescription drug plan under Part D of title XVIII, or under an MA-PD plan under Part C of title XVIII; and

(2) Is determined eligible by the State for medical assistance for full benefits under title XIX for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act. (This does not include individuals under Pharmacy Plus demonstrations or under a section 1115 of the Act demonstration that provides pharmacy only benefits to these individuals.) It also includes any individual who is determined by the State to be eligible for medical assistance under section 1902(a)(10)(C) of the Act (medically needy) or section 1902(f) of the Act (States that use more restrictive eligibility criteria than are used by the SSI program) of the Act for any month if the individual was eligible for medical assistance in any part of the month. For the 2003 baseline calculations, the full-benefit dual eligibles are those individuals reported in MSIS as having Medicaid drug benefit coverage and Medicare Part A or Part B coverage. Dual eligibility status will be established by CMS using an algorithm that incorporates the quarterly MSIS dual eligibility code for the prescription fill date and the dual eligibility code for the prior quarter.

Gross base year Medicaid per capita expenditures are equal to the expenditures, including dispensing fees, made by the State and reported in MSIS during calendar year 2003 for covered outpatient drugs, excluding drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1860D–2 of the Act, other than smoking cessation agents determined per full-benefit dual eligible individual for the individuals not receiving medical assistance for the drugs through a comprehensive Medicaid managed care plan. This amount is determined based on MSIS drug claims paid during the four quarters of calendar year 2003 and the corresponding dual eligibility enrollment status of the beneficiary. MSIS drug claims having National Drug

Codes determined by CMS to be in the Part D excluded drug class, and claims having a program type code indicating Indian Health Service or Family Planning will be excluded from the calculation.

Phased-down State contribution factor for a month in 2006 is 90 percent; in 2007 is 88 1/3 percent; in 2008 is 86 2/3 percent; in 2009 is 85 percent; in 2010 is 83 1/3 percent; in 2011 is 81 2/3 percent; in 2012 is 80 percent; in 2013 is 78 1/3 percent; in 2014 is 76 2/3 percent; or after December 2014, is 75 percent.

Phased-down State contribution payment refers to the States' monthly payment made to the Federal government beginning in 2006 to defray a portion of the Medicare drug expenditures for full-benefit dual eligible individuals whose Medicaid drug coverage is assumed by Medicare Part D. The contribution is calculated as 1/12th of the base year (2003) Medicaid per capita expenditures for prescription drugs (that is, covered Part D drugs) for full-benefit dual eligible individuals,

(1) Multiplied by the State medical assistance percentage;

(2) Increased for each year (beginning with 2004 up to and including the year involved) by the applicable growth factor;

(3) Multiplied by the number of the State's full-benefit dual eligible individuals for the given month; and

(4) Multiplied by the phased-down State contribution factor.

Rebate adjustment factor takes into account drug rebates and, for a State, is equal to the ratio of the four quarters of calendar year 2003 of aggregate rebate payments received by the State under section 1927 of the Act to the gross expenditures for covered outpatient drugs.

State medical assistance percentage means the proportion equal to 100 percent minus the State's Federal medical assistance percentage, applicable to the State for the fiscal year in which the month occurs.

§ 423.904 Eligibility determinations for low-income subsidies.

(a) *General rule.* The State agency must make eligibility determinations and redeterminations for low-income premium and cost-sharing subsidies in accordance with subpart P of part 423.

(b) *Notification to CMS.* The State agency must inform CMS of cases where eligibility is established or redetermined, in a manner determined by CMS.

(c) *Screening for eligibility for Medicare cost-sharing and enrollment under the State plan.* States must—

(1) Screen individuals who apply for subsidies under this part for eligibility for Medicaid programs that provide assistance with Medicare cost-sharing specified in section 1905(p)(3) of the Act.

(2) Offer enrollment for the programs under the State plan (or under a waiver of the plan) for those meeting the eligibility requirements.

(d) *Application form and process.* (1) *Assistance with application.* No later than July 1, 2005, States must make available—

(i) Low-income subsidy application forms;

(ii) Information on the nature of, and eligibility requirements for, the subsidies under this section; and

(iii) Assistance with completion of low-income subsidy application forms.

(2) *Completion of application.* The State must require an individual or personal representative applying for the low-income subsidy to—

(i) Complete all required elements of the application and provide documents, as necessary, consistent with paragraph (d)(3) of this section; and

(ii) Certify, under penalty of perjury or similar sanction for false statements, as to the accuracy of the information provided on the application form.

(3) *The application process and States.* (i) States may require submission of statements from financial institutions for an application for low-income subsidies to be considered complete; and

(ii) May require that information submitted on the application be subject to verification in a manner the State determines to be most cost-effective and efficient.

(4) *Other information.* States must provide CMS with other information as specified by CMS that may be needed to carry out the requirements of the Part D prescription drug benefit.

§ 423.906. General payment provisions.

(a) *Regular Federal matching.* Regular Federal matching applies to the eligibility determination and notification activities specified in § 423.904(a) and (b).

(b) *Medicare as primary payer.* Medicare is the primary payer for covered drugs for Part D eligible individuals. Medical assistance is not available to full-benefit dual eligible individuals, including those not enrolled in a Part D plan, for—

(1) Covered Part D drugs; or

(2) Any cost-sharing obligations under Part D relating to covered Part D drugs.

(3) The effective date of paragraphs (b)(1) and (b)(2) of this section is January 1, 2006.

(c) *Non-covered drugs.* States may elect to provide coverage for outpatient drugs other than covered Part D drugs in the same manner as provided for non-full benefit dual eligible individuals or through an arrangement with a prescription drug plan or a MA-PD plan.

§ 423.907 Treatment of territories.

(a) *General rules.* (1) Low-income Part D eligible individuals who reside in the territories are not eligible to receive premium and cost-sharing subsidies under subpart P of this part.

(2) A territory may submit a plan to the Secretary under which medical assistance is to be provided to low-income individuals for the provision of covered Part D drugs.

(3) Territories with plans approved by the Secretary will receive increased grants under section 1935(e)(3) of the Act as described in paragraph (c) of this section.

(b) *Plan requirements.* Plans submitted to the Secretary must include the following:

(1) A description of the medical assistance to be

provided.

(2) The low-income population (income less than 150

percent of the Federal poverty level) to receive medical assistance.

(3) An assurance that no more than 10 percent of the

amount of the increased grant will be used for administrative expenses.

(c) *Increased grant amounts.* The amount of the grant provided under section 1108 (f) of the Act as increased by section 1108 (g) of the Act for each territory with an approved plan for a year is the amount in paragraph (d) of this section multiplied by the ratio of—

(1) The number of individuals who are entitled to benefits under Part A or enrolled under Part B and who reside in the territory (as determined by the Secretary based on the most recent available data for the beginning of the year); and

(2) The sum of the number of individuals in all territories in paragraph (c)(1) of this section with approved plans.

(d) *Total grant amount.* The total grant amount is—

(1) For the last three quarters of fiscal year 2006, $28,125,000;

(2) For fiscal year 2007, $37,500,000; and

(3) For each subsequent year, the amount for the prior fiscal year increased by the annual percentage increase described in § 423.104(d)(5)(iv).

§ 423.908. Phased-down State contribution to drug benefit costs assumed by Medicare.

This subpart sets forth the requirements for State contributions for Part D drug benefits based on full-benefit dual eligible individual drug expenditures.

§ 423.910 Requirements.

(a) *General rule.* Each of the 50 States and the District of Columbia is required to provide for payment to CMS a phased-down contribution to defray a portion of the Medicare drug expenditures for individuals whose projected Medicaid drug coverage is assumed by Medicare Part D.

(b) *State contribution payment.* (1) *Calculation of payment.* The State contribution payment is calculated by CMS on a monthly basis, as indicated in the following chart. For States that do not meet the quarterly reporting requirement for the monthly enrollment reporting, the State contribution payment is calculated using a methodology determined by CMS.

ILLUSTRATIVE CALCULATION OF STATE PHASED-DOWN MONTHLY CONTRIBUTION FOR 2006

	Item	Illustrative Value	Source
(i)	Gross per capita Medicaid expenditures for prescription drugs for 2003 for full-benefit dual eligibles not receiving drug coverage through a comprehensive Medicaid managed care plan, excluding drugs not covered by Part D	$2,000	CY MSIS data
(ii)	Aggregate State rebate receipts in calendar year 2003	$100,000,000	CMS–64
(iii)	Gross State Medicaid expenditures for prescription drugs in calendar year 2003	$500,000,000	CMS–64
(iv)	Rebate adjustment factor	0.2000	(2) ÷ (3)
(v)	Adjusted 2003 gross per capita Medicaid expenditures for prescription drugs for full-benefit dual eligibles not in comprehensive managed care plans	$1,600	(1) x [1- (4)]
(vi)	Estimated actuarial value of prescription drug benefits under comprehensive capitated managed care plans for full-benefit dual eligibles for 2003	$1,500	To be Determined
(vii)	Average number of full-benefit dual eligibles in 2003 who did not receive covered outpatient drugs through comprehensive Medicaid managed care plans	90,000	CY MSIS data
(viii)	Average number of full-benefit dual eligibles in 2003 who received covered outpatient drugs through comprehensive Medicaid managed care plans	10,000	CY MSIS data
(ix)	Base year State Medicaid per capita expenditures for covered Part D drugs for full-benefit dual eligible individuals (weighted average of (5) and (6))	$1,590	[(7)x(5) + (8)x(6)]÷[(7) + (8)]
(x)	100 minus Federal Medical Assistance Percentage (FMAP) applicable to month of State contribution (as a proportion)	0.4000	**Federal Register**
(xi)	Applicable growth factor (cumulative increase from 2003 through 2006)	50.0%	NHE projections
(xii)	Number of full-benefit dual eligibles for the month	120,000	State submitted data
(xiii)	Phased-down State reduction factor for the month	0.9000	specified in statute
(xiv)	Phased-down State contribution for the month	$8,586,000	1/12 x (9) x (10) x [1+(11)] x (12) x (13)

(2) *Method of payment.* Payments for the phased down State contribution begins in January 2006, and are made on a monthly basis for each subsequent month. State payment must be made in a manner specified by CMS that is

similar to the manner in which State payments are made under the State Buy-in Program except that all payments must be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund. The policy on collection of the Phased-down State contribution payment is the same as the policy that governs collection of Part A and Part B Medicare premiums for State Buy-in.

(c) *State Medicaid Statistical Information System (MSIS) Reporting.* Effective with calendar year (CY) 2003 and all subsequent MSIS data submittals, States are required to provide accurate and complete coding to identify the numbers and types of Medicaid and Medicare dual eligibles. Calendar year 2003 submittals must be complete and must be accepted, based on CMS' data quality review, by December 31, 2004.

(d) *State monthly enrollment reporting.* Effective June 2005, and each subsequent month, States must submit an electronic file, in a manner specified by CMS, identifying each full-benefit dual eligible individual enrolled in the State for each month. This file must include specified information including identifying information, a dual eligible type code, available income data and institutional status. The file includes data on enrollment for the current month, plus retroactive changes in enrollment characteristics for prior months. This file will be used by CMS to establish the monthly enrollment for those individuals with Part D drug coverage who are also determined by the State to be eligible for full Medicaid benefits subject to the phased down State contribution payment. This file is due to CMS no later than the last day of the reporting month. For States that do not submit an acceptable file by the end of the month, the phased down State contribution for that month is based on data deemed appropriate by CMS.

(e) *Data match.* CMS performs those periodic data matches as may be necessary to identify and compute the number of full-benefit dual eligible individuals needed to establish the State contribution payment.

(f) *Rebate adjustment factor.* CMS establishes the rebate adjustment factor using total drug expenditures made and drug rebates received during calendar year 2003 as reported on CMS 64 Medicaid expenditure reports for the four quarters of calendar year 2003 that were received by CMS on or before March 31, 2004. Rebates include rebates received under the national rebate agreement and under a State supplemental rebate program, as reported on CMS–64 expenditure reports for the four quarters of calendar year 2003.

(g) *Annual per capita drug expenditures.* CMS notifies each State no later than October 15 before each calendar year, beginning October 15, 2005, of their annual per capita drug payment expenditure amount for the next year.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare Supplementary Medical Insurance Program)

Dated: January 10, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Dated: January 14, 2005.

Tommy G. Thompson,

Secretary of Health and Human Services.

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