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42 CFR Parts 417, 422, and 423
Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, and 423

[CMS–4131–F and CMS 4138–F]

RIN 0938–AP24 and 0938–AP52

Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs

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

ACTION: Final rule.

SUMMARY: This final rule finalizes revisions to the regulations governing the Medicare Advantage (MA) program (Part C), prescription drug benefit program (Part D) and section 1876 cost plans including conforming changes to the MA regulations to implement statutory requirements regarding special needs plans (SNPs), private fee-for-service plans (PFFS), regional preferred provider organizations (RPPO) plans, and Medicare medical savings accounts (MSA) plans, cost-sharing for dual-eligible enrollees in the MA program and prescription drug pricing, coverage, and payment processes in the Part D program, and requirements governing the marketing of Part C and Part D plans.

DATES: *Effective Date:* Except as otherwise specified these regulations are effective on October 31, 2011.

FOR FURTHER INFORMATION CONTACT:

Vanessa Duran, (410) 786–8697 and Heather Rudo, (410) 786–7627, General information.

Christopher McClintick, (410) 786–4682, Part C issues.

Lisa Thorpe, (410) 786–3048, Part D issues.

Frank Szeflinski, (303) 844–7119, Part C payment issues.

Camille Brown, (410) 786–0274, Marketing issues.

SUPPLEMENTARY INFORMATION:

I. Background

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) established a new ''Part C'' in the Medicare statute (sections 1851 through 1859 of the Social Security Act (the Act)) which established the current MA program. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) established the Part D program and made significant revisions to Part C provisions governing the Medicare Advantage (MA) program. The MMA directed that important aspects of the Part D program be similar to, and coordinated with, regulations for the MA program. Generally, the provisions enacted in the MMA took effect January 1, 2006. The final rules implementing the MMA for the MA and Part D prescription drug programs appeared in the January 28, 2005 **Federal Register** on (70 FR 4588 through 4741 and 70 FR 4194 through 4585, respectively).

As we gained more experience with the MA program and the prescription drug benefit program, we proposed to revise areas of both programs and issued a proposed rule on May 16, 2008 (73 FR 28556) that would have clarified existing policies or codified current guidance for both programs. The Medicare Improvements for Patients and Providers Act (MIPPA) (Pub. L. 110–275), enacted on July 15, 2008, called upon the Secretary to revise the marketing requirements for Part C and Part D plans in several areas. MIPPA also enacted changes with respect to Special Needs Plans (SNPs), Private Fee-For-Service plans (PFFS), Quality Improvement Programs, the prompt payment of Part D claims, and the use of Part D data. With the exceptions noted in this final rule, MIPPA required that these new rules take effect at a date specified by the Secretary, but no later than November 15, 2008.

Because several of these proposed regulatory revisions in our May 16, 2008 proposed rule were overtaken by statutory provisions in MIPPA, the MIPPA provisions superseded our proposed rulemaking in these areas. For example, some provisions in our May 16, 2008 proposed rule addressed issues in areas in which MIPPA required that we establish marketing limits no later than November 15, 2008. As a result, we implemented all provisions addressed in our May 16, 2008 proposed rule, and later overtaken by MIPPA provisions, in our September 18, 2008 and November 14, 2008 interim final rules with comment (IFCs). We finalized the non-MIPPA related provisions of our May 16, 2008 proposed rule in our January 16, 2009 final rule with comment period.

This final rule finalizes the MIPPA-related provisions of our September 18, 2008 IFC (73 FR 54226), our November 14, 2008 IFC (73 FR 67406), our November 21, 2008 correction notice (73 FR 70598), and one provision on two SNP-related statutory definitions that was finalized with a comment period in our January 16, 2009 final rule with comment period (74 FR 2881).

II. Provisions of This Final Rule

Revisions made in this final rule govern section 1876 cost contract plans and the MA and prescription drug benefit programs. Several of the final provisions affect both the MA and Part D programs. In our discussion that follows, we note when a provision affects both the MA and prescription drug benefit, and we include in section II.C. of this final rule, a table comparing the final Part C and Part D program changes by specifying each issue and the sections of the Code of Federal Regulations that we are revising for both programs.

A. Changes to the Regulations in Part 422—Medicare Advantage Program

1. Special Needs Plans

Congress authorized special needs plans (SNPs) as a type of Medicare Advantage (MA) plan designed to enroll individuals with special needs. The three types of special needs individuals eligible for enrollment in a SNP identified in the MMA include—(1) Institutionalized individuals (defined in § 422.2 as an individual continuously residing, or expecting to continuously reside, for 90 days or longer in a long term care facility); (2) individuals entitled to medical assistance under a State Plan under title XIX of the Act; or (3) other individuals with severe or disabling chronic conditions that would benefit from enrollment in a SNP.

As of January 2011, there are 455 SNP plan benefit packages (PBPs) in operation nationwide. These SNP PBPs include 298 dual-eligible SNP (D–SNP) PBPs, 92 chronic care SNP (C–SNP) PBPs, and 65 institutional SNP (I–SNP) PBPs.

a. Model of Care (§ 422.101(f))

Section 164 of MIPPA added care management requirements for all SNPs effective January 1, 2010, as set forth in section 1859(f)(5) of the Act (42 U.S.C. 1395w–28(f)). The new mandate required dual-eligible, institutional, and chronic condition SNPs to implement care management requirements which have two explicit components: an evidence-based model of care and a battery of care management services. While the revisions made in our September 18, 2008 IFC simply reflected the substance of the new MIPPA provisions, our May 16, 2008 proposed rule proposed other, related provisions which were finalized in our January 12, 2009 final rule.

The first component of the new mandate enacted in section 164 of MIPPA is a requirement for an evidence-based model of care with an appropriate

network of providers and specialists that meet the specialized needs of the SNP target population. We received a few comments on our September 18, 2008 IFC about whether we would issue evidence-based guidelines for the model of care, but we did not in our September 18, 2008 IFC implement this mandate to endorse any particular set of evidence-based guidelines or protocols; instead, we expected that SNPs would develop such guidelines and protocols based on the specific elements to be included in the model of care as found in the 2008 and 2009 Call Letters. We expected that SNPs would be able to use resources such as the Agency for Healthcare Research and Quality (AHRQ, *http://www.ahrq.gov/*). AHRQ does not endorse any particular set of evidence-based guidelines or protocols; however, its Web site includes access to nationally-recognized evidence-based practices. The second component is a battery of care management services that includes: (1) A comprehensive initial assessment and annual reassessments of an individual's physical, psychosocial, and functional needs; (2) an individualized plan of care that includes goals and measurable outcomes, including specific services and benefits to be provided; and (3) an interdisciplinary team to manage care. In addition, MIPPA mandated a periodic audit of SNPs to ensure SNPs meet the model of care requirements.

We also have issued guidance on the SNP model of care in our 2008 and 2009 Call Letters. In addition, care coordination and the presence of a provider network comprised of clinical experts pertinent to a SNP's target population have long been the cornerstones of the SNP model of care.

In this final rule, we are revising § 422.101(f)(1), which was effective January 1, 2010, to correct a typo. The phrase that we are replacing is ''indentifying goals,'' and adding ''identifying goals'' in its place.

b. Definitions: Institutional-Equivalent and Severe or Disabling Chronic Condition (§ 422.2)

Section 164 of MIPPA, *inter alia,* modified the requirements and definitions pertaining to an institutional special needs individual and a ''severe or disabling chronic condition'' special needs individual, without specifically defining the relevant terms. In response to our May 16, 2008 proposed rule regarding eligibility for institutional-level individuals and severe or disabling chronic condition individuals, we received public comments that requested that we propose two additional SNP definitions. Accordingly, in our January 12, 2009 final rule with comment period in which we added definitions based on comments from the May 16, 2008 proposed rule, we specified the following definitions for ''Institutional Equivalent'' and ''Disabling Chronic Condition.''

''Institutional-equivalent'' means, for the purpose of defining a special needs individual, an MA eligible individual who is living in the community, but requires an institutional level of care (LOC). The determination that the individual requires an institutional LOC must be made by—

- The use of a State assessment tool from the State in which the individual resides; and
- An assessment conducted by an impartial entity with the requisite knowledge and experience to accurately identify whether the beneficiary meets the institutional LOC criteria.

In States and territories that do not have an existing institutional LOC tool, the individual must be assessed using the same methodology that specific State uses to determine institutional LOC for Medicaid nursing home eligibility.

In our January 12, 2009 final rule with comment period, we specified that the determination of institutional LOC must be made using a State assessment tool because States have extensive experience in making LOC determinations. We also specified that this LOC determination also be made by an additional entity, other than the Medicare Advantage Organization (MAO), to ensure the impartially of the assessment.

''Severe or Disabling Chronic Condition'' means, for the purposes of defining a special needs individual, an MA eligible individual who has one or more co-morbid and medically complex chronic conditions that are substantially disabling or life-threatening; has a high risk of hospitalization or other significant adverse health outcomes; and requires specialized delivery systems across domains of care.

We did not receive any comments on these definitions. As such, they are adopted without modification in this final rule.

c. Dual-Eligible SNPs and Contracts With States (§ 422.107)

Section 164(c) of MIPPA modified section 1859(f)(3)(D) of the Act to require that, effective January 1, 2010, all MA organizations offering new dual-eligible SNPs (D–SNPs), or seeking to expand the service area of existing D–SNPs, have a contract with the State Medicaid agency(ies) in the State(s) in which the D–SNP operates to provide benefits, or to arrange for the provision of benefits to individuals entitled to receive medical assistance under title XIX of the Act. In order to implement this requirement, we specified in our (74 FR 54226) IFC published on September 18, 2008 that the contract with the State Medicaid agency(ies) must include, at minimum: (1) The MAO's responsibility to provide or arrange for Medicaid benefits; (2) the category(ies) of eligibility covered under the D–SNP; (3) the Medicaid benefits covered under the D–SNP; (4) the cost-sharing protections covered under the D–SNP; (5) the identification and sharing of information on Medicaid provider participation; (6) the verification of enrollee's eligibility for both Medicare and Medicaid; (7) the service area covered by the D–SNP; and (8) the contract period for the D–SNP. We further clarified that States are not required to enter into these contracts with a particular plan or any SNP in the state at all, and that we would not permit D–SNPs without State contracts to expand their service areas in 2010. We also specified that, for contract year 2010, MAOs with existing D–SNPs may continue to operate in their existing service area without a State Medicaid Agency contract, provided they meet all other statutory requirements, including care management and quality improvement program requirements. We set forth these requirements at § 422.107.

Comment: Many commenters supported requiring the collaboration between MAOs offering D–SNPs and State Medicaid agencies. However, the majority of comments that offered qualified support raised questions and concerns about operational issues related to the submission of these State Medicaid Agency contracts to CMS. Several commenters contended that variation in State contracting and procurement processes make it difficult for D–SNPs to obtain State Medicaid Agency contracts by CMS' deadline, and requested that we give D–SNPs additional time and flexibility, on a case by case basis, to meet our contracting deadlines.

Response: We appreciate the commenters' support for the requirement that D–SNPs contract with the State Medicaid agencies in the States within which the D–SNPs operate. Although we appreciate the information about how D–SNPs are impacted by our State Medicaid Agency contract submission deadlines, we are not modifying the provision to address the operational issues that the commenters raised because we do not

believe that rulemaking is the appropriate vehicle for addressing such issues. However, we note, that while we are not addressing these specific operational concerns in this final rule, we provided operational guidance to MAOs well in advance of the 2012 contract submission deadline. Additional guidance for the 2013 contract submission deadline will be included in the 2013 SNP Application, the Call Letter for CY 2013, and in any additional HPMS memoranda about the D–SNP–State Medicaid agency contract requirement.

Comment: A number of commenters that submitted comments sought clarification on the States' obligations to contract with D–SNPs, including whether a State Medicaid agency is required to enter into contracts with all D–SNPs that seek to operate in its State. One commenter expressed concern about being able to contract with all of the D–SNPs that operate in its State because of budgetary concerns and contended that this MIPPA requirement to contract with D–SNPs conflicts with its established Medicaid managed care models. A few commenters suggested that CMS hold D–SNPs harmless if the D–SNP made a good faith effort to contract and the State Medicaid agencies either refused to contract with the D–SNP at all or refused to include the required provisions of § 422.107(c) in the contract between the DSNP and the State Medicaid agency. Several of these commenters requested that CMS provide incentives and assistance to States to contract with D–SNPs and facilitate the contracting process between D–SNPs and the State Medicaid agencies. By contrast, one commenter recommended that CMS communicate with State Medicaid agencies about D–SNPs that seek to operate in its State so the State can let CMS know what SNPs it will not contract with, thereby alleviating CMS' burden of reviewing SNPs with which a State will not contract.

Response: As explicitly provided in section 164(c)(4) of MIPPA, States are not under any obligations to contract with D–SNPs and can decline a D–SNP's request to enter into a contract for any reason. D–SNPs must still comply with the State contract requirements as established in section 164(c) and our regulations at § 422.107. However, as required by MIPPA and modified by the Affordable Care Act of 2010, to operate during contract year 2013 and beyond, all D–SNPs must secure a State Medicaid Agency contract containing, at minimum, all provisions listed in § 422.107(c); existing D–SNPs that do not obtain a required contract with their State Medicaid agency(ies) will not be permitted to continue. We do not believe that Congress intended that we hold D–SNPs harmless if the D–SNP made a good faith effort to contract and the State Medicaid agencies either refused to contract with the D–SNP at all or refused to include the required provisions. As required by section 164(c) of MIPPA, and in an effort to facilitate the contracting process between State Medicaid agencies and D–SNPs, we have established a State Resource Center to provide States with helpful information as they engage in contract negotiations with D–SNPs. This State Resource Center is designed to facilitate integration and coordination of benefits, policies, and day-to-day business processes between State Medicaid agencies and D–SNPs, and was also developed to provide a forum for States to make inquiries and share information with CMS and each other about the coordination of State and Federal policies pertaining to SNPs. States and D–SNPs seeking assistance with these requirements may e-mail at *State_Resource_Center@cms.hhs.gov,* or visit the State Resource Center Web site at *https://www.cms.hhs.gov/SpecialNeedsPlans/05_StateResourceCenter.asp.* We are, therefore, finalizing this provision without further modification.

Comment: Several commenters requested clarification on the meaning of ''providing benefits, or arranging for benefits to be provided'' under § 422.107(b), which states that ''[t]he MA organization retains responsibility under the contract for providing benefits, or arranging for benefits to be provided, for individuals entitled to receive medical assistance under title XIX * * *''. A few commenters sought confirmation that, with this language, CMS is not requiring D–SNPs to provide the Medicaid benefits directly to the dual-eligible beneficiary; rather, these commenters suggested that they should be able to subcontract with another entity for the provision of the benefits. Additionally, one commenter questioned whether States may enter into a State Medicaid Agency contract with a D–SNP under which the SNP does not have a contractual obligation to provide any Medicaid benefits. As noted by this commenter, such an option would enable States to facilitate the continued operation of D–SNPs without creating a conflict with the State's existing managed care models.

Response: D–SNPs may provide Medicaid benefits directly, or under contract with another entity, but must retain responsibility for the Medicaid benefits. States and D–SNPs identify the package of Medicaid benefits included under the D–SNP in their contract negotiations. The requirement that the D–SNP retain responsibility for the Medicaid benefits does not allow for a MIPPA compliant State Medicaid Agency contract under which the SNP does not have a contractual obligation to provide any Medicaid benefits. We are, therefore, finalizing this provision without further modification.

Comment: Many commenters questioned and sought clarification on the minimum contract requirements specified in § 422.107(c) and questioned whether various existing contracting arrangements between MAOs and States (that is, HIPAA business associate agreements or existing contracts between States and Medicaid managed care organizations) would satisfy the requirements of § 422.107(c). Commenters also requested we clarify: (1) The meaning of ''provide or arrange for Medicaid benefits'' under § 422.107(c)(1); (2) whether under § 422.107(c)(2), the State Plan governs the categories of dual eligible beneficiaries to be specified under the State contract, and whether the D–SNP must serve all duals in a State as opposed to smaller subsets of the State's dual-eligible population; (3) the scope of Medicaid benefits to be covered under the SNP; (4) the meaning ''cost sharing provisions under the SNP''; (5) the meaning of ''identification and sharing of information on Medicaid provider participation''; (6) the meaning of ''verification of enrollee's eligibility for both Medicare and Medicaid''; (7) whether the Medicaid managed care contract service area must match up with the D–SNP service area; and (8) whether CMS will accept contracts with evergreen clauses.

Response: In order to comply with the State Medicaid Agency contract requirements under section 164 of MIPPA, all contracts must, at minimum, contain the provisions outlined in § 422.107(c). We are unable to make a blanket determination that certain agreements between SNPs and State Medicaid agencies do or do not contain all of the required provisions; rather, we will review each contract individually for each required element to determine compliance. To provide D–SNPs more information on these requirements, we released and will continue to update additional guidance through the Medicare Managed Care Manual and other guidance vehicles (that is, HPMS memos) on the minimum contract requirements specified in § 422.107. Additionally, the following explanations provide some further

clarification on the required contract provisions:

• *The MA organization's responsibility, including financial obligations, to provide or arrange for Medicaid benefits:* This requirement under § 422.107(c) simply requires that the contract between the D–SNP and the State Medicaid agency clearly outline the process by which the D–SNP will provide or arrange for Medicaid benefits and specify how the Medicare and Medicaid benefits will be integrated and/or coordinated. The meaning of ''provide or arrange for Medicaid benefits'' is previously discussed in response to the previous comment regarding the meaning of these terms under § 422.107(b).

• *The category(ies) of eligibility for dual-eligible beneficiaries to be enrolled under the SNP, including the targeting of specific subsets:* This contract provision must specify the population of dual-eligible beneficiaries eligible to enroll in the D–SNP, and any enrollment limitations for Medicare beneficiaries under this D–SNP must parallel any enrollment limitations under the Medicaid program and Medicaid State Plan. A D–SNP contract with a State Medicaid agency may be for the State's entire population of dual-eligible beneficiaries or may cover certain categories of dual-eligible individuals. To the extent a State Medicaid agency excludes specific groups of dual eligibles from their Medicaid contracts or agreements, those same groups must be excluded from enrollment in the SNP, provided that the enrollment limitations parallel the structure and care delivery of the State Medicaid program. For organizations that contract with the State as a Medicaid managed care plan, enrollment in the D–SNP must be limited to the dual-eligible beneficiaries permitted to enroll in that organization's Medicaid managed care contract.

• *The Medicaid benefits covered under the SNP:* This State contract provision must specify information on benefit design and administration, and delineate plan responsibility to provide or arrange for benefits. The contract should specify the Medicaid benefits offered under the State Plan as well as those benefits the D–SNP will offer that go beyond what is required under Original Medicare.

• *The cost-sharing protections covered under the SNP:* The State Medicaid Agency contract should include the limitation on out of pocket costs for the applicable categories of dual eligible beneficiaries (for example, full benefit dual-eligible individuals). D–SNPs must enforce limits on out-of-pocket costs for dual-eligibles, and contracts between D–SNPs and State Medicaid agencies must specify that the D–SNP will not impose cost-sharing requirements on specified dual-eligible individuals that would exceed the amounts permitted under the State Medicaid Plan if the individual were not enrolled in the D–SNP.

• *The identification and sharing of information on Medicaid provider participation:* Meeting this contracting element requires that the information provided include a process for the State to identify and share information on providers contracted with the State Medicaid agency for inclusion in the SNP provider directory. Although CMS does not require all providers to accept both Medicare and Medicaid, the D–SNP's Medicare and Medicaid networks should meet the needs of the dual-eligible population served.

• *The verification of enrollee's eligibility for both Medicare and Medicaid:* The contract must describe in detail how the State Medicaid agency will provide D–SNPs with access to real time information to verify eligibility of enrolled dual eligible members.

• *The service area covered by the SNP:* The State contract provision must clearly identify the covered service area in which the State has agreed the D–SNP may operate. The D–SNPs service area cannot exceed the service area specified in the State Medicaid Agency contract. By contrast, the Medicaid managed care service area can exceed or include more counties than the D–SNP service area.

• *The contract period for the SNP:* The State Medicaid Agency contract requires a contract term covering at least January 1 through December 31 of the relevant MA contract year. If the State is unable to meet this required contract term provision, the D–SNP may include an evergreen clause within the contract and provide information about when the State issues updates to its existing contracts with evergreen clauses. Therefore, we are finalizing this provision without modification.

Comment: One commenter sought clarification about whether a D–SNP with authority to operate without a State Medicaid Agency contract can increase enrollment in the existing counties in its service area.

Response: D–SNPs that are permitted to operate in contract year 2012 without a State Medicaid Agency contract are also permitted to increase enrollment in the counties in their existing service area. Section 164(c) of MIPPA provided that all new D–SNPs must have contracts with the State Medicaid agencies in the States in which the D–SNPs operate. This provision allowed existing D–SNPs that were not seeking to expand their service areas the authority to continue operating without a State contract through the 2010 contract year. In 2010, section 3205 of the Affordable Care Act extended this provision for existing, non-expanding D–SNPs through the end of the 2012 contract year. As such, for contract year 2012, D–SNPs are only required to have a signed State Medicaid Agency contract to operate if they: (1) Are offering a new D–SNP-type in CY 2012; (2) are expanding the service area of an existing D–SNP type in CY 2012; (3) offered a new D–SNP type in CY 2010 or CY 2011; or (4) expanded the service area of an existing D–SNP during either of these 2 contract years. Since our April 2011 final rule (76 FR 21563) entitled, Medicare Program: Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes, finalized changes to § 422.107(d)(1)(ii) such that existing D–SNPs can operate without State Medicaid contracts through CY 2012, provided they do not expand their service areas, the regulatory text changes we made to § 422.107(d)(1)(ii) in our September 18, 2008 IFC have been superseded. Therefore, in this final rule, we are not finalizing the regulatory text changes to § 422.107(d)(1)(ii) that we described in our September 18, 2008 IFC.

Comment: Two commenters sought clarification on whether MIPPA's State Medicaid Agency contract requirement applies only to D–SNPs or to all SNPs types that serve and enroll dual-eligible beneficiaries. One commenter suggested this provision broadly apply to all SNP types.

Response: Section 164(c) of MIPPA requires that D–SNPs contract with the State Medicaid agencies in the States in which the D–SNP operates to provide benefits, or arrange for benefits to be provided, for individuals entitled to receive medical assistance under title XIX. This requirement is found in section 164(c) of MIPPA under a subsection starting with the statutory text ''ADDITIONAL REQUIREMENTS FOR DUAL SNPS.'' Further, this provision specifically refers to a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(ii), which we have interpreted in past guidance to mean D–SNPs. As such, it is clear that Congress only intended that this State contract requirement apply to D–SNPs, and not C–SNPs and I–SNPs that enroll dual-eligible beneficiaries. Therefore, we are finalizing this provision without modification.

d. SNPs and Quality Improvement Program (§ 422.152)

Section 164 of MIPPA amended section 1852(e)(3)(A) of the Act to add clause (ii) and added a new paragraph (6) to section 1857(d) of the Act. Section 1852(e)(3)(A)(ii) of the Act requires that data collected, analyzed, and reported as part of the plan's quality improvement (QI) program must measure health outcomes and other indices of quality at the plan level with respect to the model of care (MOC) as required in section 1859(f)(2) through (5) of the Act. As a Medicare Advantage (MA) plan, each SNP must implement a documented QI program for which all information is available for submission to CMS or for review during monitoring visits. The focus of the SNP QI program should be the monitoring and evaluation of the performance of its MOC (see § 422.101(f)). In the September 18, 2008 IFC, we stated that, no later than January 1, 2010, the program should be executed as a three-tier system of performance improvement.

The first tier of this program consisted of collection and analysis of data on quality and outcome to enable beneficiaries to compare and select among health coverage options. As part of the first tier implementation and to pilot the development of comparative measures to facilitate beneficiary choice, SNPs were required to collect, analyze, and submit 13 Healthcare Effectiveness Data and Information Set (HEDIS®) measures and three National Committee on Quality Assurance (NCQA) structure and process measures in CY 2008. Since CY 2008, we have required SNPs to submit eight HEDIS® and six NCQA structure and process measures.

The second tier of the QI program for SNPs was effective on January 1, 2010 and was implemented consistent with the requirements § 422.152(g). As we articulated in our September 18, 2008 IFC, § 422.152(g) reflects the requirement under section 1852(e)(3)(A)(ii) of the Act, added by MIPPA, that SNPs collect, analyze, and report data that measures the performance of their plan-specific MOC. SNPs may measure the effectiveness of their MOCs, as required under § 422.152(g), using a variety of plan-determined methodologies, such as claims data, record reviews, administrative data, clinical outcomes, and other existing valid and reliable measures (for example, Assessing Care of Vulnerable Elders (ACOVE) measures, Minimum Data Set (MDS), HEDIS®, Health Outcomes Survey (HOS), and the Outcome and Assessment Information Set (OASIS)) at the plan level to evaluate the effectiveness of the process of care and clinical outcomes. Specifically, each SNP must measure the effectiveness of its MOC through the collection, aggregation, analysis, and reporting of data that demonstrate: Access to care; improvement in beneficiary health status; staff implementation of the MOC as evidenced by measures of care structure and process from the continuity of care domain; comprehensive health risk assessment; care management through an individualized plan of care; provision of specialized clinical expertise targeting its special needs population through a provider network; coordination and delivery of services and benefits through transitions across settings and providers; coordination and delivery of extra services and benefits that meet the needs of the most vulnerable beneficiaries; use of evidence-based practices and/or nationally recognized clinical protocols; and the application of integrated systems of communication. As we specified in our September 18, 2008 IFC, each SNP must coordinate the systematic collection of data using indicators that are objective, clearly defined, and based on measures having established validity and reliability. We further clarified that the indicators should be selected from a variety of quality and outcome measurement domains such as functional status, care transitioning, disease management, behavioral health, medication management, personal and environmental safety, beneficiary involvement and satisfaction, and family and caregiver support. We also stated that SNPs must document all aspects of their QI program, including data collection and analysis, actions taken to improve the performance of the MOC, and the participation of the interdisciplinary team members and network providers in QI activities.

We are currently implementing the third tier of the QI program, which is the required reporting of monitoring data, that consists of a prescribed sample of data that SNPs collect under the second tier of the QI program to measure their performance under their MOCs. MA organizations must currently collect and report ''data that permits the measurement of health outcomes and other indices of quality.'' Accordingly, MA organizations must collect and report data from the HEDIS®, HOS, and CAHPS® instruments, as well as the SNP structure and process measures. We make these performance data available to the public (on a summary basis and at the plan level).

The Affordable Care Act (ACA) requires that, starting in 2012, all SNPs be approved by the National Committee on Quality Assurance (NCQA) based on standards developed by the Secretary. In our April 2011 final rule (76 FR 21466–21448), we specified that the SNP MOC would be the basis of NCQA's approval of SNPs. We developed the standards and scoring criteria for each of the 11 elements of the MOC for the NCQA to use for the SNP approval process.

Section 1857(d)(6) of the Act stipulates that we will conduct reviews of the SNP MOC in conjunction with the periodic audits of the MA organizations. During 2010 and 2011, we conducted a pilot study to assist us in determining the best methods for assessing the MOCs once they were implemented by the SNPs. We will expand this effort in 2012, by assessing a sample of the SNPs that attained a 3-year approval as a result of the NCQA SNP approval process that was mandated under the Affordable Care Act. This assessment will help us ensure that SNPs are providing care consistent with their approved MOC and to identify MAOs' strengths and weaknesses in implementing their MOCs. We also hope to use this information to identify best practices to share with plans and the public.

After considering comments we received, we are finalizing these provisions without modification.

Comment: One commenter viewed this provision as a positive addition to demonstrating the value and effectiveness of the SNP model. To ensure successful implementation and to improve clarity the commenter offered the following suggestions:

- Section 422.152(g)(2)—To ensure that CMS, contracting plans, and other interested parties are referring to the same standard, the commenter suggested that the regulation specify the source of the domains referenced (for example, CMS, NCQA, NIH).
- Section 422.152(g)(2)(viii)—The commenter was concerned that the delivery of extra services and benefits to meet the specialized needs of the most vulnerable beneficiaries may conflict with current CMS guidance on MA bids and benefits. The commenter requests that CMS clarify how a SNP would provide a different benefit set or set of services to those populations as the term ''extra services and benefits'' seems to imply.
- Section 422.152(g)(2)(x)—The commenter believes that the use of the term ''plans demonstrating use of integrated systems of communication''

is unclear and requests that CMS provide additional clarification as to the intent of the measure CMS references.

Response: We appreciate the commenter's interest in this issue. With respect to § 422.152(g)(2), we are using the definitions of domains as described by the Care Continuum Alliance, formerly the Disease Management Association of America. An integrated system of communication is the system the plan employs to communicate with all of its stakeholders—providers, beneficiaries, the public and regulatory agencies. This definition is included in Chapter 5 of the Medicare Managed Care Manual (''Quality Improvement Program''). The chapter, which is part of the Publication 100–16, may be accessed online at *http://www.cms.hhs.gov/Manuals/IOM.*

We expect MA organizations offering SNPs to incorporate some or all of the following benefits that exceed the basic required Medicare A and B benefits offered by other MA products available in the same service area—(1) No or lower beneficiary cost-sharing; (2) longer benefit coverage periods for inpatient services; (3) longer benefit coverage periods for specialty medical services; (4) parity (equity) between medical and mental health benefits and services; (5) additional preventive health benefits (for example, dental screening, vision screening, hearing screening, age-appropriate cancer screening, risk-based cardiac screening); (6) social services (for example, connection to community resources for economic assistance); (7) transportation services; and (8) wellness programs to prevent the progression of chronic conditions.

Finally, in § 422.152(g)(2)(x), we state that, as part of its quality program, a SNP must incorporate use of integrated systems of communication as evidenced by measures from the care coordination domain. An integrated system of communication is the system the plan employs to communicate with all of its stakeholders—providers, beneficiaries, the public and regulatory agencies. An example of an integrated communication system is a call center that might, as a reminder, reach out to clients in advance of their scheduled appointments.

Comment: One commenter expressed the view that current CMS policy in the area of allowed extra services and benefits to meet the needs of vulnerable beneficiaries is unclear, resulting in instability of benefit packages (for example, an extra benefit of independent living skills was approved one year and disapproved the next year). The commenter also contends that CMS' policy is not applied consistently across organizations, resulting in an unlevel playing field for some MAOs. Another commenter advised that the plan's care management approach may be more a matter of ''how'' and ''when'' benefits are provided and reimbursed than what extra benefits and services are provided.

Response: We have provided guidance to MA organizations offering SNPs that they should incorporate some or all of the following benefits that exceed the basic required Medicare A and B benefits offered by other MA products available in the same service area—(1) No or lower beneficiary cost-sharing; (2) longer benefit coverage periods for inpatient services; (3) longer benefit coverage periods for specialty medical services; (4) parity (equity) between medical and mental health benefits and services; (5) additional preventive health benefits (for example, dental screening, vision screening, hearing screening, age-appropriate cancer screening, risk-based cardiac screening); (6) social services (for example, connection to community resources for economic assistance); (7) transportation services; and (8) wellness programs to prevent the progression of chronic conditions. As the commenter asserts, as important as the provision of ''extra'' services is plans' appropriate management of all benefits—both those covered by Parts A and B and those that extend or enrich Parts A and B services or provide supplemental benefits—for their particular populations is equally as important to us. With respect to the commenters' assertion that our policy is not applied consistently across organizations, we note that our bid review process very carefully scrutinizes permissible supplemental benefits across all MA plan.

Comment: A commenter stated that the term ''health status,'' in reference to the second-tier language in the September 18, 2008 IFC, can be interpreted in a variety of ways. In an effort to promote consistent compliance by SNPs, the commenter recommends that CMS provide an explanation of the meaning of the term. The commenter also stated that depending upon the beneficiary's disease state, the course of the beneficiary's medical condition may be expected to result in declining health status. The commenter recommends that CMS revise the regulation to accommodate this circumstance.

Response: We have not provided a specific definition of health status, as it is more appropriate for SNPs to apply a definition that is appropriate for its population. We understand that for beneficiaries with certain medical conditions, the natural course of the disease will result in a decline in health status and death. However, our intent is to improve health status for the overall Medicare population.

Comment: Several commenters contended that health outcomes cannot be achieved without consideration of other quality of life indicators, such as adequate housing, engagement in meaningful activities, employment/community activities, and self-determination. These commenters suggested that meaningful measures of outcomes and quality should include personal experience outcomes. One of the commenters urged CMS to consider how ''improvement in health status'' will apply to persons whose care plan is focused on maintaining current functioning, delaying decline, or approaching the end of life.

Response: We agree that health outcomes are linked to many other factors in a patient's life. We intend to continue to explore best practices for measuring health outcomes in the Medicare population. We will also consider how ''improvement in health status'' will apply to persons whose care plan is focused on maintaining current functioning, delaying decline, or approaching the end of life.

Comment: One commenter noted that the regulation identifies data collection, analysis, and reporting as well as audit requirements in its QI system but that it does not provide in-depth specifications. The commenter suggests that such measures and specifications need further development and should be integrated with State's quality measures and data requirements.

Response: Since the publication of the September 18, 2008 IFC, we have issued guidance to plans regarding in-depth data specifications in various guidance vehicles, including HPMS memoranda. Much of this guidance is also consolidated in Chapter 5 of the Medicare Managed Care Manual, ''Quality Improvement Program.''

We are currently revising the process that MA organizations will use to submit their 2012 Chronic Care Improvement Programs (CCIPs) and Quality Improvement Projects (QIPs) and automating collection within a new module in the Health Plan Management System (HPMS). We are also revising and streamlining the templates that MA organizations will use for CCIP and QIP submission through the Paperwork Reduction Act process. The new format will allow MA organizations to demonstrate how the CCIP and/or QIP is developed, implemented and analyzed on a continuous cycle and to show where improvements in care occur. We

will provide more detailed guidance and timelines, as well as in-depth training on the new CCIP and QIP tools in the fall of 2011. We are also developing an MA quality Web page, which we intend to use to provide important information to external stakeholders, including MA organizations.

With respect to the commenter's specific concern about integration of quality data specifications with those of individual States, we note that is it not currently possible to integrate Medicare and Medicaid quality reporting requirements at this time. However, this is an issue we are currently exploring in coordination with the Federal Coordinated Health Care Office (FCHO).

Comment: Several commenters advised that States have many quality assurance requirement processes in place for Medicaid as such the new requirements must not conflict/override/interfere with current Medicaid contract requirements. According to the commenters, SNPs are concerned that they will be forced to try and reconcile conflicting Medicare and Medicaid requirements with States without clear guidance from CMS. Areas of potential overlap include care plans, initial/annual health risk assessments, performance measures, and appeals and grievances.

Response: We understand the potential for conflicting requirements and are currently working with the FCHO to consider ways of more closely aligning Medicare and Medicaid requirements.

The FCHO published the Alignment Initiative on May 16, 2011. This Initiative is focused on the new Office's efforts to address misalignments between Medicare and Medicaid, including extensive treatment and discussion of differing Medicare and Medicaid requirements for integrated managed care plans, including SNPs. CMS is reviewing the extensive comments that it has received and is working on addressing issues identified by this Office and commenters. Further guidance will be forthcoming.

Comment: One commenter questioned how continuum of care is defined. The commenter urged that CMS be careful not to encroach on the right of State Medicaid agencies to define what benefits to include in its contracts with SNPs.

Response: We have no intention of encroaching on State Medicaid agencies' rights to define the Medicaid benefits that are available for the dual eligible population. Continuum of care refers to patients receiving the care that is appropriate for managing their specific health conditions. We recommend using the Care Continuum Alliance's definition as a resource. Additional information on continuum of care can be found at *http://www.carecontinuum.org.*

Comment: One commenter believed there was a lack of evidence based guidelines for some populations, such as specific disability groups; the commenter suggests that CMS should include language allowing locally recognized protocols to permit maximum flexibility. Another commenter stated that an evidence base does not exist for the co-morbid populations most likely to receive care via SNPs.

Response: We understand that evidence-based practice in medicine is a growing field and, as such, acknowledge that there may not be evidence-based protocols for all clinical conditions and co-morbidities. We do, however, expect plans to institute evidence-based protocols and practices that are available and appropriate for their patient population. Where there is no evidence-based guidance, then we expect that the plan will seek guidance from their account manager at the regional office and, in conjunction with CMS, determine the best approach to implement.

Comment: One commenter expressed concern that SNPs which have high cost, high need dual populations will be compared with other SNPs serving other subsets of the population without an appropriate risk adjustment and stratification system. The commenter questions whether CMS has a plan for making fair comparisons of data across such differences in populations among D–SNPs, as well as between C–SNPs, I–SNPs, and D–SNPs.

Another commenter questioned how there can be comparisons across different types of SNPs when the populations are so different. The commenter recommends that CMS exclude integrated, full benefit D–SNPs from the requirements.

Response: We understand that there are differences in SNP populations. The MOC is the vehicle for SNPs to identify, implement, provide, and coordinate appropriate health care for their specific target populations. Effecting the type of data comparisons recommended by the commenter would require us to develop data measures specific to each SNP type. At this time, we do not anticipate developing such measures. We are aware, however, of the measurement issues that SNPs with small enrollments face. We are currently focusing our attention on these issues in order to refine our measures for SNPs, including those with low enrollments. One way we are addressing this concern is through a contract to develop outcome measures for MA organizations, as well as for SNPs more specifically. Through this contract we are reviewing all current SNP measures and developing measures where there are gaps, including for SNPs with low enrollment. We expect this work on outcome measures to be completed in late 2014.

We do not agree with the commenter that fully integrated dual eligible SNPs should be exempt from data reporting requirements. All SNP types must comply with our requirements.

Comment: One commenter contended that reporting quality data by PBP/plan would result in many low enrollment SNPs not having any members in the denominator, or so few that the data/rates would not be meaningful. The commenter recommends that quality data instead be reported by SNP type (for example, D–SNP) to ensure CMS and beneficiaries have meaningful data for plan comparison purposes.

Response: We understand that there are potentially SNPs with very low enrollment (small denominators). Because of this, we currently have data reported at the contract level. We understand that plans with small enrollments, especially SNPs, may not have the data resources available to them to track and monitor quality on an ongoing basis. However, SNPs are required to collect HEDIS® data using selected measures that have been developed just for plans with smaller enrollments. These data, as well as the NCQA structure and process measures, should be used to track and monitor areas that could benefit from ongoing quality improvement. Also, small plans may have encounter data or other data specific to the operations of their organization that could be useful for quality improvement.

As part of our continued effort to explore measures that are more sensitive for plans with low enrollment, we are developing outcome measures for the MA program, including SNPs. We will also conduct a pilot study to test the measures (for example, measures that address health outcomes related to coordination of care and transitions of care), as well as a larger study to validate the measures. One of our goals is to incorporate some of these measures into the MA plan rating system. This work will also assist us in developing measures to address the concerns of plans with low enrollment that cannot report using some of the current measures in the CAHPS®; HEDIS®,

and/or HOS instruments. We expect to complete our work in late 2014.

Comment: One commenter advised that they have heard concerns from both States and plans regarding the stringency of the QI requirements and their potential impact on plans' stability.

Response: We appreciate the commenter's interest in this issue. We believe that improving quality and having the data to demonstrate these improvements will help support the stability and viability of the program.

Comment: One commenter recommended that CMS promptly issue guidance with operational instructions implementing the 2008 SNP Chronic Condition Panel Final Report. MIPPA restricted enrollment in C–SNPs to special needs individuals that ''have one or more co-morbid and medically complex chronic conditions that are substantially disabling or life-threatening, have a high risk of hospitalization or other significant adverse health outcomes, and require specialized delivery systems across domains of care.''

Response: Fifteen SNP-specific chronic conditions were recommended by the panel and adopted beginning with the CY 2009 plan year. The Special Needs Plan Chronic Condition Panel Final Report was made public on November 12, 2008. The final report is available on the CMS Web site at: *https://www.cms.gov/SpecialNeedsPlans/Downloads/SNP_CC_Panel_Final_Report.zip.*

Comment: In questioning how the new requirements to collect, analyze, and report data as well as new requirements for MOC, care management, *etc.,* relate to existing CCI, HEDIS, and structure and process measures, one commenter urged CMS to work closely with SNPs and NCQA to minimize any new data reporting burdens, to prevent duplication of data collection and reporting efforts and to maximize use of existing structure and process measures to the extent possible in meeting new reporting requirements. The commenter also requested that CMS take into consideration the development time required to ensure accurate and complete data as well as provide technical specifications well in advance (for example, plans should have the technical specifications 6 months in advance). In addition, the commenter requested, that since SNPs have to meet both standard MA reporting as well as SNP-specific reporting, CMS take into account the total data and reporting burden on SNPs and consider staggering reporting of any new SNP requirements, similar to the process for Part C reporting.

Response: We are sensitive to the potential overlap of QI data reporting requirements. As part of our overall QI strategy, are carefully and systematically evaluating the impact of data collection requirements related to QI in an attempt to decrease burden and prevent duplication, while achieving our programmatic goals. Where possible, we will attempt to stagger reporting requirements.

Many of the measures that we have received comments on are included in the 5-star plan rating system. We are looking systematically at all of our QI reporting tools and measures and making a number of changes. For example, we are in the process of improving and implementing new reporting tools for the CCIPs and the QIPs for the CY 2012 reporting cycle. We expect that these new reporting tools will decrease the data collection and reporting burden for all MA organizations. We are also developing a module in HPMS that will allow for this reporting process to be automated. CMS is committed to continuing to review and to assess the measures to address these concerns.

We acknowledge that the NCQA structure and process measures overlap heavily with the MOC and QI reporting requirements. The structure and process measures were developed in an effort to identify SNP-specific measures that are not affected by a plan's enrollment size. Another goal of these measures is to evaluate some of the specific features of SNPs that make them unique among MA plans. These measures cannot replace the QIPs, since QIPs are a tool for evaluating weaknesses in the overall QI program for and MA organization, as well as monitoring the impact of any intervention that was implemented to mitigate a specific problem.

Similarly, the MOC serves a unique purpose by ensuring that SNPs design a clinical care program to address the health care needs of the specific vulnerable populations they serve. The MOC is not a data collection system but, rather, a framework for coordinating the key evidence based elements critical to providing integrated, high quality care to vulnerable patients.

We are looking systematically at all of our QI reporting tools and measures, and are in the process of making changes to eliminate some of the burden on plans. For example, we are in the process of streamlining and improving the CCIP and QIP reporting tools. By improving the reporting tools we expect to use in the 2012 reporting cycle we expect to decrease the burden for completing the data collection and reporting. We are also developing automating the submission process through an HPMS module.

Comment: One commenter recommended that CMS require the data to be reported uniformly. The commenter pointed out that the first tier purpose of the QI program to provide data on quality and outcomes to enable beneficiaries to compare and select from among health coverage options and the second tier purpose for measuring essential components of the MOC using a variety of plan-determined methodologies discussed in the rule do not appear to require uniform data reporting that would promote comparisons among plans.

Response: We appreciate the commenter's interest in this issue. We understand the need for uniformity in reporting and will strive to incorporate this principle in the QI program.

d. Special Needs Plans and Other MA Plans With Dual-Eligibles: Responsibility for Cost-Sharing (§ 422.504(g)(1)) and Written Disclosure of Cost-Sharing Requirements (§ 422.111(b)(2)(iii))

(1) Comprehensive Written Disclosure Requirement for Dual Eligible SNPs (§ 422.111(b)(2)(iii))

Section 164(c)(1) of MIPPA requires that plan sponsors offering D–SNPs must provide each prospective enrollee, prior to enrollment, with a comprehensive written statement that describes the benefits and cost-sharing protections that the individual would be entitled to under the D–SNP and the relevant State Medicaid plan. The comprehensive written statement must include the benefits that the individual is entitled to under Medicaid (Title XIX), the cost-sharing protections that the individual is entitled to under Medicaid (Title XIX), and a description of which of these benefits and cost-sharing protections are covered under the D–SNP. This provision is effective January 1, 2010. In the September 18, 2008 IFC (73 FR 54226), we introduced the regulations at § 422.111(b)(2)(iii) to reflect these statutory requirements, and are finalizing it without modification in this final rule.

Comment: One commenter mentioned that it believed that CMS's current marketing materials for duals were confusing and inaccurate. The commenter expressed support for the comprehensive written statement requirement, which it believed would provide dual eligible enrollees with crucial information on a plan's cost-sharing benefits.

Response: We agree that the comprehensive written statement will help dual-eligible beneficiaries make more informed enrollment choices.

Comment: One commenter stated that the comprehensive written statement provision, as written in the interim final rule, was narrower than the corresponding section of MIPPA, which requires that CMS establish a standard content and format for the notice concerning cost sharing protections and Medicare and Medicaid benefits. The commenter also recommended adding language to the rule to specify that the comprehensive written statement must include a statement of the benefits that the SNP provides.

Response: We disagree with the commenter's assertion that we should modify the rule to specifically reference CMS's responsibility to establish a standard content and format for the comprehensive written notice. Section 164(c)(1) of MIPPA (section 1859(f)(3)(c) of the Act) directly mandates that CMS determine the form and content of the comprehensive written statement. Regulatory language is neither a necessary nor appropriate means of effectuating this statutory directive to the agency. Therefore, we are not adding this language to the final rule.

In addition, the language in the regulatory text for this provision includes the requirement that the comprehensive written statement must include a description of the benefits and cost-sharing protections that the D–SNP provides. We do not believe this provision requires further clarification.

Comment: Two commenters requested clarification on the format and administration of the requirements established in this provision. One commenter suggested that CMS develop a simple template that States could use to describe their Medicaid benefits, and requested that CMS clarify how the written statement could be modified to reflect States' mid-year benefit changes. The commenter additionally asked CMS to define the role of the CMS Central Office and CMS Regional offices in coordinating the flow of information between States and SNPs. Another commenter asked CMS to clarify whether a plan that included this information on its Evidence of Coverage (EOC) document would be compliant with the comprehensive written statement requirement.

Response: We are not modifying the provision to address the operational issues that the commenters raised. We do not believe that rulemaking is the appropriate vehicle for addressing comments on the operational issues related to the comprehensive written statement requirement. We will address operational issues related to the comprehensive written statement requirement for D–SNPs through operational guidance vehicles (for example, call letters, manual chapters, and HPMS memoranda). We anticipate that this future guidance will address the commenters' concerns regarding the operational aspects of the comprehensive written disclosure requirement.

(2) Limitation on Cost-Sharing for Certain Dual Eligible Special Needs Individuals (§ 422.504(g)(1))

Section 165 of MIPPA, which revised section 1852(a) of the Act, prohibits D–SNPs from imposing cost-sharing requirements on full benefit dual-eligible individuals and Qualified Medicare Beneficiaries (QMBs), as described in sections 1935(c)(6) and 1905(p)(1) of the Act, that would exceed the cost-sharing amounts permitted under the State Medicaid plan if the individual were not enrolled in the D–SNP. The effective date of this provision is January 1, 2010.

Comment: One commenter asked CMS to clarify the difference between this provision's requirement that limits cost-sharing for full benefit dual-eligible beneficiaries and the prohibition on balance billing Qualified Medicare Beneficiaries (QMBs) that is established in 1903(n) of the Act. The commenter also requested that CMS explain the difference between this provision and provisions that hold beneficiaries harmless in instances of non-payment by a health plan or a State Medicaid Agency. Another commenter asked CMS to clarify how a plan should construct its benefits and its bid for full benefit duals when the liability of the State varies by the reimbursement level in its State Medicaid plan.

Response: We will continue to provide all MA plans, including D–SNPs, with guidance on the bid submission process. We do not believe that it is appropriate to address issues relating to plan bids through formal rulemaking. Unlike the statutory prohibition on QMB balance billing that outlines State cost-sharing responsibilities and provider billing requirements, this requirement at § 422.504(g)(1)) limits the cost-sharing that MA plans may impose on their full benefit and zero-cost-share dual eligible enrollees. We are not describing the requirements of balance billing or ''hold harmless'' provisions in detail in this preamble, as they are outside the scope of this final rule.

Comment: One commenter requested that CMS address how this requirement would apply to D–SNPs that enroll dual eligible individuals who are not all eligible for full State Medicaid benefits. The commenter also suggested that CMS strengthen its language regarding States' cost-sharing responsibility. Finally, the commenter noted its belief that the protection of full-benefit dual eligible beneficiaries from cost-sharing above Medicaid levels should extend to full benefit dual eligible beneficiaries in all MA plans, not just those who are enrolled in SNPs.

Response: In our January 2009 final rule (74 FR 1499) entitled, ''Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions,'' we extended the cost-sharing requirements that MIPPA imposed on D–SNPs to all MA plans. We also applied this cost-sharing protection to individuals who belong to any Medicaid dual eligibility category for which the State provides a zero cost-share. Our January 2009 final rule (74 FR 1499) replaced and superseded the language in our September 18, 2008 IFC, and finalized changes to § 422.504(g)(1)(iii). Therefore, in this final rule, we are not finalizing the regulatory text changes to § 422.504(g)(1)(iii) that we described in our September 18, 2008 IFC.

(3) Private Fee-For-Service (PFFS) Plans

(a) Changes in Access Requirements for PFFS Plans

Section 162(a)(3) of MIPPA amended section 1852(d)(4)(B) of the Act to require, effective January 1, 2010, that PFFS plans meeting access standards based on signed contracts meet access standards with respect to a particular category of provider by establishing contracts or agreements with a sufficient number and range of providers to meet the access and availability standards described in section 1852(d)(1) of the Act. Section 1852(d)(1) of the Act describes the requirements that MA organizations offering a ''network'' MA plan must satisfy when selecting providers to furnish benefits covered under the plan.

In the September 18, 2008 IFC, we revised § 422.114(a)(2)(ii) to reflect this new statutory requirement. We did not receive any comments on this requirement; therefore, we are finalizing the revisions to § 422.114(a)(2) as described in the September 18, 2008 IFC.

(b) Requirement for Certain Non-Employer PFFS Plans to Use Contract Providers

Section 162(a)(1) of MIPPA added a new paragraph (5) to section 1852(d) of the Act. The new paragraph creates a requirement for certain non-employer MA PFFS plans to establish contracts with providers. Specifically, for plan year 2011 and subsequent plan years, MIPPA required that non-employer/union MA PFFS plans (employer/union sponsored PFFS plans were addressed in a separate provision of MIPPA) that are operating in a network area (as defined in section 1852(d)(5)(B) of the Act) must meet the access standards described in section 1852(d)(4). As noted above, section 1852(d)(4)(B) of the Act as amended by MIPPA, requires that PFFS plans must have contracts with a sufficient number and range of providers to meet the access and availability standards described in section 1852(d)(1) of the Act. Therefore, we stated in the September 18, 2008 IFC that these PFFS plans may no longer meet the access standards by paying not less than the Original Medicare payment rate and having providers deemed to be contracted, as provided under § 422.216(f).

''Network area'' is defined in section 1852(d)(5)(B) of the Act, for a given plan year, as the area that the Secretary identifies (in the announcement of the risk and other factors to be used in adjusting MA capitation rates for each MA payment area for the previous plan year) as having at least two network-based plans (as defined in section 1852(d)(5)(C) of the Act) with enrollment as of the first day of the year in which the announcement is made. For plan year 2011, we informed PFFS plans of the network areas in the announcement of CY 2010 MA capitation rates, which was published on the first Monday of April 2009. We used enrollment data for January 1, 2009 to identify the location of network areas.

''Network-based plan'' is defined in section 1852(d)(5)(C) of the Act as (1) an MA plan that is a coordinated care plan as described in section 1851(a)(2)(A)(i) of the Act, excluding non-network regional PPOs; (2) a network-based MSA plan; or (3) a section 1876 cost plan. Types of coordinated care plans (CCPs) that meet the definition of a ''network-based plan'' are HMOs, PSOs, local PPOs, as well as regional PPOs with respect to portions of their service area in which access standards are met through establishing written contracts or agreements with providers. MIPPA specified that the term ''network-based plan'' excluded a regional PPO that meets access requirements in its service area substantially through the authority of § 422.112(a)(1)(ii), rather than through written contracts. Section 422.112(a)(1)(ii) permits regional PPOs to meet access requirements using methods other than written agreements with providers (that is, allowing members to see non-contract providers at in-network cost sharing in areas where the plan does not have established a network of contracted providers).

We stated in the September 18, 2008 IFC that, for purposes of determining the network area of a PFFS plan, we will determine whether any network-based plans with enrollment exist in each of the counties in the United States. Beginning in plan year 2011, in counties where there is availability of two or more network-based plans (such as an HMO plan, a PSO plan, a local PPO plan, a network regional PPO plan, a network-based MSA plan, or a section 1876 cost plan), a PFFS plan operating in these counties must establish a network of contracted providers to furnish services in these counties in accordance with the amended section 1852(d)(4)(B) of the Act. In such counties, a PFFS plan would no longer be able to meet access requirements through providers deemed to have a contract with the plan at the point of service in these counties. In counties where there are no network-based plan options, or only one other network-based plan, the statute allows PFFS plans to continue to meet access requirements in accordance with section 1852(d)(4) of the Act and § 422.114(a)(2). Regardless of whether a PFFS plan meets access requirements through deeming or is subject to the requirement that it establish a network of providers with signed contracts, providers who do not have a contract with the PFFS plan may continue to be deemed to have a contract with the plan if the deeming conditions described in § 422.216(f) are met.

An existing PFFS plan may have some counties in its current service area that meet the definition of a network area and other counties that do not. We also stated that, in order to operationalize section 162(a)(1) of MIPPA, we will not permit a PFFS plan to operate a mixed model where some counties in the plan's service area are considered network areas and other counties are considered non-network areas. Beginning in plan year 2011, an MA organization offering a PFFS plan will be required to create separate plans within its existing service areas where it is offering PFFS plans based on whether the counties located in those service areas are considered network areas or not. For example, if an existing PFFS plan has some counties in its current service area that are network areas and other counties that are non-network areas, then in order to operate in this service area in plan year 2011 and subsequent plan years, the MA organization must establish a unique plan with service area consisting of the counties that are network areas and another plan with service area consisting of the counties that are non-network areas. Consequently, the PFFS plan operating in the counties that are network areas must establish a network of contracted providers in these counties in accordance with section 1852(d)(4)(B) of the Act in order to meet access requirements. The PFFS plan operating in the counties that are not network areas can continue to meet access requirements under § 422.114(a)(2) by paying rates at least as high as rates under Medicare Part A or Part B to providers deemed to have a contract with the plan if the conditions described in § 422.216(f) are met. The MA organization must file separate plan benefit packages for the PFFS plan that will operate in network areas and the plan that will operate in non-network areas.

We stated in the September 18, 2008 IFC that for purposes of making the judgment of provider network adequacy for PFFS plans that will be required to operate using a network of contracted providers in plan year 2011 and afterwards, we will apply the same standards for PFFS plans that we apply to coordinated care plans. To determine where a PFFS plan's proposed network meets access and availability standards, we will follow the procedure described in the section above on ''Changes in access requirements for PFFS plans.''

We are finalizing the revisions to § 422.114(a)(3) as described in the (73 FR 54226) IFC published on September 18, 2008 IFC to reflect the requirements found in section 162(a)(1) of MIPPA for non-employer PFFS plans.

Comment: A few commenters urged CMS to modify the definition of a ''network area'' to mean an area with CCPs offered by two different organizations in order to ensure that there is real competition in the area.

Response: MIPPA defines ''network area,'' for a given plan year, as the area that the Secretary identifies (in the announcement of the risk and other factors to be used in adjusting MA capitation rates for each MA payment area for the previous plan year) as ''having at least 2 network-based plans with enrollment as of the first day of the year in which the announcement is

made.'' ''Network-based plan'' is defined in MIPPA as (1) an MA plan that is a coordinated care plan as described in section 1851(a)(2)(A)(i) of the Act, excluding non-network regional PPOs; (2) a network-based MSA plan; or (3) a section 1876 cost plan. We interpret ''having at least 2 network-based plans'' to mean that there are at least 2 plans, which meet the definition of a network-based plan, that are offered by the same MA organization or by different MA organizations. We believe this interpretation is consistent with the statutory requirements for identifying network areas. We do not believe we have the statutory authority to interpret the definition of a network area in a different manner.

Comment: A commenter recommended that network-based plans ''with enrollment'' should be defined as plans with a minimum enrollment threshold of 5,000 in MSAs with a population of more than 250,000 and 1,500 in all other areas. The commenter stated that establishing a minimum membership standard would ensure that the CCPs that remain in the market are stable and minimize the possibility of future plan exit and further MA member disruption.

Response: MIPPA defines ''network area,'' for a given plan year, as the area that the Secretary identifies (in the announcement of the risk and other factors to be used in adjusting MA capitation rates for each MA payment area for the previous plan year) as ''having at least 2 network-based plans with enrollment as of the first day of the year in which the announcement is made.'' We interpret the phrase ''with enrollment'' to mean that a network-based plan is required to have at least 1 beneficiary enrolled in the plan in order to be counted for purposes of identifying the location of the network areas. We believe that interpreting ''with enrollment'' any differently would result in an artificial threshold and would not be consistent with the statute.

Comment: A commenter recommended that CMS provide preliminary information about CY 2011 network areas, based on January 1, 2009, enrollment data, in the CY 2010 announcement and later update this information in the CY 2011 announcement to reflect January 1, 2010, enrollment data. The commenter further stated that the 2010 data and resulting network areas should be the basis for determining PFFS plan compliance with the MIPPA requirement for CY 2011. Another commenter recommended that once CMS denotes a county as a network area, that county should keep the network area designation. The commenter stated that counties should not switch from network to non-network status over time, even if one of the two CCPs in the county exit.

Response: The methodology for identifying the location of network areas for a given plan year is specified in the statutory definition of a ''network area.'' MIPPA defines ''network area,'' for a given plan year, as the area that the Secretary identifies (in the announcement of the risk and other factors to be used in adjusting MA capitation rates for each MA payment area for the previous plan year) as ''having at least 2 network-based plans with enrollment as of the first day of the year in which the announcement is made.'' We accordingly used enrollment data as of January 1, 2009, to identify the network areas for plan year 2011. The methodology we used to identify the list of network areas for plan year 2011 is consistent with statutory requirements. The statute also requires us to update the list of network areas for each plan year, and not doing so would be inconsistent with the intent of the statute. Because of this requirement, we cannot allow counties to keep a network designation when one or more of the network-based plans in those counties exits the market because the county no longer meets the network designation criteria.

Comment: A commenter urged that CMS recognize that MA organizations are in the process of creating PPOs and other MA plans in areas that are likely to be network areas in 2011, and therefore establish a passive enrollment process whereby PFFS enrollees in network areas automatically enroll in their current sponsor's replacement product (if one is available) on January 1, 2011, unless the beneficiary affirmatively chooses to join another plan or return to fee-for-service Medicare.

Response: On April 16, 2010, we released guidance via HPMS on the renewal and non-renewal options for MA organizations for CY 2011. We allowed non-network PFFS plans to transition their enrollees to their full network PFFS plans in CY 2011. We extended this same option to PFFS plans for CY 2012 via the CY 2012 Final Call Letter. However, we do not believe it would be appropriate to allow transition of enrollees from one MA plan type (for example, PFFS plan) to another MA type (for example, HMO or PPO plan), as this would be a change from an ''open'' model to a closed network.

Comment: A commenter recommended that CMS permit PFFS plans to employ a mixed model for complying with the network access standards imposed by MIPPA.

Response: We believe that requiring MA organizations offering PFFS plans to have separate contracts for their non-network, partial, and full network plans would allow these organizations to better manage their plans and allow CMS to more effectively oversee these plans. We also believe that not permitting PFFS plans to offer a mixed model would help beneficiaries to better distinguish among the three types of PFFS plans.

Comment: A commenter recommended that CMS establish a special e-mail box for any PFFS-related MIPPA questions and use the questions submitted to the e-mail box to develop timely guidance issued before the annual Call Letter.

Response: All of the PFFS-related provisions in this rule became effective prior to the publication of this final rule. Since we already released operational guidance to assist with the implementation of these provisions, we do not believe it would be useful to establish an e-mail box for PFFS-related MIPPA questions at this time. We note that plans may submit questions about these provisions to their Regional Office Account Manager.

(c) Requirement for All Employer/Union Sponsored PFFS Plans to Use Contracts With Providers

Section 162(a)(2) of MIPPA amended section 1852(d) of the Act by adding a new requirement for employer/union sponsored PFFS plans. For plan year 2011 and subsequent plan years, MIPPA required that all employer/union sponsored PFFS plans under section 1857(i) of the Act meet the access standards described in section 1852(d)(4) of the Act only through entering into written contracts or agreements in accordance with section 1852(d)(4)(B) of the Act, and not, in whole or in part, through establishing payment rates meeting the requirements under section 1852(d)(4)(A) of the Act. We revised § 422.114(a) in the September 2008 IFC to reflect this statutory change. Specifically, the changes to § 422.114(a) set forth how an MA organization that offers a PFFS plan must demonstrate to CMS that it can provide sufficient access to services covered under the plan. We stated in the September 18, 2008 IFC (73 FR 54226) that, in order to meet the access requirements beginning plan year 2011, an employer/union sponsored PFFS plan must establish written contracts or

agreements with a sufficient number and range of health care providers in its service area for all categories of services in accordance with the access and availability requirements described in section 1852(d)(1) of the Act. An employer/union sponsored PFFS plan will not be allowed to meet access requirements by establishing payment rates for a particular category of provider that are at least as high as rates under Medicare Part A or Part B. We also stated that while an employer/union-sponsored PFFS plan must meet access standards through signed contracts with providers, providers that have not signed contracts can still be deemed to be contractors under the deeming procedures in 1852(j)(6) of the Act that currently apply.

We added paragraph (a)(4) to § 422.114 in order to reflect this new statutory requirement for employer/union sponsored PFFS plans.

Comment: A commenter recommended that CMS provide more clarification regarding network access standards for employer-sponsored PFFS plans. The commenter stated that CMS should adopt access standards that are unique to each group plan and eventually adopt access standards that evaluate provider access based on the population eligible for enrollment.

Response: Currently, we do not review Health Service Delivery (HSD) tables for employer/union sponsored PFFS plans to determine whether the plans meet our network access standards. However, these plans must ensure that their enrollees have adequate access to providers consistent with Chapter 9 of the Medicare Managed Care Manual.

We are finalizing § 422.114(a)(4) as described in the September 18, 2008 IFC to reflect the new requirement found in section 162(a)(2) of MIPPA for employer/union sponsored PFFS plans.

(d) Variation in Payment Rates to Providers

Section 162(b) of MIPPA added a clarification to the definition of an MA PFFS plan found at section 1859(b)(2) of the Act. Prior to MIPPA, the statute defined an MA PFFS plan as an MA plan that pays providers at a rate determined by the plan on a fee-for-service basis without placing the provider at financial risk; does not vary the rates for a provider based on the utilization of that provider's services; and does not restrict enrollees' choice among providers who are lawfully authorized to provide covered services and agree to accept the plan's terms and conditions of payment. Section 162(b) of MIPPA added that although payment rates generally cannot vary based on utilization of services by a provider, an MA PFFS plan is permitted to vary the payment rates for a provider based on the specialty of the provider, the location of the provider, or other factors related to the provider that are not related to utilization. However, this section of MIPPA allowed MA PFFS plans to increase payment rates for a provider based on increased utilization of specified preventive or screening services. Section 162(b) of MIPPA was effective at the time of publication of the September 18, 2008 IFC.

In the September 18, 2008 IFC, we revised paragraph (a)(3)(ii) of § 422.4 and paragraph (a) of § 422.216 to add the clarifications found in section 162(b) of MIPPA. We did not receive any comments on our revisions; therefore, we are finalizing the revisions to § 422.4(a)(3) and § 422.216(a) as described.

3. Revisions to Quality Improvement Programs § 422.152

a. Requirement for MA PFFS and MSA Plans to Have a Quality Improvement Program

Section 163(a) of MIPPA repealed, effective January 1, 2010, the statutory exemption found at section 1852(e)(1) of the Act for MA PFFS plans and MSA plans from the requirement that MA plans have quality improvement programs meeting specified statutory requirements. We stated in the September 18, 2008 IFC that, beginning plan year 2010, each MA PFFS and MSA plan must have an ongoing quality improvement program that meets the requirements under § 422.152(a). We also revised § 422.152(a) to delete language exempting PFFS and MSA plans from having quality improvement programs.

MAOs that offer one or more MA plans must have for each of their plans a QI program under which it meets all of the following requirements:

- Has a chronic care improvement program (CCIP), that meets the requirements of § 422.152(c), and addresses populations identified by CMS based on a review of current quality performance.
- Conducts quality improvement projects (QIP) that can be expected to have a favorable effect on health outcomes and enrollee satisfaction, meets the requirements of § 422.152(d), and addresses areas identified by CMS.
- Encourages providers to participate in CMS and Health and Human Service (HHS) QI initiatives.

1. • Develops and maintains a health information system.

2. • Contracts with an approved Medicare CAHPS vendor to conduct the Medicare CAHPS satisfaction survey of Medicare enrollees.

3. • Includes a program review process for formal evaluation that addresses the impact and effectiveness of its QI programs at least annually.

4. • Corrects problems for each plan.

Finally, MAOs must ensure that, (1) their reported data are accurate and complete, (2) they maintain health information for CMS review as requested, (3) they conduct an annual review of their overall QI program, and (4) they take action to correct problems revealed through complaints and QI program performance evaluation findings.

We did not receive any comments on this requirement; therefore, we are finalizing the revisions to § 422.152(a) as described in the September 18, 2008 IFC.

b. Data Collection Requirements for MA PFFS and MSA Plans

Section 1852(e)(3)(A)(i) of the Act amended by section 163(b)(1) of MIPPA by adding that MA PFFS and MSA plans must provide for the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality, but these requirements for PFFS and MSA plans cannot exceed the requirements established for MA local plans that are PPO plans beginning in plan year 2011 and are subject to an exception for plan year 2010 (as discussed below).

The statute provided a special rule that applies for plan year 2010, when MA PFFS and MSA plan quality requirements are not restricted to the data collection requirements established for MA local plans that are PPO plans under § 422.152(e). Instead, they must, for 2010 only, meet the data collection requirements with respect to administrative claims data, as specified in CMS guidance. We interpreted this exception to mean that for plan year 2010, MA PFFS and MSA plans are required to report quality data based on administrative claims data from all providers that include contract, deemed (applicable to PFFS plans only), and non-contract providers.

In the September 18, 2008 IFC, we added paragraph (h) to § 422.152 to describe the data collection requirements for MA PFFS and MSA plans. We stated that for plan year 2010, MA PFFS and MSA plans are not subject to the limitations under § 422.152(e)(1)(i) and must meet the data collection requirements using administrative claims data only. We also

stated that for plan year 2011 and subsequent plan years, MA PFFS and MSA plans are subject to data collection requirements that may not exceed the requirements specified in § 422.152(e) for MA local plans that are PPO plans.

Comment: A commenter suggested that CMS create an exception to the data collection requirements for 2010 for PFFS plans that will terminate in 2011.

Response: In the 2010 Call Letter, we stated that MA organizations that will terminate their PFFS or MSA contracts effective January 1, 2011 will not be required to submit a HEDIS report for 2010 for those contracts.

We are finalizing § 422.152(h) as described in the September 2008 IFC to reflect the new quality data collection requirements for PFFS and MSA plans.

c. Data Collection Requirements for MA Regional Plans

Section 163(b)(2) of MIPPA deleted clause (ii) of section 1852(e)(3)(A) of the Act. Section 1852(e)(3)(A)(ii) had provided for CMS to establish separate regulatory requirements for MA regional plans relating to the collection, analysis, and reporting of data that permit the measurement of health outcomes and other indices of quality and also provided that these requirements for MA regional plans could not exceed the requirements established for MA local plans that are PPO plans. Furthermore, section 163(b)(3) of MIPPA amended section 1852(e)(3)(iii) of the Act by adding that MA regional plans are subject to the data collection requirements under section 1852(e)(3)(A)(i) of the Act only to the extent that data are furnished by providers who have a contract with the MA regional plan. This provision is effective for plan years beginning on or after 2010 and allows for consistent data collection requirements between MA local plans that are PPO plans and MA regional plans.

We received no comments on this section and no change to regulatory text is needed since existing language in § 422.152(e) describes the requirements for MA local plans that are PPO plans as well as MA regional plans. Therefore we are finalizing this section without modification.

4. Phase-Out of Indirect Medical Education Component of MA Capitation Rate (§ 422.306)

In our September 18, 2008 IFC we noted that section 161 of MIPPA added a new paragraph (4) to 1853(k) of the Act, which directed the Secretary to phase-out indirect medical education (IME) amounts from MA capitation rates with a maximum adjustment percentage per year of 0.60 percent. We explained that implementation of the IME payment phase-out began in plan year 2010. Each year after 2010 the maximum adjustment percentage was to increase up to an additional 0.60 percent until the entire IME portion of the MA capitation rate in an area is reduced to zero. We stated that PACE programs are excluded from the IME payment phase-out. Finally, we stated that payment to teaching facilities for IME expenses for MA plan enrollees will continue to be made under section 1886(d)(11) of the Act by Original Medicare. We stated that we were adding a new paragraph (c) to § 422.306 to reflect this statutory IME phase-out.

We received no comments on this provision and are finalizing our regulatory changes without modification.

B. Changes to the Part D Prescription Drug Benefit Program

1. Use of Prescription Drug Event Data for Purposes of Section 1848(m) of the Act (423.322(b))

Section 132 of MIPPA revised section 1848(m) of the Act, as added and amended by section 131 of MIPPA, to provide incentive payments to eligible professionals for successful electronic prescribing. A successful electronic prescriber for a reporting period is one who meets the requirements for submitting data on electronic prescribing quality measures or, if the Secretary determines appropriate, submitted a sufficient number (as determined by the Secretary) of prescriptions under Part D during the reporting period. Congress added paragraph (3)(iv) to section 1848(m) of the Act to permit the Secretary to use the data regarding drug claims (prescription drug event data) submitted for payment purposes under the authority of section 1860D–15 of the Act as necessary for purposes of carrying out section 1848(m), notwithstanding the limitations set forth under section 1860D–15(d)(2)(B) and (f)(2) of the Act.

Consistent with the authority granted to the Secretary regarding the use of the prescription drug event data for purposes of section 1848(m) of the Act, in the IFC we revised § 423.322(b) to remove the restriction placed on officers, employees and contractors of the HHS when using these data in accordance with section 1848(m) of the Act.

Comment: A commenter questioned whether MAOs are required to pay e-prescribing incentive payments and if so, whether the payment will be based on MAO or national data.

Response: This provision relates to the extended authority granted under MIPAA for the Secretary to use prescription drug event data for purposed of providing incentives payments for e-prescribing. The commenter's questions are specific to e-prescribing requirements and, therefore, are outside the scope of the final rule. However, as stated in the 2010 Call Letter dated March 30, 2009, payments to physicians who are contracted with MAOs are generally governed by the terms of the contract, and it is up to the MAO whether to take the e-prescribing incentive payment into account in establishing the amount the physician is paid.

We are finalizing this provision without change.

2. Elimination of Medicare Part D Late Enrollment Penalties Paid by Subsidy Eligible Individuals (§ 423.46 and § 423.780)

In the September 18, 2008 interim final rule (73 FR 54208), we stated that each year since the beginning of the Medicare prescription drug program we had conducted a Medicare payment demonstration that provided that Medicare beneficiaries who qualified for the low-income subsidy for Medicare prescription drug coverage were able to enroll in a Medicare prescription drug plan with no penalty. We stated the demonstration had tested the number and characteristics of the beneficiaries that benefited from waiver of the late enrollment penalty (LEP), and the cost of the waiver to Medicare. Originally this payment demonstration allowed certain Medicare beneficiaries to enroll in a Medicare prescription drug plan in 2006 with no LEP. Under the original waiver, we did not collect the LEP from beneficiaries who enrolled in Medicare Part D in 2006 and were either eligible for the low-income subsidy or lived in an area affected by Hurricane Katrina. This payment demonstration was amended to include beneficiaries who were eligible for the low-income subsidy and enrolled ''late'' in Medicare Part D in 2007 and 2008.

Section 114 of MIPPA revised the statute to waive the late enrollment penalty for subsidy eligible individuals. Accordingly, we revised our regulation at § 423.780(e) in order to reflect this MIPPA change. Under the revised regulation, we will no longer charge subsidy eligible individuals (defined in § 423.773) a late enrollment penalty. This eliminated the need for the LEP payment demonstration. Finally, we stated this provision was effective January 1, 2009, when the current demonstration ended. We stated that we

were also are making a conforming change to § 423.46(a) to reflect the fact that subsidy eligible individuals may enroll in Medicare prescription drug plan with no penalty.

We received no comments on these provisions and are finalizing our regulatory changes without modification.

3. Prompt Payment of Clean Claims (§ 423.505 and § 423.520)

Section 171 of MIPPA amended sections 1860–12(b) and 1857(f) of the Act by adding provisions with regard to prompt payment by prescription drug plans (PDPs) and Medicare Advantage prescription drug (MA–PD) plans, both of which are Part D sponsors as defined in § 423.4. We codified these new requirements in § 423.505 and § 423.520 of the September 18, 2008 interim final rule.

In accordance with the new sections 1860D–12(b)(4) and 1857(f)(3)(A) of the Act, and as codified in § 423.520 effective January 1, 2010, CMS' contract with Part D sponsors must include a provision requiring sponsors to issue, mail, or otherwise transmit payment for all clean claims submitted by network pharmacies—except for mail-order and long-term care pharmacies—within specified timeframes for electronic and all other (non-electronically submitted) claims.

Consistent with section 1860D–12(b)(4)(A)(ii) of the Act, a clean claim is defined in § 423.520(b) of the regulations as a claim that has no defect or impropriety—including any lack of any required substantiating documentation—or particular circumstance requiring special treatment that prevents timely payment of the claim from being made under the requirements of § 423.520.

As provided in section 1860D–12(b)(4)(B) of the Act and codified in § 423.520(a)(1)(i) and § 423.520(a)(1)(ii), Part D sponsors must make payment for clean claims within 14 days of the date on which an electronic claim is received and within 30 days of the date on which non-electronically submitted claims are received. Consistent with MIPPA, § 423.520(a)(2)(i) and (ii) define receipt of an electronic claim as the date on which the claim is transferred, and receipt of a non-electronically submitted claim as the 5th day after the postmark day of the claim or the date specified in the time stamp of the transmission, whichever is sooner.

Additionally, as provided in section 1860D–12(b)(4)(D)(i) of the Act and as codified in § 423.520(c)(1), a claim will be deemed to be a clean claim to the extent that the Part D sponsor that receives the claim does not issue notice to the submitting network pharmacy of any deficiency in the claim within 10 days after an electronic claim is received and within 15 days after a non-electronically submitted claim is received. A claim deemed to be a clean claim must be paid by the sponsor within 14 days (for an electronic claim) or 30 days (for a non-electronic claim) of the date on which the claim is received, as provided in § 423.520(a)(1)(i) and § 423.520(a)(1)(ii).

Comment: One commenter suggested that we clarify that the word ''day'' as used throughout these provisions means ''calendar day.''

Response: Section 1860D–12(b)(4)(B) defines the term ''applicable number of calendar days'' as ''14 days'' with respect to electronic claims and ''30 days'' with respect to non-electronic claims. Elsewhere in the statute, Congress simply used the term ''days.'' Since Congress did not define ''days,'' nor use another more restrictive term, such as ''business days,'' we interpret ''calendar days'' and ''days'' to have the same meaning for purposes of the prompt pay requirements and thus have simply used the term ''days'' throughout the regulation.

Comment: Several commenters asserted that claims that are electronically adjudicated at point of sale (POS) should be deemed ''clean claims'' that are payable within 14 days, with no retroactive review allowed during the 10-day period for sponsors to provide notice of deficiencies. These commenters suggested that issues such as eligibility issues which are discovered during the 10-day period should be resolved among plans.

Response: We believe that section 1860D–12(b)(4)(D)(i) clearly provides that claims are deemed to be clean if the Part D sponsor involved does not provide notice to the claimants of any deficiencies within the statutory time period, which is 10 days for claims submitted electronically. The fact that a Part D sponsor adjudicates an electronic claim at POS does not preclude the sponsor from notifying the claimant of a deficiency within the ten day period. While a sponsor's failure to pay a claim can cause the claim to be deemed clean pursuant to section 1860D–12(b)(4)(D)(iii) of the Act, payment of the claim in and of itself does not deem it to be a clean claim under the Act. Since the statute did not provide a time period for a pharmacy to cure a deficiency, we expect that such a time period would be a matter of negotiation between the parties, as well as whether payment for such a claim may be retracted in the meantime.

Under section 1860D–12(b)(4)(D)(ii) of the Act and in § 423.520(c)(2) of the regulations, if the Part D sponsor determines that a submitted claim is not a clean claim, it is required to notify the submitting pharmacy that the claim has been determined not to be clean, specify all the defects or improprieties rendering the claim not a clean claim, and list all additional information necessary for the sponsor to properly process and pay the claim. This notification must be provided within 10 days after an electronic claim is received, and within 15 days after a non-electronic claim is received.

Once the submitting pharmacy resubmits the claim with the additional information specified by the Part D sponsor as necessary for properly processing and paying the claim, the sponsor has 10 days, consistent with section 1860D–12(b)(4)(D)(iii) of the Act, and, as specified in § 423.520(c)(3), provide notice to the submitting pharmacy of any defect or impropriety in the resubmitted claim. If the sponsor does not provide notice to the submitting pharmacy of any defect or impropriety in the resubmitted claim within 10 days of the sponsor's receipt of such claim, the resubmitted claim is deemed to be a clean claim and must be paid consistent with the timeframes specified in § 423.520(a)(1) (within 14 days of the date on which a resubmitted electronic claim is received and within 30 days of the date on which a non-electronically resubmitted claim is received).

Comment: Several commenters stated that CMS should clarify the September 18, 2008 IFC to limit the number of requests plans can make for additional information about a non-clean claim to one request and to only information readily available to pharmacies. The commenters provided the example of a plan asking for proof of eligibility on the 10th day after receiving a non-clean electronic claim, and then waiting an additional 10 days after receipt of this additional documentation to request information on fulfillment of prior authorization requirements.

Response: The statute and IFC State that if a Part D sponsor determines that a submitted claim is not a clean claim, it must notify the submitting pharmacy within the specified time period and ''such notification must specify all defects or improprieties in the claim and must list all additional information necessary for the proper processing and payment of the claim.'' Since the statute and regulation use the term ''notification'' in the singular and use the phrases ''all defects and improprieties'' and ''all additional

information necessary,'' we believe this provision plainly requires plans to identify all of the problems with the claim in a single notice and, therefore, plans cannot make multiple requests for additional information during the applicable time period (10 days for a non-clean electronic claim and 15 days for a non-clean non-electronic claim). Therefore, we disagree that a clarification of the regulation text is needed on this point. In addition, we believe that the statute and September 18, 2008 IFC, which state that a claim is deemed to be a clean claim if the Part D sponsor that receives the claim does not provide notice to the submitting network pharmacy of any defect or impropriety in the claim within ten days after the date on which *additional* information is received, is intended only to provide a timeframe for a sponsor to notify a pharmacy of previously requested information that was not received or is still deficient, or of a new deficiency raised by the additional information received, and is not intended to permit Part D sponsors to request new information for the first time to cure a deficiency that could have been identified in the original claim submission. Therefore, we agree and have revised § 423.520(c)(2)(ii) to clarify that a Part D sponsor may only provide notice of any remaining defects or improprieties in the claim, or of any new deficiencies raised by the additional information.

Comment: One commenter noted that there appeared to be an error in § 423.520(c)(3) in referencing only § 423.520(a)(1)(i) and (ii).

Response: We agree with the commenter that the regulation should be drafted more clearly. While the regulation as currently written mirrors the statute in only cross-referencing the timeframe for paying a clean claim, and not the timeframe for deeming a claim clean where a sponsor does not provide timely written notice of any deficiencies, we believe it is clear that the intent of the statute is for sponsors to pay claims that are deemed clean within the time frame for paying a clean claim. Section 1860D–12(b)(4)(D)(i) of the Act is clear that claims that are not contested within the applicable timeframes are deemed clean. Therefore, we have revised the regulation accordingly to reference the timeframes for paying a clean claim in § 423.505(a)(1)(i) and (ii) and the timeframes for contesting a claim in (c)(1)(i) and (ii).

With respect to the act of payment itself, in accordance with section 1860D–12(b)(4)(D)(iv) of the Act, § 423.520(d) specifies that payment for a clean claim is considered to have been made on the date payment for an electronic claim is transferred. Payment for a clean claim is considered to have been made on the date payment for a non-electronic claim is submitted to the United States Postal Service or common carrier, respectively.

Comment: One commenter suggested that the payment date for electronic claims should be when the transaction is initiated, and payment for non-electronic claims should be when payment is given to the USPS or common carrier. Other commenters disagreed, suggesting that payment for electronic claims should be the date when funds are made available to the provider, and that there should be no exceptions in batch payments—meaning all payments in a batch should be made available to the provider on or before the 14th day after the date on which the earliest clean electronic claim of the batch was received.

Response: Section 1860D–12(b)(4)(D)(iv) of the Act states plainly that payment of a clean claim is considered to have been made on the date on which the payment is transferred (for electronic claims) and the date the payment is submitted to the U.S. Postal Service or common carrier for delivery. Section 423.520(d) is consistent with the statute. We interpret the term ''transferred'' to mean when payment has been made to the payee. Thus, for an electronic claim, this would be the date on which funds will be posted to the payee's (or its agent's) account. For a non-electronic claim, we interpret ''submitted'' to mean the date when the payment is postmarked by the USPS or recorded as received by a common carrier. Payment for all claims must meet applicable statutory and regulatory timeframes, regardless of whether the claims are paid in batches or not.

To the extent that a Part D sponsor does not issue, mail, or otherwise transmit payment for a clean claim within 14 days of the date on which an electronic claim is received and within 30 days of the date on which a non-electronically submitted claim is received, as specified in § 423.520(a)(1), section 1860D–12(b)(4)(C) of the Act requires that the sponsor pay interest to the submitting pharmacy. As required under section 1860D–12(b)(4)(C)(i) of the Act, and as codified in § 423.520(e)(1), the Part D sponsor must pay such interest at a rate equal to the weighted average of interest on 3-month marketable Treasury securities determined for such period, increased by 0.1 percentage point for the period beginning on the day after the required payment date and ending on the date on which the payment is made under § 423.520(d). For purposes of CMS payments to Part D sponsors for qualified prescription drug coverage, any interest amounts paid under § 423.520(e)(1) do not count against the Part D sponsor's administrative costs, nor are they treated as allowable risk corridor costs, under § 423.308. In other words, the Part D sponsor is fully liable for any interest payments for claims not paid timely, consistent with § 423.520(d). In accordance with section 1860D–12(b)(4)(C)(ii) of the Act and as codified in § 423.520(e)(2), CMS may determine that a Part D sponsor will not be charged interest under § 423.520(e)(1) as appropriate, including in exigent circumstances such as natural disasters and other similar unique and unexpected events that prevent timely claims processing. We will make such determinations on a case-by-case basis at the sponsor's request.

Comment: One commenter suggested that CMS's authority is limited when determining exigent circumstances under which plans will not be charged interest on late paid claims and that the language was too broad.

Response: We agree that the language in § 423.520(e)(2) could be interpreted as giving us slightly broader authority than MIPPA bestowed. Therefore, we have revised the section to more closely track the statutory language.

The Act addressed payment of claims by electronic funds transfer (EFT). Section 1860D–12(b)(4)(E) of the Act and § 423.520(f) require that a Part D sponsor pay all electronically submitted clean claims by EFT if the submitting network pharmacy requests payment via EFT or has previously requested payment via EFT. For ease of sponsor execution, the requirement that payment be provided via EFT if a sponsor has previously requested EFT payment means that any such previous request must have occurred during the current contract year. This requirement also means that all Part D sponsors must have the capacity to pay via EFT so that they may pay via EFT any of their network pharmacies requesting payment for submitted claims in this manner. In addition, under § 423.520(f), for any payment made via EFT, the Part D sponsor may also make remittance electronically.

In accordance with section 1860D–12(b)(4)(F)(i) of the Act and as codified in § 423.520(g)(1), the requirements in § 423.520 do not in any way prohibit or limit a claim or action that any individual or organization may have against a pharmacy, provider, or Part D sponsor that is unrelated to the new

requirements in § 423.520. Further, as provided under section 1860D–12(b)(4)(F)(ii) of the Act and § 423.520(g)(2), consistent with any applicable Federal or State law, a Part D sponsor may not retaliate against an individual, provider, or pharmacy for any such claim or action. Finally, as provided under section 1860d–12(b)(4)(G) of the Act and codified in § 423.520(h), any determination that a claim submitted by a network pharmacy is a clean claim as defined in § 423.520(b) must not be construed as a positive determination regarding the claim's eligibility for payment under Title XVIII of the Act. In addition, any determination that a claim is a clean claim as defined in § 423.520(b) of the Act is not an indication that the government approves, or acquiesces regarding the submitted claim and does not relieve any party of civil or criminal liability, nor offer defense to any administrative, civil, or criminal action, with respect to the submitted claim. We received no comments on § 423.520(f), § 423.520(g), or § 423.520(h).

In addition to adding a new § 423.520 to reflect the prompt payment requirements of section 1860D–12(b)(4) of the Act, we amended § 423.505(b) to include the prompt payment provisions as one of the required elements of the contract between CMS and the Part D sponsor. Therefore, § 423.505(b)(19) required that, effective contract year 2010, the contract between CMS and the Part D sponsor must include the prompt payment provisions at § 423.520.

We also amended § 423.505(i)(3) with respect to contracts or written arrangements between Part D sponsors and pharmacies or other providers, first tier, downstream and related entities to ensure that Part D sponsors' contracts with these entities include prompt payment provisions consistent with § 423.520. Section 423.505(i)(3)(vi) thus required that sponsors' pharmacy contracts include the prompt payment provisions of § 423.520. We review pharmacy contract templates (except for mail-order and LTC pharmacy templates) for new applicants to ensure the addition of these prompt payment provisions. To the extent that such agents are authorized to receive payment on behalf of a participating pharmacy for claims submitted to a Part D sponsor, there is no distinction between a pharmacy and its agent for purposes of the prompt payment provisions at § 423.520. Thus, the prompt payment provisions at § 423.520 extend to an agent authorized to receive payment for claims submitted to a Part D sponsor, as long as it is in compliance with all Federal and State laws. We received no comments on these provisions.

The revisions to the regulations reflecting the previously-described MIPPA prompt payment provisions were all effective on January 1, 2010. We are finalizing these provisions with the amendments previously described.

4. Submission of Claims by LTC Pharmacies (§ 423.505)

Section 172 of MIPPA amended sections 1860D–12(b) and 1857(f)(3) of the Act to add a provision on the submission of claims by pharmacies located in or having a contract with a long term care facility. Effective January 1, 2010, new sections 1860D–12(b)(5) and 1857(f)(3)(B) of the Act direct us to incorporate into each contract CMS enters into with a Part D sponsor a provision addressing the submission of claims by long-term care pharmacies. Specifically, our contracts with Part D sponsors must provide that long-term care pharmacies must have not less than 30 days, nor more than 90 days, to submit claims to the sponsor for reimbursement under the plan. We codified this new statutory contract requirement at § 423.505(b)(20). Effective January 1, 2010, this provision applies to any claim submitted by a long-term care pharmacy, as defined in § 423.100.

Effective contract year 2010, new sections 1860D–12(b)(5) and 1857(f)(3)(B) of the Act require that CMS contracts with Part D sponsors include a provision requiring sponsors to provide long-term care pharmacies (as defined in § 423.100) not less than 30 days, nor more than 90 days, to submit claims for reimbursement under the plan. In addition to adding this requirement to the contract provisions specified in § 423.505(b), in the IFC we amended § 423.505(i) to specify that timeframes for submission of claims by long-term care pharmacies must be contained in Part D sponsor contracts with the long-term care pharmacies. As provided in § 423.505(i)(3)(vii), all sponsor contracts with long-term care pharmacies must contain a provision that establishes timeframes, consistent with § 423.505(b)(20), for the submission to the sponsor of claims for reimbursement.

Comment: Two commenters stated the 90-day limit for claims submission is problematic given the time required to process Medicaid applications, the retroactivity of many Medicaid eligibility determinations, and the time lags associated with updates to State eligibility data bases. These commenters noted that LTC pharmacies are holding receivables for copayments for beneficiaries who have Medicaid pending or are dual eligible, but whose status has not been updated or who had a retroactive Medicaid effective date.

The commenters recommended that CMS codify in the regulation the statement in our September 18, 2008 IFC preamble that the statute does not eliminate CMS' policy requiring a new timely filing period for claims incurred during a period of retroactive Medicaid eligibility, or specify in the PDP contract that this provision does not preclude a LTC pharmacy from rebilling when the claim was not paid fully or correctly, or clarify the 90 days applies only to ''clean claims.''

Response: This provision applies to claims for reimbursement of prescription drugs—not to claims adjustments resulting from retroactive changes affecting the beneficiary's cost-sharing, premiums and plan benefit phase (such as changes in low-income subsidy (LIS) status). Since the publication in the September 18, 2008 IFC, we published proposed and final rules on October 22, 2009 (74 FR 54634) and April 15, 2010 (75 FR 19678), respectively. In the April 2010 final rule, we codified at § 423.464 and § 423.466 our previous policy guidance requiring sponsors to make retroactive claim adjustments and take into account other payer contributions as part of the coordination of benefits. We also added a new timeliness standard at § 423.466 to require adjustment and issuance of refunds or recovery notices within 45 days of the sponsor's receipt of the information necessitating the adjustment.

The specific change at § 423.464 added a new paragraph (g)(7) to require sponsors to account for payments by State Pharmaceutical Assistance Programs (SPAPs) and other providers of prescription drug coverage in reconciling retroactive claims adjustments that create overpayments and underpayments, as well as to account for payments made and for amounts being held for payment, by other individuals for entities. We acknowledged in the preamble of the April 2010 final rule (75 FR 19724) that pharmacies are not providers of other prescription drug coverage, but noted it was our intention to apply the 45-day limit to all retroactive changes. As a result, we also amended § 423.800 to add a new paragraph (e) to make it clear that the 45-day timeframe applies to adjustments involving pharmacies and beneficiaries, including LTC pharmacies holding cost-sharing amounts due. The new paragraph (e) requires sponsors to process retroactive adjustments to cost-sharing for low-income subsidy

individuals and any resulting refunds and recoveries within the timeframe specified in § 423.466(a). We note that by definition ''adjustments'' can only be made to previously adjudicated claims.

Comment: One commenter recommended the regulatory text explicitly address retroactive Part D enrollment for dual eligible beneficiaries and continue to operate under the CMS May 25, 2007 policy guidance requiring the use of the date of Medicaid notification to establish a timely claims filing period under § 423.505(b)(20). The commenter noted that this would ensure beneficiaries and other parties, including pharmacies, have the opportunity to request reimbursement for claims incurred during the retroactive Part D enrollment period.

Response: We stated in the September 18, 2008 IFC preamble that the new LTC pharmacy claim submission requirement would not eliminate the requirement for Part D sponsors to provide a new timely claims filing period for claims incurred by dual eligible beneficiaries during a period of retroactive Part D enrollment as specified in May 25, 2007 memorandum. However, since the publication in the September 18, 2008 IFC, we have changed the manner in which these claims are processed. Beginning in January 2010, CMS implemented a demonstration project, known as the low-income newly eligible transition (NET) program, to handle retroactive Part D enrollment. Under the demonstration, a single, competitively procured Part D sponsor covers all Part D prescription drug claims for all periods of retroactive coverage for full benefit dual eligible and SSI-eligible individuals, as well as point-of-sale coverage at the pharmacy for certain LIS individuals who are not yet enrolled in a Part D plan. Beneficiaries who are retroactively auto/facilitated enrolled by CMS and LIS beneficiaries confirmed eligible for the demonstration are temporarily enrolled in the demonstration contractor's plan. These beneficiaries are then prospectively auto/facilitated enrolled in a qualified PDP.

Because the low-income NET demonstration eliminates the routine need for sponsors to reimburse claims incurred by individuals eligible for the program during periods of retroactive Part D enrollment, there is no longer a need for Part D sponsors to provide the special transition period required by the May 25, 2007 memorandum. This policy change is described in section 50.10 of the updated Coordination of Benefits (COB) chapter of the Medicare Prescription Drug Benefit Manual issued on March 19, 2010 which is available on the CMS Web site at *http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter14.pdf.* Beneficiaries and pharmacies, including LTC pharmacies, can submit claims incurred during the period of retroactive Part D enrollment to the low-income NET program contractor without timely filing limits during the period of enrollment in the low-income NET program and for up to 180 days following the beneficiary's disenrollment from the program. Claims filing requirements are specified in the CMS contract with the low-income NET program contractor. As a result, we do not believe it is necessary to revise the regulatory language to address retroactive Part D enrollment.

Comment: One commenter argued that the timeframe for claims submission is too restrictive for ICF/MR and IMD business cycles and noted further that PDP contract negotiations with LTC institutions can take 6 to12 months, so flexible timeframes are necessary.

Response: We recognize that the statutory timeframes for LTC pharmacy claims submission may not be aligned with previous billing practices, but we have no authority to revise the statutory timeframes to provide the flexibility sought by the commenter.

After considering the comments received in response to the September 18, 2008 IFC, we are finalizing these provisions without change.

5. Regular Update of Prescription Drug Pricing Standard (§ 423.505)

Section 173 of MIPPA amended sections 1860D–12(b) and 1857(f)(3) of the Act, effective January 1, 2009, to add a provision on the regular updating of prescription drug pricing standards. In accordance with new sections 1860D–12(b)(6) and 1857(f)(3)(C) of the Act, which we codified in § 423.505(b)(21) effective January 1, 2009, CMS' contracts with Part D sponsors must include a provision requiring sponsors to regularly update any prescription drug pricing standard they use to reimburse network pharmacies based on the cost of the drug (for example, average wholesale price, wholesale average cost, average manufacturer price average sales price). As codified in § 423.505(b)(21)(i) and § 423.505(b)(21)(ii), these updates, if applicable, must occur on January 1 of each contract year and not less frequently than every 7 days thereafter.

We also amended § 423.505(i)(3) with respect to contracts or written arrangements between Part D sponsors and pharmacies or other providers, first tier, downstream and related entities to ensure that Part D sponsors' contracts with these entities include provisions for regularly updating any prescription drug pricing standard used by sponsors to reimburse their network pharmacies, as provided in § 423.505(b)(21). Specifically, § 423.505(i)(3)(viii)(A) requires that sponsors' pharmacy contracts include the pricing standard update requirements at § 423.505(b)(21), if applicable, and § 423.505(i)(3)(viii)(B) further specified that a Part D sponsor's pharmacy contract must indicate the source used by the Part D sponsor for making such pricing updates.

We review pharmacy contract templates (except for mail-order and LTC pharmacy templates) for new applicants beginning for contract year 2010 to ensure the addition of this provision, if applicable.

Comment: One commenter requested a definition of ''prescription drug pricing standard.''

Response: We do not believe that such a definition is necessary at this time. The preamble to the September 18, 2008 interim final rule provided the following examples of prescription drug pricing standards: ones that are based on ''wholesale average cost, average manufacturer price, average sales price.'' We believe these examples sufficiently illustrate what is meant by a prescription drug pricing standard—that is, it is an accepted methodology based on published drug pricing. We believe that defining the standard beyond this may be overly prescriptive and might not be flexible enough to evolve with industry changes. Also, we are prohibited under the section 1860D–11(i)(1) of the Act from interfering in negotiations between sponsors and network pharmacies, and we presume such negotiations would address if a ''prescription drug pricing standard'' will be used between the parties.

Comment: There were several related comments submitted by a number of commenters about the applicability of prescription drugs pricing standards and the 7-day update requirement, which were: (1) Plans must promptly use updated standards to actually process claims; (2) plans should have to update benchmark prices to reflect price on date of service if plans could have access to such data; (3) plans should have to use a benchmark provider that updates data at least weekly; and (4) plans should not be able to now update their standards every seven days if they previously updated more frequently or have access to more frequent updates.

Response: Section 1860D–12(b)(6) requires that if a Part D sponsor ''uses

a standard for reimbursement of pharmacies based on the cost of a drug,'' the sponsor must update the standard on January 1 of the year and not less frequently than once every 7 days.'' We believe the statute's use of the word ''*reimbursement,''* here makes it clear that Part D sponsors must not only update prescription drugs pricing standards but actually *use* them to reimburse claims. Nevertheless, we have clarified the language of § 423.505(b)(21) to apply to prescription drug pricing standards used for reimbursement by Part D sponsors. Further, the statute plainly indicates that updates must occur at least every 7 days, but does not contemplate that we could require more frequent updates—though we note that a Part D sponsor can arrange with its contracted pharmacies to make more frequent updates. Finally, the statute is silent on the issue of whether sponsors must use the price on the date of service (DOS) to process a claim. The statute does not address this issue, and we believe it is best decided by the parties. Thus, pricing used to process Part D claims can be no older than 7 days, when a prescription drug pricing standard is used for reimbursement. This is consistent with our previous subregulatory guidance issued as a memo titled, ''Guidance for regulations in the IFC on September 15, 2008, in which we stated, ''* * * sponsors must ensure they design their internal processes to ensure that fee schedules tied to any drug pricing standard are updated within these prescribed timeframes, and that all claims are adjudicated in accordance with appropriately updated fee schedules.'' However, pharmacies are not precluded from negotiating with Part D sponsors for more frequent updating, or for DOS pricing to be used, or for a particular standard to be applied, for that matter.

Comment: Several commenters stated that CMS should require plans to maintain current pricing for 60 days while plans and pharmacies negotiate new pricing when benchmarks are eliminated or methods for deriving benchmarks materially altered.

Response: Section 173 of MIPPA did not address this issue. In the absence of specific direction on this point, we believe Congress intended to leave that issue to the discretion of the Part D sponsors and its contracted pharmacies. Also, as previously noted, we are prohibited under section 1860D–11(i)(1) of the Act from interfering in negotiations between sponsors and network pharmacies, and therefore, we presume these matters would be addressed in the negotiations between the parties. However, we note that the regulation requires that if a standard is used, it be identified in the contract between the parties, and of course any existing contract between the parties that identifies a standard would have to be amended according to the amendment terms of the contract if the pricing standard were to change.

In the September 18, 2008 interim final rule, we stated that we are aware that some pharmacies, particularly independent pharmacies, work with agents for purposes of negotiating and signing contracts with Part D sponsors on their participating pharmacies' behalf, and that to the extent that such agents are authorized to receive payment on behalf of a participating pharmacy for claims submitted to a Part D sponsor, there is no distinction between a pharmacy and its agent for purposes of the drug pricing standard update requirements at § 423.505(b)(21). Thus, we stated the drug pricing standard update requirements at § 423.505(b)(21) extend to an agent authorized to receive payment for claims submitted to a Part D sponsor, as long as it is in compliance with all Federal and State laws. We received no comments on these provisions.

The regulations reflecting the previously described MIPAA provisions on the regular update of prescription drug pricing standards were all effective January 1, 2009. We are finalizing these provisions as corrected on November 21, 2008 (73 FR 70598) with the amendments previously described.

6. Use of Part D Data (§ 423.505(m))

On May 28, 2008, prior to the passage of MIPPA, CMS published a final regulation (73 FR 30664) regarding the collection and use of Part D claims data. This regulation resolved the statutory ambiguity between section 1860D–12(b)(3)(D) and section 1860D–15 of the Act. One of the incorporated provisions at section 1860D–12(b)(3)(D) of the Act, is section 1857(e)(1) of the Act, which provides broad authority for the Secretary to add terms to the contracts with Part D sponsors, including terms that require the sponsor to provide the Secretary, ''with such information as the Secretary may find necessary and appropriate.'' As we stated in our final rule on Part D claims data, we believe that the broad authority of section 1860D–12(b)(3)(D) of the Act authorizes CMS to collect the same prescription drug event data we currently collect to properly pay sponsors under the statute for other purposes unrelated to payment. However, we acknowledged that section 1860D–15 of the Act contains provisions that might be viewed as limiting such collection, thus compelling us to clarify the Secretary's broad authority under section 1860D–12(b)(3)(D) in our final regulation. Accordingly, in the final Part D data rule, we implemented the broad authority of section 1860D–12(b)(3)(D) of the Act to permit the Secretary to collect claims data that are collected for Part D payment purposes for other research, analysis, reporting, and public health functions.

Section 181 of MIPPA amended section 1860D–12(b)(3)(D) to make clear that, notwithstanding any other provision of law, information provided to the Secretary under the application of section 1857(e)(1) may be used for purposes of carrying out Part D, and may be used to improve public health through research on the utilization, safety, effectiveness, quality, and efficiency of healthcare services. Thus, MIPPA further strengthened our final rule on Part D claims data and confirms our authority to use claims data collected under 1860D–12 of the Act for purposes of reporting to the Congress and the public, conducting evaluations of the overall Medicare program, making legislative proposals to Congress, and conducting demonstration projects.

While MIPPA did not alter our ability to collect and use data for purposes outlined in our final rule on Part D claims data, section 181 of MIPPA added a provision with respect to the disclosure of claims data to Congressional support agencies. Specifically, section 181 of MIPPA added clause (ii) to section 1860D–12(b)(3)(D) of the Act, which requires the Secretary to make data collected under section 1860D–12(b)(3)(D) of the Act available to Congressional support agencies, in accordance with their obligations to support Congress as set out in their authorizing statutes, for the purposes of conducting Congressional oversight, monitoring, making recommendations, and analysis of the Part D program. In our previously issued final rule on Part D claims data, we specified that we would only release the minimum data necessary to Congressional oversight agencies in accordance with our data sharing policies. Section 1860D–12(b)(3)(D) of the Act, as amended, removed the minimum necessary data restriction when data are requested by a Congressional support agency that is requesting the data in accordance with its obligation to support Congress as set out in its authorizing statute.

Section 423.505(f)(3) of the regulations now requires that Part D plan sponsors must submit all data elements included as part of their drug claims ''for purposes deemed necessary

and appropriate by the Secretary, including, but not limited to,'' reporting to Congress and the public on the operation of the Part D program, conducting evaluations of the overall Medicare program, making legislative proposals, conducting demonstrations and pilot projects, supporting care coordination and disease management programs, supporting quality improvement and performance measurement activities, and populating personal health care records. Prior to the issuance of the September 18, 2008 IFC, § 423.505(m)(1) of the regulations provided that with respect to data collected under § 423.505(f)(3), ''CMS may release the minimum data necessary for a given purpose to Federal executive branch agencies, congressional oversight agencies, States, and external entities in accordance with the applicable Federal laws, CMS data sharing procedures, and subject, in certain cases to encryption and or aggregation of certain sensitive information.'' MIPPA revised section 1860D–12(b)(3)(D) of the Act to provide specifically that information collected pursuant to this section be made available to Congressional support agencies, in accordance with their obligations to support Congress as set out in their authorizing statutes, for the purposes of conducting Congressional oversight, monitoring, making recommendations, and analysis of the Medicare Part D program. Consistent with this new statutory provision, in the September 18, 2008 IFC, we revised § 423.505(m)(1) of our regulations, to omit any reference to ''Congressional oversight agencies.'' We also added a new paragraph (m)(3) to § 423.505 specifying that the Secretary will make the information collected under § 423.505(f)(3) available to Congressional support agencies for the purposes of conducting congressional oversight, monitoring, making recommendations, and analysis of the Medicare program.

We used the same definition for Congressional support agencies in § 423.505(m)(3) that we previously used for Congressional oversight agencies in the regulation at § 423.505(m)(1)(iv). As with the definition of Congressional oversight agencies at § 423.505(m)(1)(iv), we did not include the Congressional Research Service (CRS) as a Congressional support agency unless it is requesting the data on behalf of a Congressional committee consistent with 2 U.S.C. 166(d)(1). As previously explained in the preamble to the final rule on Part D claims data (73 FR 30664), when CRS is not acting as the agent of a Congressional committee, it does not have the same authority to request data from departments or agencies of the United States, and would be restricted in the same manner as external entities when requesting prescription drug event data.

We received no comments on this section, and therefore are finalizing these provisions without modification.

7. Exemptions From Income and Resources for Determination of Eligibility for Low-Income Subsidy (§ 423.772)

Section 1860D–14 of the Act describes the rules for determining financial eligibility for the Medicare Part D Low-Income Subsidy (LIS). These rules closely conform to the Supplemental Security Income (SSI) methodology for determining financial eligibility. Section 116 of MIPPA amended the types of income and resources to be taken into consideration for determining financial eligibility for LIS to deviate from the SSI methodology in two areas. Specifically, section 116 of MIPPA amended 1860D–14(a)(3) of the Act by exempting from the determination of LIS the following:

- Support and maintenance furnished in kind from income.
- Value of any life insurance policy from resources.

Support and maintenance furnished in kind is any food or shelter that is given to the applicant/spouse or received because someone else pays for it. This includes room, rent, mortgage payments, real property taxes, heating fuel, gas, electricity, water, sewage, and garbage collection services.

Life insurance policy includes whole life, term, and products that combine features of whole life and term policies.

In general, it is the responsibility of the Social Security Administration to determine eligibility for LIS. However, the CMS maintain in regulation broad parameters for income and resources for the Medicare Part D Low-Income Subsidy. These regulations also govern how State Medicaid agencies process LIS applications when individuals apply there. In order for CMS regulations to conform to the new law, we are updating our regulations to reflect the new exclusions from income and resources.

In order to reflect these changes, we revised the definitions of ''income'' and ''resources'' in § 423.772.

The amendments made by this provision were effective with respect to LIS applications filed on or after January 1, 2010.

We did not receive any comments and are therefore finalizing these provisions without modification.

C. Changes to the MA and Prescription Drug Benefit Programs

In order to assist readers in understanding how the final provisions we discuss in this section apply to both programs, we are including Table 1, which highlights the provisions affecting both programs and the pertinent sections of Parts 422 and 423.

TABLE 1—PROVISIONS AFFECTING BOTH THE PART C AND PART D PROGRAMS

Provision	Part 422 subpart	Part 422 CFR section	Part 423 subpart	Part 423 CFR section
Disclosure of plan information	Subpart C	422.111	Subpart C	
Marketing: Standards for MA/Part D marketing:	Subpart V	422.2268	Subpart V	423.2268
• Nominal gifts				
• Scope of marketing				
• Co-branding				
• Including plan type in plan name				
Marketing: reporting terminations	Subpart V	422.2272	Subpart V	423.2272
Marketing:	Subpart V	422.2274	Subpart V	423.2274
• Broker and agent compensation				
• Training and testing				

1. Disclosure of Plan Information (§ 422.111)

Section 164 of MIPPA revised section 1859(f) of the Act to require, effective January 1, 2010, disclosure of SNP plan information to beneficiaries. In order to reflect the MIPPA changes, the September 18, 2008 IFC added a new paragraph (b)(iii) to § 422.111. The addition requires dual-eligible SNPs to provide the information specified in § 422.111(b) 15 days before the annual coordinated election period to each prospective enrollee, both prior to enrollment and at least annually thereafter. We developed a model comprehensive statement for beneficiaries that could be included with any description of benefits offered by the SNP plan.

We did not receive comments on this provision. Therefore, we are finalizing this provision without modification.

2. Medicare Advantage and Prescription Drug Program Marketing Requirements (New Subparts V)

a. General

With this final rule, we are finalizing the provision of our September 18, 2008, and November 14, 2008 interim final rules with comment periods ((73 FR 54226) and (73 FR 67406), respectively). With the exception of the provisions relating to including plan type in the name of the plan (effective January 1, 2010), and the reporting by plans of agent and broker terminations to States (effective January 1, 2009), all of the Part C and Part D marketing requirements discussed below were effective upon publication of our September 18, 2008 and November 10, 2008 IFCs.

b. Standards for MA and PDP Marketing (§ 422.2268 and § 423.2268)

We received a number of comments on the provisions contained in § 422.2268 and § 423.2268 requesting clarification or pointing out areas of disagreement with the provisions. These comments were as follows:

(1) Nominal Gifts (§ 422.2268(b) and § 423.2268(b))

Plan sponsors are required to limit the offering of gifts and other promotional items to potential enrollees at promotional events to those gifts of ''nominal value'' that are offered to all potential enrollees.

Comment: One commenter requested clarification on the meaning of ''all potential enrollees'' in relation to the provision of nominal gifts at promotional events.

Response: By ''all potential enrollees,'' we mean anyone in attendance at the event. Additionally, we specify that when plan sponsors provide nominal gifts at promotional events, anyone in attendance can get a gift. There should be no further requirements for gift receipt beyond attendance at the event. For example, at an event, the plan sponsor offers small piggy banks as a nominal gift. The plan sponsor cannot require that an attendee provide an address or phone number in order to receive the gift.

(2) Limiting the Scope of Health Care Products To Be Discussed (§ 422.2268(g) and (h) and § 423.2268(g) and (h))

Any appointment with a beneficiary involving the marketing of health care related products (for example, where Medicare supplement, MA, and/or stand-alone PDP will be discussed) must be limited by the plan sponsor to the scope agreed upon by the beneficiary. In advance of any marketing appointment, the beneficiary must have the opportunity to agree to the range of choices that will be discussed, and that agreement must be ''documented'' by the plan sponsor. Discussion of additional lines of plan business (for example, MA, MA–PD, PDP or Medigap) not identified prior to the individual appointment requires a separate appointment that may not be rescheduled until 48 hours after the initial appointment, unless requested by the beneficiary.

Comment: We received several comments on the requirement that the scope of the appointment be documented. Some commenters stated that the requirement for such documentation is a hassle for seniors to complete in advance of the appointment. A commenter believed that seniors get so much paper and complicated forms that they appreciate ''simple'' communications, and suggested they would be put off by needing to complete some form documenting the scope of their appointment in order to speak to an agent. While the commenter appreciated the efforts of CMS to protect the public and regulate agents, he did not believe that a documentation requirement was the best way to accomplish either goal. Yet another commenter found requiring that a scope of appointment form be filled out in advance of appointments and home visits to be a reasonable protection for beneficiaries. However, this commenter also believed that requiring a scope of appointment form for a walk-in visit at an office or during seminars confuses the beneficiary since they do not understand why they have to sign a form when they have voluntarily initiated a walk-in visit or attending a seminar. Also, some commenters supported the scope of appointment requirements, but believed that requiring the provision in the proposed rule that 48 hours pass before a return visit to discuss additional health-related lines of business puts an unreasonable burden on the beneficiary and an added cost to plans and ultimately to enrollees. Also mentioned by these commenters as problematic was the difficulty this requirement poses for rural agents due to driving distances to meet face-to-face with beneficiaries that end up being costly and difficult to reschedule. We received additional comments pertaining to a specific draft form for use in documenting the scope of an appointment.

Response: We believe the scope of appointment requirement is necessary beneficiary protection to document a beneficiary's agreement to an appointment and the content of the discussion during the appointment. We disagree with the commenter suggesting that filling out a form documenting the scope of the appointment creates a hassle for seniors and note that agents/brokers play a significant role in providing guidance and advice to beneficiaries when selecting health plan options including assistance with filling out applications. Because of their unique position, agents/brokers have the opportunity to unduly influence beneficiary choices. Therefore, we believe that the scope of appointment should be documented regardless of whether the beneficiaries walk into an agent's office without an appointment seeking information. For example, if during the discussion of the agreed upon plan products, the beneficiary requests information regarding other products, it does no good to require the beneficiary to return (or the agent to come to the beneficiary) 48-hours later to continue the discussion. Instead, an expansion of the scope should be documented and the discussion may continue. We have also made allowances through operational guidance to accommodate the circumstances of rural agents like those described herein. In response to the comment on the 48-hour waiting period, we have moved this requirement to paragraph (g), and in response to the comments we have provided that a 48-hour waiting period must only be provided where ''practicable.''

Since neither the proposed nor final scope of appointment requirement specifies that a particular format must be used to document appointments, we

are not responding to comments related to any specific formats as that is outside of the scope of these regulations.

Comment: A few commenters recommended that CMS exempt the scope of appointment form used by agents/brokers from requiring review and approval by a plan, since agents/brokers represent multiple plans. The commenters do not see any advantage from a beneficiary protection perspective requiring agents/brokers to carry separate approved scope of appointment forms from each plan they represent.

Response: MA and PDP sponsors are free to create their own scope of appointment form as long as it makes clear that the potential enrollee understood the scope of the appointment. There is no requirement from CMS that sponsors create their own forms and require agents or brokers to use them. Our requirement is that the scope of appointment be documented. To the extent that sponsors create their own forms for this purpose, CMS does require they have the plan name and logo on them.

Comment: A commenter questioned whether any meeting outside the enrollee's home that involves more than one potential enrollee could be considered a sales (or educational) event that does not require scope of appointment documentation.

Response: A scope of appointment is not required at educational events. In the case of marketing/sales events, if the event is advertised to the general public, a scope of appointment is not required. On the other hand, if an agent holds a small group event with individuals who were personally invited (or requested the event), a scope of appointment would be required.

Comment: A commenter strongly disagreed with the requirement that individual agents send every form documenting the scope of an appointment to the related health plan for every sales appointment, whether or not the beneficiary purchases a policy from the agent or not.

Response: The purpose of the scope of appointment documentation requirement is to document each beneficiary appointment with an agent/broker to discuss various Medicare plan products whether or not the beneficiary purchases a policy. While we do not specify how plan sponsors comply, it does hold plan sponsors accountable for complying with the scope of appointment requirements.

Comment: A couple commenters questioned whether documentation of the scope of an appointment had to be kept for 10 years on sales calls, and asked about its compliance with the Paperwork Reduction Act (PRA).

Response: The scope of appointment documentation is subject to the requirement in the MA regulations that it be maintained for a period of 10 years (§ 422.504(d) and § 423.504(b)(4)). Therefore, if the documentation is in the form of a recorded sales call, that recording is subject to the 10-year maintenance requirement. However, the Scope of Appointment Form, is not subject to PRA requirements because we are not collecting information or specifying the use of a particular format for doing so. If plans choose to use a form to document the scope of appointment, they are required to maintain that documentation.

Comment: A commenter requested that the existing scope of appointment documentation requirement and 48-hour cooling off period be applied solely to Medicare Advantage.

Response: We disagree and believe beneficiaries deserve the same marketing protection regardless of the nature of the Medicare product being marketed. While the statutory scope of appointment requirements apply to the marketing of all Medicare Advantage (including MA-only) and Prescription Drug plans, we have previously exercised our authority under section 1876(i)(3)(D) of the Act to impose ''necessary and appropriate'' requirements on section 1876 cost plans to require that they comply with MA marketing requirements.

Comment: A commenter requested that CMS allow the practice of cold calling beneficiaries.

Response: The prohibition against cold calling beneficiaries is set forth in the statute at section 1851(j)(1)(A) of the Act, and thus could not be changed by regulation. The request to do so is outside the scope of this rulemaking.

Comment: Several commenters objected to beneficiaries with an existing relationship with an agent as having their ''hands tied'' in discussing Medicare coverage with their agents.

Response: We have guidance in the Medicare Marketing Guidelines that describes how agents may interact with beneficiaries after they establish an ongoing relationship with them. For example, agents are not allowed to cold-call beneficiaries or contact beneficiaries unsolicited. However, an agent that has an established relationship with a beneficiary, would be expected to call the beneficiary to provide them with information about benefit options, updates, or plan changes. These follow-up calls would not be considered unsolicited contacts or cold-calls.

Comment: A commenter requested that SNPs be allowed to work with trusted referral sources to obtain consent from the beneficiary to be contacted by the plan. The trusted referral source could include a family member, physician, social service providers, home health agency staff or other entities that are committed to the best interests of the beneficiary. Such a ''trusted referral source'' would, under the commenter's suggested approach, help the beneficiary execute a business reply form by explaining the scope of the marketing appointment and documenting beneficiary consent. In the view of the commenter, it would allow plans to deal with language, literacy and other barriers to effective direct mail marketing, comply with cold call and appointment rules, and protect the best interests of the beneficiary. In addition, the commenter requested that plans be able to bring a scope of appointment form to marketing meetings in cases where the agent is marketing to their beneficiary.

Response: Beneficiaries may turn to a number of sources for advice and assistance with making health care choices. However, because providers like physicians, social workers, home health agency staff, and others, are trusted sources of information and are in a position to unduly influence a beneficiary's decision, they must follow the guidance contained in the Medicare Marketing Guidelines with regard to the interactions between beneficiaries and providers. We do appreciate and recognize the marketing challenges faced by special needs plans. However, we believe that these issues are addressed adequately in subregulatory guidance and that further regulation is not necessary. For example, agents may document a new scope of appointment at a marketing meeting when the beneficiary indicates that he or she would like information beyond the scope of the original appointment.

Comment: A commenter recommended that we integrate full benefit dual eligibles' need for flexibility in the marketing rules that accommodate the challenges of selling to full benefit dual eligibles, while maintaining adequate protections for vulnerable populations.

Response: While we recognize that there may be unique challenges when marketing to the dual eligible population, at this time, CMS believes that additional regulatory changes would not be necessary, beyond the scope of those changes addressed herein. CMS will consider whether further subregulatory guidance is needed.

(3) Use of Names and Logos, Co-Branding (§ 422.2268(n) and § 423.2268(n))

In section 103(b)(1)(B) of MIPPA, the Secretary was charged with ''establish[ing] limitations'' with respect to ''[t]he use of the name or logo of a co-branded provider on Medicare Advantage plan membership and marketing materials.'' Section 103(b)(2) of MIPPA revises the Act to apply these same guidelines to PDP sponsors.

Comment: We received mixed comments regarding this provision. One commenter had no major concerns about the co-branding provisions, but another commenter recommended that we clarify that the inclusion of the name and/or logo of the plan's PBM and/or parent company on the member's identification card is not considered ''co-branding'' and so not subject to § 423.2268(n). Another commenter supported the prohibition on displaying names or logos on plan cards. However, the commenter requested clarification regarding ''other marketing materials'' that are subject to a disclaimer, stating that in many cases, the use of a network provider's name will be necessary to convey information to beneficiaries. Such instances could include network directory or brochures (under § 422.2260 and § 423.2260) that list the names of providers in the plan's network. Thus, the commenter believes that a broad use of the term without more clarity on what CMS intends to be captured by its proposal could create confusion to plans and network providers about the range of acceptable practices.

Response: We agree that PBMs are not typically co-branding partners; however, PBMs assume different roles in the MA and Part D programs, including: plan sponsor, plan subcontractor, or health care provider (mail order pharmacy). Since beneficiaries may not always understand the relationship of the PBM to the plan sponsor, we believe that including the PBM's name on the identification card may create confusion or lead the beneficiary to interpret this as a co-branding arrangement. Therefore, we believe that the co-branding requirements do apply and the name of the PBM cannot be included on the member identification card. We believe that unless a beneficiary must obtain services from a specific provider organization, the provider organization name should not be included on the ID card. We do not believe that additional clarification in the regulations is necessary regarding the specific materials that are intended as ''other marketing materials.'' We provide further interpretive guidance in the Medicare Marketing Guidelines.

(4) Inclusion of Plan Type in Plan Name (§ 422.2268 and § 423.2268)

Section 103(c)(1) of MIPPA requires that MA organizations and PDP sponsors include the plan type within the name of each plan being offered. For consistency across plans, the plan type is required to be included at the end of the plan name.

Comment: One commenter was concerned about the clarity of the regulations containing various references to ''lines of business'' and ''plan type'' in sections § 422.2268(h) and § 422.2268(q) and elsewhere. This commenter believed that the terms are employed somewhat interchangeably, but are not defined explicitly in the regulation. The commenter noted that there is a definition of plan type in § 422.2274(a)(3)(i) but it was unclear as to whether CMS intended that this definition apply throughout the regulation.

Response: We clarified the definition of ''plan type'' in the Medicare Marketing Guidelines and include examples of all of the plan type indicators. We do not believe that further regulatory definitions are necessary.

c. Reporting Agent and Broker Terminations (§ 422.2272(d) and § 423.2272(d))

Section 103 of the MIPPA, requires us to expand our proposed requirements on plans that use licensed agents and brokers. In accordance with MIPPA, § 422.2272(d) and § 423.2272(d) implement the requirement that MA organizations and Part D sponsors are required to report to the State in which the MAO or Part D sponsor appoints an agent or broker, the termination of any such agent or broker, including the reasons for the termination if State law requires that the reasons for the termination be reported.

We did not receive any comments on this provision; and are therefore, finalizing this provision without modification.

d. Broker and Agent Compensation (§ 422.2274, § 423.2274)

Section 103(b)(1)(B) of MIPPA revised the Act to charge the Secretary with establishing guidelines to ''ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the Medicare Advantage plan that is intended to best meet their health care needs.'' Section 103(b)(2) of MIPPA revised the Act to apply these same guidelines to PDP sponsors.

In our November 18, 2008 IFC, we invited comment on the approach taken in that rule to implementing the foregoing requirements. We are particularly interested in comments on whether this goal would be served by: (1) Providing for higher levels of compensation for an initial enrollment in Part C or Part D (given the added costs of explaining how the programs work) than for a change in enrollment from one Part C plan or Part D plan to another, (2) establishing a flat fee schedule; or (3) providing for lower payments in early years and higher payments in the renewal years, or in later renewal years, to incentivize agents or brokers to keep enrollees in the same plan rather than giving them an incentive to move enrollees.

We are also concerned about amounts paid to Field Marketing Organizations (FMOs) or similar typoes of entities for their services that do not necessarily flow down to the agent or broker who deals with the beneficiary. Specifically, we are concerned that these FMOs or other similar entities could engage in a ''highest bidders'' for their services.

We received a number of comments from plan sponsors, individuals, and trade associations, concerning compensation. These covered aspects of compensation including: compensation rules, structures and rates, and data. A summary of the comments we received and our responses follow:

(1) Compensation Rules

Comment: Commenters recommended varied approaches, including: providing generous initial compensation payments and no renewal payments, eliminating renewal payments, paying renewals on a declining scale, paying compensation based on enrollment type (SEP, ICEP/ICP), creating special compensation structures for PDPs, and relying on market forces. Reasons given for these recommendations included: renewal payments increase costs, diverted money could be better spent on benefits, and the compensation payments reduce efficiency.

Response: We believe that our current compensation processes have reduced the incidence of aggressive marketing and encourage agents and brokers to assist beneficiaries with making health care decision based on the beneficiaries' interests. We have done this by implementing a process that encourages agents and brokers to develop long-term relationships with beneficiaries. Thus, the 6-year compensation cycle is intended to recognize that beneficiaries need assistance from year-to-year in

understanding plan benefit changes so they can ensure that they are in the appropriate plan to meet their needs.

While we agree that the amount of work required to adequately explain the various Medicare product lines to beneficiaries will vary based on the beneficiaries' prior knowledge of the program, we believe that we have developed a process that recognizes the difference in experience of the beneficiary as well as the uniqueness of each product type. We have done this by allowing agents to be paid initial compensation for *unlike* plan changes, changes among MA/MA–PD, PDP, and 1876 cost plans. For *like* plan changes (MA/MA–PD to MA/MA–PD, PDP to PDP, or cost to cost), agents, and brokers are paid renewal compensation.

(2) Compensation Structures and Rates

Comment: Commenters expressed the concern that the variation allowed plans in developing compensation structures could potentially create financial incentives for agents to push low-value (less expensive) plans or MA products (over PDPs); leading to increased ''cherry picking'' or steering by independent agents and brokers.

Response: We believe that some variation in compensation is unavoidable. For example, the amount of work required to explain to a beneficiary the benefits, policies, and procedures of a particular MA plan compared with the amount of work required to explain to a beneficiary the benefits, policies, and procedures of a PDP are quite different. One would not expect for the compensation to be the same. Furthermore, we think that making the amounts for both plans the same would only incentivize agents to maximize profits by aggressively selling the plan that takes the least amount of time to explain.

At the time that our November 10, 2008 IFC was promulgated, we collected historical agent and broker compensation data from Medicare plan sponsors. Analysis of that data resulted in the establishment by us of fair-market value cut-off amounts (FMV). We then allowed plan sponsors to adjust their 2009 compensation amounts to an amount at or below the FMV. This allowed plan sponsors to be competitive in the marketplace while simultaneously limiting the high-end amount. We believe these amounts limit the variation in compensation paid to agents and brokers selling Medicare plans within specific geographic areas.

In addition to the fair-market value cut-off amounts, we implemented a strong surveillance and compliance program as well as a number of operational policy changes designed to strengthen beneficiary protections against aggressive and deceptive marketing practices by agents or brokers. We implemented enrollment verification processes that require plans to verify with beneficiaries that they are enrolling in the plan of their choice and understand the benefits of that plan. We also require plans to report terminated agents or brokers to State Departments of Insurance. We believe that with these policy refinements and the existing rules requiring plans to recover all payments for an enrollment from agents or brokers when a rapid disenrollment occurs provide necessary protections for beneficiaries as they make their health care choices.

Comment: We also received comments requesting that we create single commissions by product type (MA, MA–PD, PDP), create a flat rate for all product types that is the same for new plans as well as renewals, equalize commissions across all product types, or set benchmarks. In addition, commenters recommended that we limit the ability of agents and brokers to contract with multiple organizations and allow market forces to strengthen all Medicare plan products through competition.

Response: Since the issuance of our November 10, 2008 IFC, we released the FMV cut-off amounts, which are essentially benchmarks. These amounts set ceilings for agent or broker compensation payments for enrollments based on geographic areas. Because the 2009 FMV amounts were established through a blind bidding process that may have put low-bidding sponsors at a competitive disadvantage. During the summer of 2009, sponsors were allowed the opportunity to adjust their compensation amounts to any amount at or below the FMV. This was an important policy decision because, by regulation, all future compensation amounts are based on the 2009 amount filing.

We believe that setting the FMV cut-off amounts was the best approach because it allows for market forces to act while limiting the amount of spending. We also believe that this approach, along with the compensation regulatory provisions achieves the goals of the policy, and is the most efficient option because it does not require a significant investment of time, money, and staff resources. For example, in order to create a flat rate, we would have to consider a number of variables like individual local market dynamics, the impacts on small versus large plan sponsors, and plan benefit changes from year-to-year. In order to update the rate, we would have to engage in a similar process each subsequent year. Such an endeavor would require additional systems development and staff resources.

(3) Compensation Data

Comment: Commenters questioned CMS's ability to gather accurate and reliable market data, found the blind-bidding process unfair, and contended that the 2006 rates were not sustainable market rates. We also received a request to share aggregate data, with plan sponsors, and allow plans to adjust their compensation amounts. A commenter also requested that national plans' rates be included when making local plan comparisons.

Response: We recognize the inherent problems with the initial data collection process and that it was a blind-bidding process that potentially disadvantaged plans that submitted more conservative compensation estimates. In the spring of 2009, we published our FMV cut-off amounts based on the historical data submitted by plan sponsors in November 2008. The data included information in local markets for local and national plans. In July 2009, we allowed plan sponsors to adjust their original compensation amount submissions to an amount at or below the FMV. The purpose of this adjustment was to level the playing field allowing plans that initially submitted low compensation amounts (whether due to limited ability to collect historical data or underestimating the current market rates), the opportunity to become more competitive. In 2009, we began requiring plan sponsors to submit the range of amounts (high and low values) they pay their agents and brokers. These amounts are automatically updated from year-to-year and plan sponsors are only required attest to the amount and their continued use of independent agents and brokers. We currently posts plan compensation information on its Web site by State and county.

At this time, we cannot change the way plan sponsors update their annual compensation amounts. However, we will consider this proposal for future rulemaking.

(4) Spending Limits

Comment: We received comments requesting that we establish limits on marketing expenditures. One suggestion was for a limit based on the percentage of the sponsor payments rates that can be expended on marketing. Another would apply limits on spending for marketing based on sponsor history of marketing misrepresentation. A third

would place hard caps on spending for marketing to limit the share of per capita payments to sponsors that is diverted away from extra benefits or lower cost sharing.

Response: We believe that at this time it is unnecessary to place the types of limits on spending that were recommended by these commenters because, in addition to the establishment of the FMV cut-off amounts, we have in place a sophisticated surveillance and compliance program to monitor the activities of sponsors, agents, and brokers in the marketplace. The program includes the monitoring of marketing events, targeted audits of sponsors, coordination with the State Departments of Insurance, and penalties for sponsors who are not adequately ensuring that their agents or brokers are complying with our rules.

(5) Marketing Entities

Comment: We received several comments recommending that we charge plan sponsors a fee or increase existing users' fees that would be used to pay SHIPs and other community volunteer organizations to ''provide beneficiaries with advice and counseling on plan selection.''

Response: In our October 2009, proposed rule (74 FR 54634), we solicited public comment on a number of ideas including whether or not State Health Insurance Assistance Programs had the capacity to serve significantly more Medicare beneficiaries. We received a number of comments and suggestions, and as in our April 2010 final rule (75 FR 19678), there were a number of concerns about the adequacy of the funding necessary for SHIPs to serve more Medicare beneficiaries, the ability of SHIPs to create networks to service entire States, and the limits of SHIPs under their current structure to handle increased capacity. In addition to these concerns about the ability to transfer the responsibilities of independent agents and brokers to organizations like SHIPs, we believe that we do not have the statutory authority to increase or create new fees as a means of providing additional resources to SHIPs so that they can increase their capacity.

Comment: We also received several comments regarding payments to FMOs which focused on the language the commenter found to be unclear describing the responsibility of plan sponsors to ensure that the payments made by FMOs, are consistent with the compensation regulations. The commenters recommended direct regulation of FMOs or more explicit regulation language pertaining to the payment arrangements between the FMOs and the agents who work for them. One comment compared FMO/agent relationships to real estate broker/agent relationships, and argued for flexibility in the way that FMOs paid agents based on factors like experience and tenure.

Response: We agree that while it was always our intent that the compensation rules would apply at all levels including the FMO/writing agent level, our regulations language did not clearly express this intent. Therefore, we are explicitly clarifying our intent in § 422.2274(a)(1)(iv)(A) (B) and § 423.2274(a)(1)(iv)(A) and (B) of this final rule that the compensation rules apply to payments made by plan sponsors to the FMOs, as well as the FMOs'' agents. We also note that our September 18, 2008 IFC provided plan sponsors with the flexibility to use factors like tenure and experience when developing compensation structures.

(6) Employed Agents

Comment: Commenters sought clarification of the fact that there were fundamental differences between compensation streams and responsibilities for employed agents and independent agents. These differences included the structure of the payment arrangements (salary and benefits for employees, straight commission for independent agents), responsibilities (employees typically do not maintain a relationship with beneficiaries beyond the point of enrollment), and level of oversight (in-house oversight of employees). A few commenters requested language that exempts employees of plan sponsors and their subcontractors (like call center staff) from the compensation requirements that they believe were intended for independent agents and brokers.

Response: We clarified in the preamble of the September 18, 2008, interim final marketing regulations, that customer service representatives were not required to be licensed as long as they were engaged in duties specific to their job as customer service representatives (CSRs) (for example, providing factual responses to beneficiary questions or assisting with the enrollment process of beneficiaries who have decided on their own to enroll in the plan). We also clarified in the same regulations the differences between treatment of employed and independent agents and brokers (contracted). In addition, we have published the Medicare Marketing Guidelines which clarifies these issues and believes that further regulatory clarification is unnecessary.

(8) Recommendations

Comment: Several commenters requested that CMS consider the following recommendations:

- Guaranteeing a 7-day reconciliation cycle for payments of compensation.
- Eliminating charge backs for disenrollments.
- Eliminating product specific training.
- Clarifications of policy, definitions, and approach to controlling plan changes.

Response: Since the time that public comments were solicited on these regulations, we have put in place a number of operational policies that address the concerns expressed by the commenters. For example, in 2009, we did not have the systems capability to provide plans with information so that they could reconcile payments. Instead, we used an ad hoc report that provided basic information to assist plan sponsors with paying agents appropriately. As of January 2010, we have been providing plan sponsors with an agent and broker compensation report that is generated from the Medicare Advantage and Prescription Drug System (MARX) and delivered with the monthly MARX enrollment reports. Since its implementation, plan sponsors are able to use the system to pay agents timely and accurately. We have also published guidance on a number of policy issues in the Medicare Marketing Guidelines including chargebacks for different types of disenrollments, the relationship of referral fees to total compensation, examples of types of remuneration under the definition of compensation, clarification that the compensation cycle operates on a calendar year, and the exclusion of employer group plans from some of the agent and broker requirements. Therefore, we believe that additional regulatory provisions are unnecessary.

In addition to the aspects of compensation that we have learned through the comments we received on the interim final regulations, we have also identified several areas in our guidance which are not sufficiently clear. For example, we received a number of questions from plan sponsors, agents, and FMOs requesting clarification on the actual months for which agents or brokers could be compensated. The provision in the interim final regulations (§ 422.2274(a)(4) and § 423.2274(a)(4)) stated that ''compensation shall be paid for months 4 through 12.'' The intent of this provision was to ensure that, in the

case of a rapid disenrollment (a disenrollment within the first 3 months of enrollment), agents did not receive compensation. However in subregulatory guidance, we have since clarified the compensation policy around rapid disenrollments by clarifying the circumstances when a disenrollment would not be considered a rapid disenrollment (for example, when a beneficiary moves out of the plan service area within in the first three months of enrollment).

We also learned that plan sponsors were interpreting ''year'' in different ways (§ 422.2274(a)(4) and § 423.2274(a)(4)). Some sponsors were interpreting ''year'' to mean a year from the date of enrollment. Some sponsors have interpreted it to mean a calendar year, while others have interpreted it to mean a fiscal year. We have since clarified in subregulatory guidance that ''year'' means a plan year, from January through December.

We also have learned that plan sponsors and FMOs are unclear about the delineation between the activities that are part of the total compensation amount and those that are outside of our definition of compensation (§ 422.2274(a)(1)(iv) and § 423.2274(a)(1)(iv)). We have clarified in subregulatory guidance that compensation ''for activities other than selling Medicare products'' must be at fair market value. However, we do not intend to define fair market value for these activities.

Lastly, we have learned that plan sponsors are not clear what is meant by ''new compensation'' in § 422.2274(a)(1)(ii) and § 423.2274(a)(1)(ii). By ''new compensation'' we meant that when an unlike plan type change is made, a new 6-year compensation cycle begins. Thus, the agent would receive an initial compensation amount.

After considering the comments received and experience we have gained over the past 3years, we are finalizing these requirements with modification.

e. Agent and Broker Training (§ 422.2274(b) and § 423.2274(b))

Section 103(b)(1)(B) of MIPPA revised the Act to charge the Secretary with establishing ''limitations with respect to the use by a Medicare Advantage organization of any individual as an agent, broker, or other third party representing the organization that has not completed an initial training and testing program and does not complete an annual retraining and testing program.'' Section 103(b)(2) of MIPPA revises the Act to apply these same limitations to PDP sponsors.

In § 422.2274(b) and § 423.2274(b), MA organizations and PDP sponsors are required to train all agents selling Medicare products on Medicare rules, regulations and compliance-related information annually.

In § 422.2274(c) and § 423.2274(c), agents selling Medicare products are required annually to pass written or electronic tests on Medicare rules, regulations and information on the plan products they intend to sell.

Comment: A commenter requested clarification of the term ''selling'' as it applies to various roles within a plan. The commenter asserted that confusion exists as to whom ''selling'' pertains. It was asked if all licensed agents being paid any commission or administrative payment by a plan are considered to be ''selling'' MA and Part D plans, or if only the writing agent is considered to be ''selling.'' The commenter further recommended that CMS clarify, in the final rule, that all agents receiving any level of commission must be trained and tested annually to ensure that all levels of the sales force have up-to-date information.

Response: We describe who would qualify as ''one who sells'' in the Medicare Marketing Guidelines. In the definitions section of the Medicare Marketing Guidelines we define a Sales Person, or one who sells, as follows: The term ''sales person'' is used in these Medicare Marketing Guidelines to define an individual who markets and/or sells products for a single plan sponsor or numerous plan sponsors. It includes employees, brokers, agents, and all other individuals, entities, and downstream contractors that may be utilized to market and/or sell on behalf of a plan sponsor. While we realize that, in many instances, there may be many individuals involved in selling, it is the intent of the guidance for plans to encompass all possible points of contact which could reasonably be expected to sell and that those contacts are included in their respective training and testing programs.

Comment: We received another comment which asserted that regulations requiring more standardized industry training and testing may have some negative impacts on beneficiary choices. While the commenter agreed that in years past not all agents were properly trained and that previous responses encouraged an industry certification process, they suggested that there is too much duplication of training. Specifically, it is mentioned that requiring agents and brokers to receive separate training and certification from each company that they represent for each product, discourages qualified agents and brokers from representing a wide variety of products. The commenter further asserted that agents and brokers would most likely select one or two products to promote due to the duplicative and time-consuming requirements imposed upon them, and that this would be detrimental to Medicare beneficiaries in an environment where choice is critical.

Response: While we agree with the commenter that requiring different certifications from separate plan sponsors does create duplication in areas of training and testing in addition to considerable time (depending on the number of certifications desired), it is a requirement that will better protect beneficiaries. Many Medicare beneficiaries have suffered tremendous damages both monetarily and at a cost to their health due to poorly informed sales representatives. The training and testing certification process has been identified by both the industry and Medicare beneficiaries as a good protection. By implementing regulations that provide consistent and routine training and testing of agents, brokers, and all manner of personnel that may conduct sales-related activity, beneficiaries will be less likely to make important health decisions based on incomplete or inaccurate information. We will continue to evaluate the requirements and methods utilized to implement the training and testing in the future.

Since our April 2011 final rule (76 FR 21432) entitled, Medicare Program: Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes, finalized changes to § 422.2274 and § 423.2274, paragraphs (b) and (c), we are not finalizing these provisions in this final rule.

In § 422.2274(d) and § 423.2274(d), MA organizations and PDP sponsors are required to provide us the information designated by CMS as necessary to conduct oversight of marketing activities.

We received no comments on these provisions and are finalizing them without modification.

In § 422.2274(e) and § 423.2274(e), MA organizations and PDP sponsors are required to comply with State requests for information about the performance of licensed agents or brokers as part of a state investigation into the individual's conduct. We will establish and maintain a memorandum of understanding (MOU) to share compliance and oversight information with States that agree to the MOU.

We received no comments on these provisions and are finalizing them without modification.

D. Changes to Section 1876 Cost Plans

1. Clarifying the Conditions Under Which 1876 Cost Plans or Portions of Their Service Areas May Be Prohibited

In the September 2008 IFC, we implemented statutory requirements affecting section 1876 cost contract plans and policies related to the ability to offer cost contract plans when in the same service area or portion of a service area as MA coordinated care plans. Section 1876(h)(5)(C) of the Act prohibits the renewal of a cost plan, or a portion of a cost plan's service area in an area where, during the previous year, two or more organizations offering a local MA plan meet a minimum enrollment test, or two or more organizations offering a regional MA plan meet the same test. The test is that the local or regional plan must have at least 5,000 enrollees in any portion of its service area that includes a Metropolitan Statistical Area (MSA) with a population over 250,000 (enrollment in counties contiguous to the MSA count toward the 5,000) and enrollment of at least 1,500 in the other portion of its service area. Section 167 of MIPPA clarified the application of minimum enrollment requirements by revising paragraphs 1876(h)(5)(C) of the Act.

The MIPPA-based revisions include clarifying in section 1876(h)(5)(C)(iii) of the Act that the two plans triggering the prohibition may not be offered by the same MA organization.

In addition, by revising section 1876(h)(5)(C)(iii)(I) of the Act, MIPPA clarified that if a cost plan's service area falls within more than one MSA with a population over 250,000 and the local or regional plans have a minimum of 5,000 enrollees, the determination to prohibit a plan will be made with respect to each MSA and counties contiguous to each MSA that are not in another MSA with a population of more than 250,000.

If a cost plan's service area or portion of a service area falls in one MSA only, the determination to prohibit a plan will be based on the competing local or regional plans' enrollments in that MSA only.

In order to reflect these changes we revised paragraphs of § 417.402(c)(1) through (3). We received two comments on this provision and, with one exception discussed below, are finalizing the provision as specified in the IFC.

Comment: A commenter suggested that we update our regulations at § 417.402(c) to reflect the MIPPA-revised date of January 1, 2010 on or after which CMS will nonπrenew affected service areas of cost contract plans.

Response: Subsequent to this comment, new statutory language revised the nonπrenewal date from January 1, 2010 to January 1, 2013. We specified the new timeline in our final rule that appeared in the April 15, 2010 **Federal Register** (76 FR 21732) and that implemented this and other provisions of the Affordable Care Act.

Comment: A commenter requested that we clarify in our revision of § 417.402(c)(3) that in determining minimum enrollment in MSAs and contiguous counties we specify that only those contiguous counties are taken into account if not in another MSA with a population of more than 250,000.

Response: This clarification is consistent with the statute and we have revised § 417.402(c)(3) accordingly.

III. Collection of Information Requirements

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Under the Paperwork Reduction Act of 1995, 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 OMB for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 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.

The title, description, and respondent description of the information collection provisions and an estimate of the annual reporting burden were provided in a series of interim final rules, (73 FR 54208) and (73 FR 54226) issued September 18, 2008. Included in the estimate was the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information. We solicited public comment on each of the issues in the interim final rule that contained information collection requirements (ICRs). This final rule requires no new information collection. In the document below, we describe the information collection burden associated with provisions of the interim final rule that we are finalizing.

A. ICRs Regarding the Model of Care (MOC) Requirements for Special Needs Plans (§ 422.101)

Section 422.101(f)(1) states that MA organizations offering special needs plans (SNPs) must implement a model of care (MOC) with care management as a centerpiece designed to meet the specialize needs of the plan's targeted enrollees. The burden associated with this requirement is the time and effort put forth by the SNP to establish a MOC that meets the requirements under § 422.101(f). In our September 18, 2008 IFC, we estimated that it would take each SNP 80 hours to meet this requirement in the initial year of development. We estimated that it would take 10 hours per year in subsequent years to revise the MOC based on performance data analysis through the plan's quality improvement program. Existing SNPs already have MOCs and revise, rather than develop, their MOCs in response to this requirement. In our September 18, 2008 IFC, we estimated that the 335 existing SNPs would have a cumulative annual burden of 3,350 hours to revise their MOC. We also estimated that we would approve approximately 150 new SNPs in January 2010, and that these 150 new SNPs would have a cumulative initial year burden of 12,000 hours to develop their MOC, and a cumulative annual burden of 1,500 hours to revise their MOC in subsequent years. We projected the total annual burden to be 3,350 hours in calendar year 2009. We projected that the total annual burden to be 13,500 hours in calendar year 2010 (12,000 hours for SNPs approved to begin operating January 1, 2010 and 1,500 hours for SNPs approved prior to January 1, 2010). In this final rule, we are modifying the annual burden estimate reported in the interim final rule to reflect a significant increase in the number of existing SNPs in 2010 as compared to 335 existing SNPs that we estimated in the interim final rule. We are also modifying the estimate to reflect a significant decrease in the number of new SNPs approved for 2010 as compared to the 150 new SNPs that we estimated in the interim final rule. We estimate that the 544 SNPs existing in 2010 will expend 10 hours per year in

subsequent years to revise the MOC based on performance data analysis through the plan's quality improvement program. Therefore, we estimate a cumulative annual burden of 5,440 hours for these existing SNPs to revise their MOCs. We estimate that the 15 new SNPs approved in 2010 will have a cumulative initial year burden of 1,200 hours (15 new SNPs multiplied by 80 hours in the initial year of development) to develop their MOC, and a cumulative annual burden of 150 hours (15 new SNPs multiplied by 10 hours per year) to revise their MOC in subsequent years.

In our September 18, 2008 IFC, we assumed hourly wages of $37.15 (based on United States Department of Labor (DOL) statistics for a management analyst) plus the added OMB figures of 12 percent for overhead and 36 percent for benefits for a total hourly labor cost of $54.98, respectively, to represent average costs to plans, sponsors, and downstream entities for the provisions discussed in our September 18, 2008 IFC. While we recognized that SNPs may need to utilize medical personnel or senior staff to comply with this requirement, we were unsure of these costs when we developed the cost estimate for this provision in the interim final rule. Therefore, in our September 18, 2008 IFC, we requested comment on the additional cost impact of the MOC requirement on SNPs. We did not receive any comments in response to our request for comment on the cost estimate for this provision. Based on new information regarding the labor wages of staff that review the MOCs we are revising our hourly labor estimate from the estimate we reported in the interim final rule. In this final rule, our estimate of the information collection burden associated with this provision reflects an hourly salary of $55.46 for a GS 13, Step 10 analyst for 2010, with an additional 48 percent increase to account for fringe benefits and overhead. Therefore, we estimate a total hourly labor cost of $82.08, and a total cost (including start-up and annual costs) of $598,068 to implement the requirements of this provision.

B. ICRs Regarding the State Contracting Requirements for Dual Eligible Special Needs Plans (§ 422.107)

Section 422.107(a) requires that an MA organization seeking to offer a SNP serving beneficiaries eligible for both Medicare and Medicaid (dual-eligible SNPs) must have a contract with the State Medicaid agency. The MA organization retains responsibility under the contract for providing benefits, or arranging for benefits to be provided, for individuals entitled to receive medical assistance under Title XIX. Such benefits may include long-term care services consistent with State policy.

Section 422.107 also allows MA organizations with an existing dual-eligible SNP without a State Medicaid agency contract to continue to operate through 2010 provided they meet all other statutory requirements, that is, care management and quality improvement requirements and do not expand their service areas.

The burden associated with this requirement is the time and effort put forth by each dual-eligible SNP to contract with the State Medicaid agency. In our September 18, 2008 IFC, we estimated it would take 460 SNPs 18 hours each for 6 months to comply with this requirement (36 hours per year). Therefore, we estimated that the total annual burden associated with this requirement was 16,560 hours. In this final rule, we are revising the estimates we reported in the interim final rule to reflect a significant decrease in the number of SNPs that were required to comply with this requirement in 2010. In 2010, 43 SNPs were required to have State contracts. Therefore, we estimate that it will take 43 SNPs 36 hours to comply with this requirement each year, resulting in a total annual burden of 1,548 hours. In our September 18, 2008 IFC, we assumed hourly wages of $37.15 (based on DOL statistics for a management analyst) plus the added OMB figures of 12 percent for overhead and 36 percent for benefits, respectively, to represent average costs to plans, sponsors and downstream entities for the provisions discussed in the interim final rule. In this final rule, we are updating the labor estimates we reported in our September 18, 2008 IFC to reflect the most recent 2009 data available from the DOL's Bureau of Labor Statistics (BLS) for the hourly wages of management analysts. Therefore, our final labor cost estimate reflects a median hourly rate of $36.18 for a management analyst, and a, 48 percent addition to this hourly rate for overhead and fringe benefits, for a total hourly labor cost estimate of $53.55 per response. We estimate a total annual cost of $82,895 in order to implement this provision's requirements.

C. ICRs Regarding the Comprehensive Written Statement Requirement for D–SNPs (§ 422.111)

Section 422.111(b)(2)(iii) states that each SNP must provide for prospective dual-eligible individuals, prior to enrollment, a comprehensive written statement describing cost-sharing protections and benefits that the individual is entitled to under title XVIII and the State Medicaid program under title XIX. This may be developed by the SNPs and distributed by the agents selling Medicare products.

The burden associated with this requirement is the time and effort put forth by each SNP to develop and provide such written statement. In our September 18, 2008 IFC, we estimated that 460 SNPs would be affected annually by this requirement and that it would take each SNP 10 hours to comply with this requirement. Therefore, we estimated that the total annual burden associated with this requirement would be 4,600 hours. In this final rule, we are revising the annual burden estimate we reported in the interim final rule to reflect the most recent information we have regarding the number of D–SNP plan benefit packages (PBPs). In this final rule, we are revising the estimate we reported in the final rule to reflect an increase in the number of D–SNPs affected by this requirement. In 2010, 487 D–PBPs were affected by this requirement. Accordingly, we estimate the total annual burden associated with this requirement is 4,870 hours (10 hours multiplied by 487 D–SNP PBPs). We are also revising our labor cost estimates in this final rule to reflect the most recent hourly wage data available from the BLS. In our interim final rule, we estimated an hourly labor rate of $14.68 for the hourly wages of word processors and typists based on 2006 BLS data. Our labor cost estimate in this final rule assumes a median hourly rate of $15.67, based on the most recent 2009 BLS data available for the hourly wages of word processors and typists. To account for fringe benefits and overhead, we add 48 percent to this hourly rate to obtain a total hourly labor cost estimate of $23.19 per response. We estimate total annual costs of $112,935 in order to implement this provision's requirements.

D. ICRs Regarding the Access to Services Under an MA Private Fee-for-Service (PFFS) Plan (§ 422.114)

1. Clarification Regarding Utilization

The revised § 422.114(a)(2)(ii)(A) requires that for plan year 2010 and subsequent plan years, a private fee-for-service (PFFS) plan that meets access requirements, with respect to a particular category of provider, by establishing contracts or agreements with a sufficient number and range of providers must meet the network accessibility and adequacy requirements described in 1852(d)(1) of the Act. This

section of the statute describes the network adequacy requirements that coordinated care plans currently must meet when contracting with providers to furnish benefits covered under the plan.

We use the network adequacy standards established for coordinated care plans in order to determine whether PFFS plans who want to meet access requirements under § 422.114(a)(2)(ii) satisfactorily meet those requirements. Therefore, in our September 18, 2008 IFC, we assumed that there would be no additional burden on PFFS plans in order to comply with § 422.114(a)(2)(ii)(A). We did not receive any comments on our assumption on no additional burden on PFFS plans, and we are not changing this assumption in this final rule.

2. Requirement for Certain Non-Employer PFFS Plans To Use Contract Providers

Section 422.114(a)(3) requires that for plan year 2011 and subsequent plan years, an MA organization that offers a PFFS plan that is operating in a network area as defined in § 422.114(a)(3)(i) meets the access requirements in § 422.114(a)(1) only if the MA organization has contracts or agreements with providers in accordance with the network accessibility and availability requirements described in 1852(d)(1) of the Act.

The burden associated with this requirement is that beginning in plan year 2011, an MA organization offering a PFFS plan is required to create separate plans within its existing service area based on whether the counties located in that service area are considered network areas. In our September 18, 2008 IFC, we estimated the burden of this administrative requirement on the 77 MA organizations that offered 838 non-employer MA PFFS plans at the time that the interim final rule was published. We also estimated that an additional 300 plans would be created as a result of organizations creating separate PBPs for their network area and non-network area plans. We estimated that it would take 2 hours to create a new plan benefit package for a total of 600 hours to create 300 plan benefit packages. We are not modifying this total burden hour estimate in this final rule. However, as stated earlier, we are modifying our estimate of the hourly labor costs incurred through this requirement to reflect the most recent hourly wage data available from the BLS. Therefore, we estimate a total hourly labor cost of $53.55 for this provision, assuming an hourly labor cost of $36.18 for a management analyst in 2009, and a 48 percent increase to account for fringe benefits and overhead. We estimate a total annual cost of $32,130 associated with implementing this provision's requirements.

3. Requirement for all Employer/Union-Sponsored PFFS Plans To Use Contracts With Providers

Section 422.114(a)(4) requires that an employer/union sponsored PFFS plan operating on or after plan year 2011 must establish written contracts or agreements with a sufficient number and range of health care providers in its service area for all categories of services in accordance with the network accessibility and availability requirements described in 1852(d)(1) of the Act.

The burden associated with this requirement is the time and effort necessary for an organization offering an employer/union sponsored PFFS plan to submit the required application to CMS according to § 422.501. In our September 18, 2008 IFC, we estimated that approximately 10 organizations would submit applications for a year, and that it would take each of these organizations approximately 100 hours to complete an application, for a total burden of 1,000 hours for all applicants on an annual basis. We are not modifying this total burden hour estimate in this final rule. However, we are modifying our estimate of the hourly labor costs incurred through this requirement to reflect the most recent hourly wage data available from the BLS. We calculate a total hourly labor cost of $53.55 for this provision assuming the hourly salary of $36.18 for a management analyst in 2009, with a 48 percent increase to account for fringe benefits and overhead. This burden associated with the requirement under § 422.501 imposes $53,550 in annual costs and is captured in OMB #0938–0935. We have updated this PRA package approved under OMB #0938–0935 for this ICR to reflect our revised burden estimates.

E. ICRs Regarding the Quality Improvement Program (§ 422.152)

Section 422.152(g) states that MA organizations offering SNPs must conduct a QI program that: (1) Provides for the collection, analysis, and reporting of data that measures health outcomes and indices of quality at the plan level; (2) measures the effectiveness of its MOC; and (3) makes available to CMS information on quality and outcomes measures that will enable—(i) beneficiaries to compare health coverage options; and (ii) CMS to monitor the plan's MOC performance.

The burden associated with this requirement is the time and effort put forth by the SNP to develop, collect, and analyze the quality and health outcomes measures that meet the requirements under § 422.152(g). This requirement is for new and existing SNPs. The cumulative burden on SNPs is reflected in two parts: the burden on plans operating before implementation of this provision in our September 18, 2008 IFC; and the burden on new SNPs that were approved to operate beginning on January 1, 2010.

In our September 18, 2008 IFC, we estimated that it would take each SNP 120 hours to meet this requirement in the initial year of development. We estimated that it would take 40 hours per year in subsequent years to revise the quality and health outcomes measures based on performance data analysis through the plan's quality improvement program. In our September 18, 2008 IFC, we estimated that 335 existing SNPs would have a cumulative annual burden of 40,200 hours (120 hours × 335 plans) to develop the quality and health outcomes measures needed to evaluate their model of care and overall plan performance. In calendar year 2010 and subsequent years, we estimated the existing SNPs would have a cumulative annual burden of 13,400 hours (40 hours × 335 plans) to revise the quality and health outcomes measures based on performance data analysis through the plan's quality improvement program. We anticipated that we would approve 150 new SNPs by January 1, 2010, and that the 150 new SNPs would have a cumulative initial year (calendar year 2010) burden of 18,000 hours (120 hours multiplied by 150 plans) to develop their quality and health outcomes measures needed to evaluate their model of care and overall plan performance, and a cumulative annual burden of 6,000 hours (40 hours multiplied by 150 plans) to revise their model of care in subsequent years.

As stated elsewhere in this section, in this final rule we are modifying our September 18, 2008 IFC estimates to reflect a significant increase in the number of existing SNPs in 2010 as compared to 335 existing SNPs that we estimated in the interim final rule. We are also modifying the estimate to reflect a significant decrease in the number of new SNPs approved for 2010 as compared to the 150 new SNPs that we estimated in the interim final rule.

First, we estimate that the 544 existing SNPs existing in 2010 incurred a cumulative annual burden of 65,280

hours (120 hours × 544 plans) to develop the quality and health outcomes measures needed to evaluate their MOC and overall plan performance. For subsequent years, we estimate that these existing SNPs will have a cumulative annual burden of 21,760 hours (40 hours × 544 plans) to revise the quality and health outcomes measures based on performance data analysis through the plan's quality improvement program. Second, we estimate the 15 new SNPs that CMS approved by January 1, 2010 incurred a cumulative initial year (FY 2010) burden of 1,800 hours (120 hours multiplied by 15 plans) to develop the quality and health outcomes measures needed to evaluate their MOC and overall plan performance. We estimate that these SNPs will have a cumulative annual burden of 600 hours (40 hours multiplied by 15 plans) to revise their MOC in subsequent years. In summary, we are revising our September 18, 2008 IFC estimates in this final rule to reflect a cumulative annual burden of 65,280 hours in calendar year 2009, and a total annual burden of 23,560 hours (21,760 hours for existing SNPs revising their measures, and 1,800 hours for new SNPs developing their measures) for calendar year 2010.

As stated earlier in this section, while we recognized that SNPs may need to utilize medical personnel or senior staff to comply with this requirement, we were unsure of these costs when we developed the cost estimate for this provision in the interim final rule. Therefore, in our September 18, 2008, we requested comment on the additional cost impact of the MOC requirement on SNPs. We did not receive any comments in response to our request for comment on the cost estimate for this provision. However, based on new information regarding the labor wages of staff that review the MOCs we are revising our hourly labor estimate from the $54.98 hourly wage estimate that we reported in the interim final rule. In this final rule, our estimate of the information collection burden associated with this provision reflects an hourly salary of $55.46 for a GS 13, Step 10 analyst for 2010, with an additional 48 percent increase to account for fringe benefits and overhead. Therefore, we estimate a total hourly labor cost of $83.08 to implement the requirements of this provision, resulting in a onetime $5,573,006 start-up cost and $1,857,668 in total annual costs.

F. ICRs Regarding the Standards for MA Organization Marketing (§ 422.2268)

Section 422.2268(g) states that MA organizations cannot market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment.

The burden associated with this requirement is the time and effort put forth by the MA organization to document a beneficiary's acknowledgement confirming the specific types of choices that the marketing representative is authorized to discuss. In our November 10, 2008 IFC, we stated that the burden associated with these requirements was exempt from the requirements of the PRA as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities. We received no comment on our burden determination in the interim final rule, and are therefore finalizing the burden estimate associated with this ICR without modification.

G. ICRs Regarding the Licensing of Marketing Representatives and Confirmation of Marketing Resources (§ 422.2272)

Section 422.2272(d) states that MA organizations must report to the State in which the MA organization appoints an agent or broker, the termination of any such agent or broker, including the reasons for such termination if State law requires that the reasons for the termination be reported.

The burden associated with this requirement is the time and effort put forth by the MA organization to comply with the State requests for information. In our November 10, 2008 IFC, we stated that the burden associated with these requirements is exempt from the requirements of the PRA as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities. We received no comment on our burden determination in our November 10, 2008 IFC, and are therefore finalizing the burden estimate associated with this ICR without modification.

H. ICRs Regarding the Broker and Agent Compensation and Training of Sales Agents Under MA Organizations (§ 422.2274(b) and § 422.2274(d)) and PDP Sponsors (§ 423.2274(b) and § 423.2274(d))

Section 422.2274(b) states that if a MA organization markets through independent brokers or agents, they must train and test agents selling Medicare products concerning Medicare rules and regulations specific to the plan products they intend to sell. The burden associated with this requirement is the time and effort put forth by the MA organization to provide training and test agents. In our November 10, 2008 IFC, we stated that the burden associated with these requirements is exempt from the requirements of PRA as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities. We received no comment on our burden determination for § 422.2274(b) in our November 10, 2008 IFC, and are therefore finalizing the burden estimate associated with the § 422.2274(b) ICR without modification.

In our November 10, 2008 IFC, we required all MA plans to post revised compensation structures to brokers or agents that conform precisely to our regulations and guidance under § 422.2274(d). We additionally required every complete submission of a compensation structure to include a signed certification from an authorized senior official within the organization. The burden associated with this requirement was the time and effort put forth by the organization to post the compensation structures and to provide the structures and certification to CMS. In our November 10, 2008 IFC, we estimated it would take each 670 MA organizations 56 hours each to fulfill this requirement for a total of 37,520 hours annually. Although this requirement applied to plans in 2009, we did not require plans to post their compensation structures in 2010 or 2011. Instead, we now require MA organizations to update and attest to their information in the Health Plan Management System (HPMS). This Web-based system in HPMS allows new plans to submit information and automatically updates organization compensation information for existing plans. Once the information has been submitted or reviewed, the system allows the organization to attest to the accuracy of the information. In this final rule, we revise the November 10, 2008 IFC's estimate to reflect this burden. We

believe that the time necessary to complete this process is 2 hours. Based on our revised estimate in this final rule for the number of MA organizations, the total annual burden associated with this requirement is 1,326 hours (663 MA organizations multiplied by 2 hours per response). In this final rule, we are additionally revising our interim final rule hourly labor cost estimate of $14.68 to reflect the most recent 2009 BLS data available. We estimate a median hourly rate of $15.67 for the wages of word processors and typists. To account for fringe benefits and overhead, we add 48 percent to this hourly rate to obtain a total hourly labor cost estimate of $23.19 per response, and a total annual burden cost of $30,750. We are revising the PRA package approved under OCN 0938–0753 to reflect these information requirements.

Section 423.2274(b) requires the Part D sponsor to ensure that agents selling Medicare products are trained on Medicare rules and regulations specific to the plan products they intend to sell. The burden associated with this requirement is the time and effort put forth by the Part D sponsor to provide training and test agents. In our November 10, 2008 IFC, we determined that the burden associated with these requirements was exempt from the requirements of the PRA as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities. We received no comments on our burden determination for § 423.2274(b) in our November 10, 2008 IFC, and are therefore finalizing our burden estimate for § 423.2274(b) without modification.

In our November 10, 2008 IFC, we also required all Medicare PDPs to post revised compensation structures to brokers or agents that conform precisely to our regulations and guidance under § 423.2274(d). Additionally, we required every complete submission of a compensation structure to include a signed certification from an authorized senior official within the organization. The burden associated with this requirement was the PDP's time and effort to post its compensation structures and to provide the structures and certification to CMS. In our November 10, 2008 IFC, we anticipated it would take each Part D sponsor 49 hours to fulfill this requirement and that 87 Part D sponsors would be affected annually for a total of 4,263 hours annually. Although this requirement applied to Part D sponsors in 2009, we did not require Part D sponsors to post their compensation structures in 2010 or 2011. Instead, we now require Part D sponsors to update and attest to their information in the Health Plan Management System (HPMS). This Web-based system in HPMS allows new sponsors to submit information and automatically updates organization compensation information for existing sponsors. Once the information has been submitted or reviewed, the system allows the organization to attest to the accuracy of the information. In this final rule, we revise the November 10, 2008 IFC's estimate to reflect this burden. We believe that the time necessary to complete this process is 2 hours. We are also revising the burden estimate to reflect updated figures for the number of Part D sponsors that were operating in CY 2009. Seventy-nine Part D sponsors are affected annually by this requirement, resulting in a total annual burden of 158 hours (79 Part D sponsors multiplied by 2 hours per response). Our labor cost estimate assumes a median hourly rate of $15.67, based on the most recent 2009 BLS data available) for the hourly wages of word processors and typists. To account for fringe benefits, we add 48 percent to this hourly rate to obtain a total hourly labor cost estimate of $23.19 per response and a total cost estimate of $3,664 annually. We are revising the PRA package approved under OCN 0938–0964 to reflect these information collection requirements.

I. ICRs Regarding the Prompt Payment for Part D Sponsors (§ 423.520)

Section 423.520(a)(ii)(2) requires the Part D sponsor to notify the submitting network pharmacy that a submitted claim is not a clean claim. Such notification must specify all defects or improprieties in the claim and must list all additional information necessary for the proper processing and payment of the claim.

The burden associated with this requirement is the time and effort put forth by the Part D sponsor to provide proper notification to the network pharmacy. While there is burden associated with this requirement, in our September 18, 2008 IFC, we stated that the burden associated with these requirements is exempt from the requirements of the PRA, as defined in 5 CFR 1320.3(b)(2), because the time, effort, and financial resources necessary to comply with this requirement would be incurred by persons in the normal course of their activities. We received no comment on our burden determination in the interim final rule, and are therefore finalizing the burden estimate without modification.

J. ICRs Regarding the Standards for Part D Marketing (§ 423.2268)

Section 423.2268(g) states that Part D organizations cannot market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment.

The burden associated with this requirement is the time and effort put forth by the Part D organization to document a beneficiary's signed acknowledgement confirming the specific types of choices that the marketing representative is authorized to discuss. While there is burden associated with this requirement, in our November 10, 2008 IFC, we stated that the burden associated with these requirements is exempt from the requirements of the PRA as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities. We received no comment on our burden determination in the interim final rule, and are therefore finalizing the burden estimate associated with this ICR without modification.

K. ICRs Regarding the Licensing of Marketing Representatives and Confirmation of Marketing Resources (§ 423.2272)

Section 423.2272(d) states that Part D sponsors must report to the State in which the Part D sponsor appoints an agent or broker, the termination of any such agent or broker, including the reasons for such termination if State law requires that the reasons for the termination be reported.

The burden associated with this requirement is the time and effort put forth by the Part D sponsor to comply with the State requests for information. While there is burden associated with this requirement, in our November 10, 2008 IFC, we stated that the burden associated with these requirements is exempt from the requirements of the PRA as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities. We received no comment on our burden determination in the interim final rule, and are therefore finalizing the burden estimate associated with this ICR without modification.

TABLE 2—ESTIMATED FISCAL YEAR REPORTING RECORDKEEPING BURDENS

Regulation sections	OMB Control No.	Respondents	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost ($)	Total capital/ maintenance costs ($)	Total cost ($)
422.101(f)(1)	0938–New	544	10	5,440	83.08	551,651	0	551,651
(Start-up)		15	80	1,200				
422.101(f)(1)	0938–New	544	10	5,440,150	83.08	464,417	0	46,417
(Annual)		15	10					
422.107(a)	0938–New	43	36	1,548	53.55	82,895	0	82,895
422.111(b)(2)	0938–New	487	10	4,870	23.19	112,935	0	112,935
422.114(a)(3)	0938–New	300	2	600	53.55	32,130	0	32,130
422.114(a)(4)	0938–0935	10	100	1,000	53.55	53,550	0	53,550
422.152(g)	0938–New	544	120	65,280	83.08	5,573,006	0	5,573,006
(Start-up)		15	120	1,800				
422.152(g)	0938–New	544	40	21,760	83.08	1,857,668	0	1,857,668
(Annual)		15	40	600				
422.2274(d)	0938–0753	663	26	1,326	23.19	30,750	0	30,750
423.2274(d)	0938–0964	79	29	158	23.19	3,664	0	3,664
Total		2.141		111,172		8,762,666	0	8,762,666

IV. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this rule as required by Executive Orders 12866 on Regulatory Planning and Review (September 30, 1993) and 13563 on Improving Regulation and Regulatory Review (January 18, 2011). Executive Orders 12866 and 13563 direct 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 impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year). This final rule has been designated an ''economically significant'' rule under section 3(f)(1) of Executive Order 12866. In addition, this is a major rule under the Congressional Review Act (5 U.S.C. 804(2)). Accordingly, the rule has been reviewed by the Office of Management and Budget.

B. Statement of Need

The purpose of this final rule is to finalize provisions of several interim final rules that provide revisions to the Medicare Advantage (MA) program (Part C) and Prescription Drug Benefit Program (Part D), to implement provisions specified in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), and to make other changes to the regulations based on our continued experience in the administration of the Part C and Part D programs. These latter revisions are necessary to: (1) Clarify various program participation requirements; (2) make changes to strengthen beneficiary protections; (3) strengthen our ability to identify strong applicants for Part C and Part D program participation and remove consistently poor performers; and (4) make other clarifications and technical changes. Refer to section I. of this final rule for background on the interim final rules that we are finalizing. The scope of the analysis of economic impacts for this final rule is limited to the costs and savings associated with the provisions in the interim final rule that we are finalizing.

C. Overall Impacts

The CMS Office of the Actuary has estimated savings and costs to the Federal government as a result of various provisions of this final rule. Tables 4 and 6 detail the breakdown of costs by cost-bearing entity. Specifically, Table 4 describes costs and savings to the Federal government and Table 6 describes costs to MA organizations and/or PDP sponsors and third party entities. As detailed in Table 4, we expect an aggregate net savings to the Federal government of approximately $520 million for fiscal years (FYs) 2010 through 2015 as a result of the provisions in this final rule. This estimate represents $1.02 billion in savings to the Federal government, as a result of the requirement that certain non-employer and all employer private-fee-for-service plans must establish contracts with providers and costs of approximately $500 million as a result of the implementation of prompt payment by prescription drug plans and MA–PD plans from FYs 2010 through 2015. Administrative costs associated with the provisions of the interim final rule as finalized by this final rule add negligibly to the total administrative costs of the MA or Part D programs. Table 6 describes the administrative costs that MA organizations and PDP sponsors will incur ($19.55 million) from FYs 2010 through 2015 as a result of the requirements in this final rule. Refer to section III. of this final rule (Collection of Information Requirements) for additional information on the calculations and assumptions that form the basis of our cost estimates for these provisions.

As described in Table 3 reflecting the costs and savings in this RIA, we conclude that the provisions in this final rule result in a net savings of approximately $500.5 million over FYs 2010 to 2015.

D. Detailed Impacts

1. Provider Contracts for Employer and Non-Employer PFFS Plans (§ 422.114(a)(3) and § 422.114(a)(4))

In our September 18, 2008 IFC, we estimated an incurred savings (before the Part B premium offset) of $780 million for FY 2011 to $1.59 billion in FY 2018 as a result of the requirement that certain non-employer and all employer PFFS plans establish contracts with providers. We arrived at this figure by first determining how many coordinated care plans (excluding regional PPOs) were currently operating in counties that had PFFS plans. We then used this estimate to project how many PFFS plans and members would be subject to the new requirement to set up networks of providers by 2011. Based on the information, as well as the level of payments that these plans receive, we estimated how many members would end up in PFFS plans that did not need to form networks, how

many would be in plans that converted to network PFFS plans, how many would end up in a coordinated care plan, and how many would switch to original Medicare. We used different assumptions for individual plans and for group plans. However, for both group and individual plans, we assumed that most members would remain in a PFFS plan (either network or non-network). For members who stayed in either a network or non-network PFFS plan, we assumed a higher plan bid and, therefore, a cost to Medicare. We assumed a savings for those beneficiaries that we believed would enroll in a MA coordinated care plan, and projected an even larger savings for beneficiaries that would enroll in original fee-for-service (FFS) Medicare. We assumed that 20 percent of the 2009 cohort PFFS enrollees would migrate to Medicare FFS in 2011. Based on this projected enrollment, we assumed that the per-capita savings for those migrating would range from 12 to 15 percent, depending on plan type (employer vs. non-employer).

In this final rule, we are revising the cost estimate projected in our September 18, 2008 interim final rule to reflect the actual proportion of 2009 PFFS enrollees who migrated to Medicare FFS as compared to those who remained in an MA plan. Based on an analysis of enrollment in counties with the largest PFFS share in 2009, we estimated that only 6 percent of the 2009 PFFS enrollees migrated to Medicare FFS as a result of the PFFS network requirements; with approximately half of these enrollees having migrated in 2010 and the other half having migrated in 2011. Our revised 6 percent migration assumption is based on actual MA enrollment changes from 2009 to 2011 in countries where PFFS enrollment comprised at least 50 percent of total MA enrollment. We additionally assume a 13 percent per-capita savings for those migrating from PFFS to FFS—a figure that is consistent with the 12 to 15 per-capita savings we estimated in our interim final rule—based upon 2010 data from the Medicare Payment Advisory Commission (MedPAC).

Also, in this final rule, we are modifying the window over which we estimate costs and savings to conform to methodology specified by the Office of Management and Budget (OMB). We begin our measurement of costs and savings in FY 2010, which is the first year that the requirements finalized in this final rule resulted in a monetized impact. We then project the impacts forward over the minimum 5-year outlook window, resulting in costs and savings estimates for the period from FYs 2010 through 2015. In Table 4 we estimate a savings to the Federal government of $1.02 billion over FYs 2010 through 2015 as the result of the requirement that certain non-employer and all employer private-fee-for-service plans must establish contracts with providers. We provide a detailed breakdown of these impacts in Table 5. We indicate the total costs and savings incurred by this provision over FYs 2010 through 2015 in Table 3.

2. Prompt Payment Provisions (§ 423.505 and § 423.520)

In our September 18, 2008 IFC, we estimated that the prompt payment provisions contained this final rule would impose significant costs to PDPs, MA–PD plans, and their subcontractors. We estimated the loss of investment income resulting from the prompt payment provisions would increase the costs of the Part D program by $670 million from FY 2010 through FY 2018. In this final rule, we are revising the cost estimates reported in the interim final rule based on new data projections from the CMS Office of the Actuary (OACT). In our September 18, 2008 IFC, we originally assumed that 80 percent of scripts would be electronic and that the clean claim percentage would be 80 percent. However, we now believe that both of these percentages are too low. We have revised the original estimate under the assumption that 99 percent of claims are electronic and that 95 percent of them are clean claims. This modification results in a higher cost estimates that are reflected in Tables 3 and 4. As stated earlier, in this final rule, we are also modifying the window over which we estimate costs and savings to conform to OMB convention for estimating costs and savings in major rulemaking. Based on the revised estimates and impact analysis window, we estimate a total cost of $500 million to PDPs, MA–PD plans, and their subcontractors from FY 2010 through FY 2015.

TABLE 3—ESTIMATED COSTS AND SAVINGS BY PROVISION FOR FISCAL YEARS 2010 THROUGH 2015

[$ In millions]

Provision	Regulation section(s)	Fiscal year						Total (FYs 2010–2015) ($ in millions)
		2010	2011	2012	2013	2014	2015	
Developing SNP Models of Care (MOC)	422.101(f)(1)	0.55	0.46	0.46	0.46	0.46	0.46	2.85
D–SNP Contracting Requirement with States	422.107(a)	0.08	0.08	0.08	0.08	0.08	0.08	0.48
Comprehensive Written Statement Requirement for D–SNPs	422.111(b)(2)	0.11	0.11	0.11	0.11	0.11	0.11	0.66
Non-employer and Employer PFFS Network Requirements	422.114(a) 422.114(b)	−69.92	−159.92	−179.92	−189.92	−199.92	−219.92	−1,019.52
SNP Quality Requirements	422.152(g)	5.57	1.86	1.86	1.86	1.86	1.86	14.87
Training and Testing of Agents and Brokers	422.2274(d) 423.2274(d)	0.03	0.03	0.03	0.03	0.03	0.03	0.21
Prompt payment by prescription drug plans and MA–PD plans under Part D	423.505 423.520	50.0	70.0	80.0	90.0	100.00	110.00	500.00
Total		−13.58	−87.38	−97.38	−97.38	−97.38	−107.38	−500.45

TABLE 4—ESTIMATED COSTS AND SAVINGS TO THE FEDERAL GOVERNMENT FOR FISCAL YEARS 2010 THROUGH 2015

[$ In millions]

Provision	Regulation section(s)	Fiscal year						Total (FYs 2010–2015) ($ in millions)
		2010	2011	2012	2013	2014	2015	
Non-Employer and Employer PFFS Network Requirements	422.114(a) 422.114(b)	−70.00	−160.00	−180.00	−190.00	−200.00	−220.00	−1,020.00
Prompt payment by prescription drug plans and MA–PD plans under Part D	423.505 423.520	50.00	70.00	80.00	90.00	100.00	110.00	500.00
Total		−20.00	−90.00	−100.00	−100.00	−100.00	−110.00	−520.00

TABLE 5—ESTIMATED FEDERAL SAVINGS FOR NON-EMPLOYER AND EMPLOYER PFFS NETWORK REQUIREMENTS FOR FISCAL YEARS 2010 THROUGH 2015

[$ In millions]

	Fiscal year						Total (FYs 2010–2015) ($ in millions)
	2010	2011	2012	2013	2014	2015	
Total HI (Part C & FFS)	40.00	90.0	100.00	110.00	120.00	130.00	590.00
Total SMI (Part C & FFS)	40.00	90.0	100.00	110.00	110.00	120.00	570.00
Total Medicare (without Part B premium offset)	80.00	180.00	200.00	220.00	230.00	250.00	1,160.00
Total Medicare (with Part B premium offset)	70.00	160.00	180.00	190.00	200.00	220.00	1,020.00

TABLE 6—ESTIMATED COSTS TO MA ORGANIZATIONS AND PDP SPONSORS FOR FISCAL YEARS 2010 THROUGH 2015

[$ In millions]

	Regulation section(s)	Fiscal year						Total (FYs 2010–2015) ($ in millions)
		2010	2011	2012	2013	2014	2015	
Developing SNP Models of Care (MOC)	422.101(f)(1)	0.55	0.46	0.46	0.46	0.46	0.46	2.85
D–SNP Contracting Requirement with States	422.107(a)	0.08	0.08	0.08	0.08	0.08	0.08	0.48
Comprehensive Written Statement Requirement for D-SNPs	422.111(b)(2)	0.11	0.11	0.11	0.11	0.11	0.11	0.66
Non-employer and Employer PFFS Network Requirements	422.114(a)(3)	0.03	0.03	0.03	0.03	0.03	0.03	0.48
	422.114(a)(4)	0.05	0.05	0.05	0.05	0.05	0.05	
SNP Quality Requirements	422.152(g)	5.57	1.86	1.86	1.86	1.86	1.86	14.87
Training and Testing of Agents and Brokers	422.2274(d)	0.03	0.03	0.03	0.03	0.03	0.03	0.18
	423.2274(d)	*0.00	*0.00	*0.00	*0.00	*0.00	*0.00	0.02
Total		6.42	2.62	2.62	2.62	2.62	2.62	19.55

*Costs appear as zero due to rounding. CMS estimates actual costs of 0.003 million.

E. Alternatives Considered

The implementation of all of the economically significant provisions of the interim final rule as finalized by this final rule was directly mandated by MIPPA. Therefore, we did not consider alternative proposals for these self-implementing provisions.

F. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/index.html*), in Table 7, we have prepared an accounting statement showing the classification of the expenditures associated with the prompt payment provisions of this final rule and the benefits associated with the PFFS network provisions. This table provides our best estimate of the costs and savings as a result of the changes presented in this interim final rule.

TABLE 7—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers ($ in millions)
Incurred Savings for the Non-Employer and Employer PFFS Network Provision, FYs 2010–2015	
Annualized Monetized Transfers Using 7% Discount Rate	−164.9.
Annualized Monetized Transfers Using 3% Discount Rate	−167.7.
From Whom To Whom?	Federal Government to PFFS Plans.
Prompt payment by prescription drug plans and MA–PD plans under Part D, FYs 2010–2015	
Annualized Monetized Transfers Using 7% Discount Rate	81.1.
Annualized Monetized Transfers Using 3% Discount Rate	82.4.
From Whom To Whom?	Federal Government To Part D Sponsors.
Costs for all other (non-marketing) provisions, FYs 2010–2015	
Annualized Monetized Costs Using 7% Discount Rate	3.0.
Annualized Monetized Costs Using 3% Discount Rate	2.9.
Who is Affected?	MAOs/PDP Sponsors.

V. Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), as modified by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (Pub. L. 104–121), requires agencies to determine whether proposed or final rules would have a significant economic impact on a substantial number of small entities and, if so, to prepare a Regulatory Flexibility Analysis and to identify in the notice of proposed rulemaking or final rulemaking any regulatory options that could mitigate the impact of the proposed regulation on small businesses. For purposes of the RFA, small entities include businesses that are small as determined by size standards issued by the Small Business Administration, nonprofit organizations, and small governmental jurisdictions). Individuals and States are not included in the definition of a small business entity.

The RFA also requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. The Secretary determined that the September 18, 2008 IFC (73 FR 54226–54254) that we are finalizing would have a significant impact on a substantial number of small entities, such as small retail pharmacies and pharmacy benefit managers (PBMs). The cost impacts for these entities result from the prompt payment provision discussed earlier in this document. We provide a detailed analysis of this provision's impact on small entities in the regulatory impact analysis in our September 18, 2008 IFC (73 FR 54226–54254).

In addition, section 1102(b) of the Act requires us to prepare an 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. We are not preparing an analysis for section 1102(b) of the Act because the Secretary has determined this final rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

VI. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately $136 million. This final rule does not mandate any spending by State, local, or Tribal governments, in the aggregate, or by the private sector of $136 million.

VII. Federalism Analysis

Executive Order 13132 on Federalism (August 4, 1999) establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

List of Subjects

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 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, 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 the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 1. The authority citation for part 417 continues to read as follows:

Authority: Sec. 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.

Subpart A—General Provisions

■ 2. Amend § 417.402 by revising the second sentence of paragraph (c)(3) to read as follows:

§ 417.402 Effective date of initial regulations.

* * * * *

(c) * * *

(3) * * *. If the service area includes a portion in more than one MSA with a population of more than 250,000, the minimum enrollment determination is made with respect to each such MSA and counties contiguous to the MSA that are not in another MSA with a population of more than 250,000.

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 3. The authority citation for part 422 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart C—Benefits and Beneficiary Protections

§ 422.101 [Amended]

■ 4. In 422.101, paragraph (f)(1)(ii) is amended by removing the phrase ''indentifying goals'' and adding the phrase ''identifying goals'' in its place.

Subpart V—Medicare Advantage Marketing Requirements

■ 5. Section 422.2268 is amended by revising paragraphs (g) and (h) to read as follows:

§ 422.2268 Standards for MA organization marketing.

* * * * *

(g) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment (48 hours in advance, when practicable).

(h) Market additional health related lines of plan business not identified prior to an individual appointment without a separate scope of appointment identifying the additional lines of business to be discussed.

* * * * *

■ 6. Section 422.2274 is amended by revising paragraphs (a)(1)(ii) introductory text, (a)(1)(ii)(B), (a)(1)(iv), and (a)(4) to read as follows:

§ 422.2274 Broker and agent requirements.

(a) * * *

(1) * * *

(ii) The compensation amount paid to an agent or broker for enrollment of a Medicare beneficiary into an M A plan is as follows:

* * * * *

(B) For renewals, an amount equal to 50 percent of the initial compensation in paragraph (a)(1)(ii)(A) of this section.

* * * * *

(iv) If the MA organization contracts with a third party entity such as a Field Marketing Organization or similar type entity to sell its insurance products, or perform services (for example, training, customer service, or agent recruitment)—

(A) The total amount paid by the MA organization to the third party and its agents for enrollment of a beneficiary into a plan, if any, must be made in accordance with paragraph (a)(1) of this section; and

(B) The amount paid to the third party for services other than selling insurance products, if any, must be fair-market value and must not exceed an amount that is commensurate with the amounts paid by the MA organization to a third party for similar services during each of the previous 2 years.

* * * * *

(4) Compensation may only be paid for the beneficiary's months of enrollment during a plan year (that is, January through December).

(i) Subject to paragraph (a)(4)(ii) of this section, compensation payments may be made up front for the entire current plan year or in installments throughout the year.

(ii) When a beneficiary disenrolls from a plan during the—

(A) First 3 months of enrollment, the plan must recover all compensation paid to agents and brokers.

(B) Fourth through 12th month of their enrollment (within a single plan year), the plan must recover compensation paid to agents and brokers for those months of the plan year for which the beneficiary is not enrolled.

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 7. The authority citation for part 423 continues to read as follows:

Authority: Sec. 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 K—Application Procedures and Contracts With Part D Plan Sponsors

■ 8. Amend § 423.505 by revising paragraph (b)(21) introductory text to read as follows:

§ 423.505 Contract provisions.

* * * * *

(b) * * *

(21) Effective contract year 2009 and subsequent contract years, update any prescription drug pricing standard based on the cost of the drug used for reimbursement of network pharmacies by the Part D sponsor on—

* * * * *

■ 9. Amend § 423.520 by revising paragraphs (c)(2)(ii), (c)(3), and (e)(2) to read as follows:

§ 423.520 Prompt payment by Part D sponsors.

* * * * *

(c) * * *

(2) * * *

(ii) *Determination after submission of additional information.* A claim is deemed to be a clean claim under paragraph (b) of this section if the Part D sponsor that receives the claim does not provide notice to the submitting network pharmacy of any remaining defect or impropriety, or of any new defect or impropriety raised by the additional information, in the claim within 10 days of the date on which additional information is received under paragraph (c)(2)(i) of this section. A Part D sponsor may not provide notice of a new deficiency or impropriety in the claim that could have been identified by the sponsor in the original claim submission under this paragraph.

(3) *Obligation to pay.* A claim submitted to a Part D sponsor that is not paid by the Part D sponsor within the timeframes specified in paragraphs (a)(1)(i) and (ii) or contested by the Part D sponsor within the timeframe specified in paragraph (c)(1)(i) and (ii) of this section must be deemed to be a clean claim and must be paid by the Part D sponsor in accordance with paragraph (a) of this section.

* * * * *

(e) * * *

(2) *Authority not to charge interest.* As CMS determines, a Part D sponsor is not charged interest under paragraph (e)(1) in exigent circumstances that prevent the timely processing of claims, including natural disasters and other unique and unexpected events.

* * * * *

Subpart V—Part D Marketing Requirements

■ 10. Section 423.2268 is amended by revising paragraphs (g) and (h) to read as follows:

§ 423.2268 Standards for Part D marketing.

* * * * *

(g) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment (48 hours in advance, when practicable).

(h) Market additional health related lines of plan business not identified prior to an individual appointment without a separate scope of appointment identifying the additional lines of business to be discussed.

* * * * *

■ 11. Section 423.2774 is amended by revising paragraphs (a)(1)(ii) introductory text, (a)(1)(ii)(B), (a)(1)(iv), and (a)(4) to read as follows:

§ 423.2274 Broker and agent requirements.

* * * * *

(a) * * *

(1) * * *

(ii) The compensation amount paid to an agent or broker for enrollment of a Medicare beneficiary into a PDP is as follows:

* * * * *

(B) For renewals, an amount equal to 50 percent of the initial compensation in paragraph (a)(1)(ii)(A) of this section.

* * * * *

(iv) If the Part D sponsor contracts with a third party entity such as a Field Marketing Organization or similar type entity to sell its insurance products or perform services (for example, training, customer service, or agent recruitment)—

(A) The total amount paid by the Part D sponsor to the third party and its agents for enrollment of a beneficiary into a plan, if any, must be made in accordance with paragraph (a)(1) of this section; and

(B) The amount paid to the third party for services other than selling insurance products, if any, must be fair-market value and must not exceed an amount that is commensurate with the amounts paid by the Part D sponsor to a third party for similar services during each of the previous 2 years.

* * * * *

(4) Compensation may only be paid for the beneficiary's months of enrollment during a plan year (that is, January through December).

(i) Subject to paragraph (a)(4)(ii) of this section, compensation payments may be made up front for the entire current plan year or in installments throughout the year.

(ii) When a beneficiary disenrolls from a plan during the—

(A) First 3 months of enrollment, the plan must recover all compensation paid to agents and brokers.

(B) Fourth through 12th month of their enrollment (within a single plan year), the plan must recover compensation paid to agents and brokers for those months of the plan year for which the beneficiary is not enrolled.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: May 5, 2011.

Marilyn Tavenner,

Principal Deputy Administrator and Chief Operating Officer, Centers for Medicare & Medicaid Services.

Approved: August 12, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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