DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 447 and 457

[CMS–2244–F]

RIN 0938–A047

Medicaid Program; Premiums and Cost Sharing

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

ACTION: Final rule.

SUMMARY: This final rule implements and interprets the provisions of sections 6041, 6042, and 6043 of the Deficit Reduction Act of 2005 (DRA), and section 405(a)(1) of the Tax Relief and Health Care Act of 2006 (TRHCA). The DRA was amended by the TRHCA which revised sections 6041, 6042, and 6043 of the DRA including limitations on cost sharing for individuals with family incomes at or below 100 percent of the federal poverty line. These sections amended the Social Security Act (the Act) by adding a new section 1916A to provide State Medicaid agencies with increased flexibility to impose premium and cost sharing requirements on certain Medicaid recipients. This flexibility supplements the existing authority States have to impose premiums and cost sharing under section 1916 of the Act. The DRA provisions also specifically address cost sharing for non-preferred drugs and non-emergency care furnished in a hospital emergency department.

DATES: *Effective Date:* These regulations are effective 60 days after the date of publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Donna Schmidt, (410) 786–5532.

SUPPLEMENTARY INFORMATION:

I. Background

A. General

For more than a decade, States have been asking for the tools to modernize their Medicaid programs. With the enactment of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171, enacted on February 8, 2006), States now have new options to create programs that are aligned with today's Medicaid populations and the health care environment. The alternative cost sharing discussed in this issuance is one part of that modernization; other parts include benefit flexibility through benchmark plans, and the health opportunity accounts (HOA) demonstration projects. Together, these innovations provide the opportunities for States to modernize Medicaid by expanding coverage, making the overall cost of the program and health care more affordable, and providing a bridge to private insurance coverage. States will be able to reconnect families to the larger insurance system that serves most Americans and promote continuity of coverage. The sweeping DRA provisions on Medicaid include six chapters and 39 sections. Through a combination of new options for States and new requirements related to program integrity, the DRA will help to ensure the sustainability of the Medicaid program over time.

B. Statutory Authority

Sections 6041, 6042, and 6043 of the DRA established a new section 1916A of the Social Security Act (the Act), which was amended by section 405(a)(1) of the Tax Relief and Health Care Act of 2006 (TRHCA) (Pub. L. No. 109–432, enacted on December 20, 2006). Section 1916A of the Act sets forth options for alternative premiums and cost sharing, including options for higher cost sharing for non-preferred prescription drugs and for non-emergency use of a hospital emergency room.

Section 6041 of the DRA established new subsections 1916A(a) and (b) of the Act, which allow States to amend their State plans to impose alternative premiums and cost sharing on certain groups of individuals, for items and services other than drugs (which are subject to a separate provision discussed below), and to enforce payment of the premiums and cost sharing. Subsections 1916A(a) and (b) of the Act set forth limitations on alternative premiums and cost-sharing that vary based on family income, and exclude some specific services from alternative cost sharing. Section 6041 of the DRA also created a new section 1916(h) of the Act, which requires the Secretary to increase the ''nominal'' cost sharing amounts under section 1916 of the Act for each year (beginning with 2006) by the annual percentage increase in the medical care component of the consumer price index for all urban consumers (CPI–U) as rounded up in an appropriate manner. Section 405(a)(1) of the TRHCA modified subsections 1916A(a) and (b) of the Act.

Section 6042 of the DRA created section 1916A(c) of the Act, which provides States with additional options for establishing cost sharing requirements for drugs to encourage the use of preferred drugs. Section 405(a)(1) of the TRHCA also modified section 1916A(c) of the Act. Under section 1916A(c) of the Act, States may amend their State plans to require increased cost sharing by certain groups of individuals for non-preferred drugs and to waive or reduce the otherwise applicable cost sharing for preferred drugs. States may also permit pharmacy providers to require the receipt of a cost sharing payment from an individual before filling a prescription.

Section 6043 of the DRA created section 1916A(e) of the Act, which permits States to amend their State plans to allow hospitals, after an appropriate medical screening examination under section 1867 (EMTALA) of the Act, to impose higher cost sharing upon certain groups of individuals for non-emergency care or services furnished in a hospital emergency department. Section 405(a)(1) of the TRHCA modified section 1916A(e) of the Act. Under this option, if the hospital determines that an individual does not have an emergency medical condition, before providing the non-emergency services and imposing cost sharing, it must inform the individual that an available and accessible alternate non-emergency services provider can provide the services without the imposition of the same cost sharing and that the hospital can coordinate a referral to that provider. After notice is given, the hospital may require payment of the cost sharing before providing the non-emergency services to the individual.

II. Provisions of the Proposed Rule and Analysis of and Response to Public Comments

We published a proposed rule in the **Federal Register** on February 22, 2008 (73 FR 9727) that proposed to implement sections 6041, 6042, and 6043 of the DRA. In response to the proposed rule, we received approximately 50 timely items of correspondence. Many of the commenters represented State and local advocacy groups, national associations that represent various aspects of beneficiary groups, physician and provider groups, medical associations and hospitals, and State Medicaid agency senior officials. The remaining comments were from individuals and human services agencies.

A. Public Comment Process

On February 22, 2008, the date we published the Premiums and Cost Sharing proposed rule, we also published a proposed rule entitled, ''State Flexibility for Medicaid Benefit Packages'' (73 FR 9714 through 9727) that proposed to implement provisions of the DRA. The comment period for

both proposed rules closed on the same day and commenters submitted comments on both the State Flexibility for Medicaid Benefit Packages proposed rule, and Premiums and Cost Sharing (73 FR 9727 through 9740) proposed rule. To the extent that the comments relate to Premiums and Cost Sharing, we believe that the concerns expressed by commenters are addressed in the comments and responses presented below. We note that we will address comments related to the State Flexibility for Medicaid Benefit Packages proposed rule (73 FR 9714 through 9727) in a subsequent final rule.

In this section, we briefly describe our proposed regulatory changes, followed by a discussion of the comments we received on each proposal. Comments related to the paperwork and other burdens are addressed in the Collection of Information Requirements section in this preamble.

B. Medicaid Regulations

1. Maximum Allowable and Nominal Charges (§ 447.54)

We proposed to revise § 447.54 to update the existing ''nominal'' Medicaid cost sharing amounts, specifically the nominal deductible amount described at § 447.54(a)(1) and the nominal copayment amounts described at § 447.54(a)(3). We also proposed to add a new § 447.54(a)(4) to establish a maximum copayment amount for services provided by a managed care organization (MCO).

Section 6041(b)(2) of the DRA requires the Secretary to increase the nominal cost sharing amounts under section 1916 of the Act for each year (beginning with 2006) by the annual percentage increase in the medical care component of the consumer price index for all urban consumers (U.S. city average) as rounded up in an appropriate manner. In accordance with the statute, we proposed to increase the nominal amounts effective as of October 1 of each year, the beginning of the Federal fiscal year (FY), by the percentage increase in the medical care component of the Consumer Price Index for All Urban Consumers (CPI–U) for the period of September to September ending in the preceding calendar year. We use this period to update other amounts, such as the Medicaid spousal impoverishment standards, by inflation. The first adjustment would be for FY 2007, and would be based on the CPI–U increases during the period September 2004 to September 2005. The medical care component of the CPI–U increased by 3.9 percent between September 2004 and September 2005; therefore, we proposed to update the nominal amounts by that factor. We also proposed to round to the next higher 10-cent increment because it would simplify calculation and collection of the amounts involved. Based on this methodology, we proposed a maximum deductible for $2.10 per month per family for each period of Medicaid eligibility. In addition, we proposed the following copayment schedule for FY 2007:

State payment for the service	Maximum copayment
$10 or less	$.60
$10.01 to $25	1.10
$25.01 to $50	2.10
$50.01 or more	3.20

We proposed that these amounts would be updated each October 1 by the percentage increase in the medical care component of the CPI–U for the period of September to September ending in the preceding year, rounded to the next higher 10-cent increment.

In addition, we proposed at 447.54(a)(4) to specify a maximum copayment amount for services provided by an MCO. When we published the final Medicaid managed care rules on June 14, 2002 (67 FR 40989), we also required at § 447.60, that contracts with MCOs limit cost sharing charges an MCO may impose on Medicaid enrollees to the amounts that could be imposed if fee-for-service payment rates were applicable.

Specific comments to this section and our responses to those comments are as follows:

Comment: One commenter stated that the matrix of cost sharing requirements and exemptions established under the proposed rule is complex and the commenter requested a chart for clarification.

Response: We agree with the commenter that the cost sharing matrix established under the proposed rule is complex. We believe it is sufficiently clear to establish a Federal framework defining the State flexibility available. Actual cost sharing will be specified in State plans and may vary based on circumstances. We expect States to clearly communicate applicable cost sharing responsibilities to affected beneficiaries in simple and understandable terms, consistent with the requirement in 42 CFR 435.905. We included in the proposed rule information for FY 2007: A chart of updated maximum levels for cost sharing, the maximum deductible level, and a chart of maximum allowable charges. The amounts for Federal FY 2008 increase by the percentage increase in the MCPI–U from September 2005 to September 2006 of 4.2 percent, and, as we discuss below, we are including the FY 2008 updated levels in this final rule. Since we are currently in Federal FY 2009, we are also including the FY 2009 updated levels. The amount for Federal FY 2009 increased by the percentage increase in the MCPI–U from September 2006–2007 is 4.6 percent.

Additionally, we set forth in other regulatory provisions the limitations that apply to alternative cost sharing under section 1916A of the Act that apply based on income level. We discuss these limitations in § 447.70 of this final rule—General Cost Sharing Protections.

Comment: Several commenters stated that the proposed rule did not give effect to the statutory provisions for lower cost sharing (10 percent of the cost of the service) for those with family incomes above 100 percent of the Federal poverty but below 150 percent of the FPL than for those with family incomes over 150 percent (20 percent of the cost of the service) in fee-for-service plans by varying the maximum copayment by income and setting lower managed care maximum copayments for those with lower incomes. Commenters believe this would be more consistent with Congressional intent.

Response: The statute provides for variance of copayments by income level only when alternative copayments are imposed. The provision at § 447.54 in this final rule defines nominal levels under section 1916 of the Act. In section 1916A of the Act, the income related limitations apply to alternative cost sharing in addition to the definition of nominal levels, and are set forth in the regulations that directly apply to alternative cost sharing at §§ 447.62 through 447.82.

Comment: Several commenters stated that clarification is needed on whether the ''per visit'' qualification on the MCO maximum co-payment restricts charging of co-payments by the MCO.

Response: We have not defined what constitutes a ''visit'' in a managed care context because we wish to maintain State flexibility. However, we agree that it would be problematic if an MCO was generating excess ''visits'' for the purpose of extracting extra co-payments. We believe that States should not permit MCOs to impose more than one co-payment for any service or services that could be furnished by a provider during one office visit, even if it actually delivered in multiple office visits.

Comment: Some commenters stated that CMS should annually publish a notice in the **Federal Register** of the maximum cost sharing amounts by

March 31 for the upcoming Federal FY. Other commenters stated that there is no statutory basis for imposing this cost sharing.

Response: We will publish annually the updated amounts, increased based on the medical care component of the consumer price index for urban consumers. We cannot commit to publication on or by March 31, since publication will be dependent on the availability of data. We may publish before or after that time, but will seek to give sufficient advance notice to facilitate timely adjustment of State cost sharing levels. Since the update methodology is detailed in the published rule and does not involve discretionary elements, the implementation of updated maximum levels should not depend upon CMS publication of specific figures. Nevertheless, we intend to publish updates either in the **Federal Register** or in some other form that ensures general availability. We do not wish to limit publication options in light of the increasing shift toward electronic media.

To respond to the commenters concerning the statutory basis for imposing this cost sharing, as stated earlier, this final rule implements sections 6041 through 6043 of the DRA of 2005, which amended the Social Security Act to add section 1916A. The authority to set nominal levels for cost sharing is contained in sections 1916(a)(3) and (b)(3) of the Social Security Act, and the authority to update those amounts annually is section 6041(b)(2) of the DRA, which added section 1916A(h) to the Social Security Act. We established the MCO nominal cost sharing levels based on these same authorities. The MCO nominal cost sharing levels are consistent with the longstanding levels for fee for service nominal cost sharing, and clarify how nominal levels are applied in a managed care context. The MCO nominal cost sharing levels are updated annually in the same manner as are fee-for-service nominal cost sharing levels.

Comment: Several commenters believe that the proposed methodology to update the nominal cost sharing amounts would round up the amounts at a faster rate than Congress intended. Specifically, several individuals asserted that, under the proposed methodology, each year's new maximum co-payment amount would be calculated by applying the annual inflation adjustment to the previous year's cost sharing limit after it was rounded up. The new maximum would be higher than warranted if the inflation adjustment had been applied without the rounding increase. As a result, this would increase the nominal cost sharing limits at a rate faster than Congress intended.

Response: We agree that to calculate each subsequent year's new maximum co-payment amount by applying the annual inflation adjustment to the previous year's cost sharing limit after it was rounded up would increase the nominal cost sharing limits at a rate faster than Congress intended. To round up the nominal Medicaid and SCHIP amounts based on the ''rounded'' values would provide that the nominal amounts would grow larger over time, thus, making the nominal Medicaid and SCHIP co-payments charged by States increasingly onerous for the poorest beneficiaries.

We clarify that it was always our intent that, for the purpose of increasing the nominal cost sharing for a future FY, we would increase the unrounded values underlying the previous FY's nominal amounts by the percentage increase in the MCPI–U for the 12-month period ending in September of the preceding calendar year.

Comment: Commenters stated that the impact is exacerbated by the decision to also round up by a 10-cent increment rather than a 5-cent increment. The commenters noted that the DRA does not specify a rounding methodology, and pointed out that a 5-cent increment is used in the Medicare Part D program. They also questioned whether a 5-cent increment would be harder to collect and calculate, and asserted that consistency with Medicare would be simpler for both providers and for beneficiaries enrolled in both programs.

Response: We agree with the commenters, and in this final rule, we provide that in calculating maximum nominal amounts for Medicaid and SCHIP, we will update the amounts by the annual percentage increase in the MCPI-U and round up to the next 5-cent increment. As discussed above, we will calculate the update each year without considering any rounding adjustment made in the previous year. The revised chart for FY 2007 would therefore read as follows:

State payment for the service	Maximum copayment
$10 or less	$ 0.55
$10.01 to $25	1.05
$25.01 to $50	2.10
$50.01 or more	3.15

The amounts for Federal FY 2008 reflect an increase in the FY 2007 levels set forth above based on the percentage increase in the MCPI–U from September 2005 to September 2006 of 4.2 percent, rounded up to the next highest 5-cent increment. The chart for Federal FY 2008 reads as follows:

State payment for the service	Maximum copayment
$10 or less	$ 0.55
$10.01 to $25	1.10
$25.01 to $50	2.20
$50.01 or more	3.25

In this final rule at 42 CFR 447.54 we are including the chart for FY 2009, since it will provide more immediate useful information for States.

Comment: One commenter questioned if the requirement to increase the nominal cost sharing amounts annually also requires the State to adjust its amounts annually.

Response: There is no requirement under Medicaid that States impose the maximum level of cost sharing. If the maximum nominal cost sharing levels increase as a result of updating, a State may nevertheless maintain a lower cost sharing level.

Comment: Several individuals were concerned about the proposed $5.20 per visit maximum cost-sharing for Medicaid services provided by a MCO, stating that it could significantly increase the burden on Medicaid beneficiaries because it would permit imposition of the maximum cost sharing level regardless of the cost of the services provided. These commenters stated that beneficiaries with family incomes below the poverty line should not be subject to the new $5.20 co-payment.

Response: In proposing a maximum managed care co-payment under the Medicaid program, we looked to the SCHIP program for guidance. Under SCHIP rules at § 457.555, promulgated in 2001, we established a maximum per visit copayment level for managed care services at the highest level for fee-for-service cost sharing under SCHIP, instead of applying the same copayment limitations applicable to services received on a fee-for-service basis. Based on that precedent, we proposed a similar structure in Medicaid to effectively replace limitations on managed care cost sharing that were tied to the same limitations as fee-for-service copayments. Instead of reflecting the proposed maximum Medicaid fee-for-service co-payment level of $3.20 (consistent with § 447.54(a)(3)(i)), we proposed a maximum level per visit at the maximum SCHIP fee-for-service level at $5.20.

Our reasoning in both SCHIP and Medicaid is related to the different way services are delivered under managed

care. We believe that managed care services are typically less fragmented than services furnished on a fee-for-service basis, and, for virtually all services for which managed care entities charge cost sharing (for example, physician visits), the cost sharing would be at the maximum level. We also considered reducing the burden on managed care entities of justifying each individual cost sharing charge based on a comparison to fee-for-service levels when, in many States, there is no comparable fee-for-service program.

After consideration of public comments, we have determined to alter our approach. In this final rule, the maximum MCO per visit rate would apply only when there is no comparable fee-for-service delivery system. When there is a comparable fee-for-service delivery system, managed care copayments must follow the same limitations applicable to fee-for-service. Because it is important to align Medicaid and SCHIP, so that States can provide benefits seamlessly under either program to individuals referenced in the title XXI State child health plan, we include an exception applicable only to such individuals. For these individuals, the maximum MCO copayment level will be the same level permitted under the SCHIP program. The higher nominal levels permitted for individuals referenced in the title XXI State child health plan is consistent with the fact that such individuals would not be Medicaid-eligible except for the SCHIP-related expansion of Medicaid.

Therefore, this final rule provides for a managed care maximum copayment based on the applicable Medicaid fee-for-service maximum rate or, where there is no fee-for-service delivery system, at a per-visit maximum based on the highest fee-for-service level of $3.15 in FY 2007, $3.25 in FY 2008, and $3.40 in FY 2009. In addition, in this final rule, we provide for a specific exception to permit alignment with SCHIP levels for individuals in a Medicaid expansion referenced in the approved State child health plan, so that the maximum copayment level would be the maximum under the SCHIP program, which for FY 2007 is $5.20, for FY 2008 is $5.45, and for FY 2009 is $5.70.

States that impose alternate cost sharing under 1916A of the Act, as implemented by this rule, are still required to comply with the other requirements under 1916A of the Act, such as the limits on cost sharing for populations under 100 percent of the FPL, and the aggregate maximum and the individual service limits.

2. Alternative Premiums and Cost Sharing: Basis, Purpose and Scope (§ 447.62)

Section 1916A of the Act allows States to impose alternative premiums and cost sharing that are not subject to the limitations on premiums and cost sharing under section 1916 of the Act. Section 1916A of the Act does not affect the Secretary's existing waiver authority with regard to premiums and cost sharing. Section 447.62 of the regulations as stated in this final rule briefly describes this statutory provision which is the basis for §§ 447.64 through 447.82.

Section 447.62 also makes clear, as specified in section 1916A(b)(6) of the Act, that these regulations do not limit the Secretary's waiver authority, or affect existing waivers, concerning premiums or cost sharing.

Section 405(a)(1) of the TRHCA amended section 1916A of the Act by explicitly providing certain exemptions from certain alternative cost sharing provisions for the population with family incomes at or below 100 percent of the FPL. The statute also includes protections for individuals with family incomes between 100 and 150 percent of the FPL and individuals with family incomes above 150 percent of the FPL. CMS proposed to implement the protections outlined in the TRHCA including the imposition of nominal cost sharing for individuals with family income at or below 100 percent of the FPL.

Specific comments on this section and our responses to those comments are as follows:

Comment: Several commenters supported the proposed regulation. They believe that permitting cost sharing under an approved State plan provides States with increased flexibility, provides for States to better meet the health care needs of Medicaid enrollees, and provides States with the ability to contain the growth in the program. The commenters believe that the flexibilities approved in the DRA may lead to cost efficiencies over time; however, they also stated these flexibilities cannot, nor were they intended to, address broader economic downturns.

Response: We agree with the commenters that alternative premiums and cost sharing can lead to cost-efficiencies and that these provisions can be used to sustain State Medicaid programs. If States submit State plan amendments to implement the flexibility outlined in the DRA to impose alternative premiums and cost sharing, we anticipate that Federal and State savings will be generated. The projected savings can be found in the Regulatory Impact Analysis section of this final rule and include savings through 2011. These savings are based on only those States that currently charge co-payments and/or premiums. If additional States choose to implement these flexibilities, these savings could be even more. Although CMS is not in a position to address future economic downturns, we do believe that savings can be generated beyond 2011 and that savings can be generated for more States if additional States choose to implement these provisions. We encourage States to consider these flexibilities and the potential savings that can be generated to help with a State's economic concerns.

Comment: Other commenters believe these provisions will have negative consequences for beneficiaries and will cause individuals to delay or forgo needed care. These commenters requested that the regulation be withdrawn.

Response: While it is possible that some individuals may choose to delay or forgo care rather than pay their cost sharing obligations, the Medicaid statute has been amended to permit State flexibility to impose cost sharing as outlined in this regulation. Because the rule implements these statutory provisions, withdrawal of the rule is not an option consistent with administration of the statutory Medicaid program. Moreover, we disagree with the commenter's suggestion that the impact of the rule will be wholly negative. States requested maximum flexibility in designing their Medicaid programs in order to expand and maintain health care coverage to our nation's most vulnerable populations and to maintain growth and control costs of Medicaid and SCHIP programs over the long term. This flexibility will help protect the program from cutbacks in a time of tight State budgets, and permit program expansion. Any adverse impact is mitigated by the fact that Congress has protected numerous Medicaid eligibility groups and services from the imposition of alternative premiums and cost sharing.

Comment: One commenter believes that States should carefully evaluate their health care resources in order to identify and remedy problems with access to alternative care options for Medicaid recipients before imposing co-payments for non-emergency care furnished by emergency rooms. The commenter believes that CMS should undertake a national initiative to identify creative solutions to the lack of accessible routine medical services for

the poor. CMS should make a commitment by revising the rules of the DRA to protect the lives of some of our most vulnerable citizens.

The commenter states that CMS should carefully monitor and evaluate the impact of the new Medicaid policies being rolled out so that the impact on cost and services can be analyzed and used for future policy-making.

Response: We believe that States are in the best position to evaluate their health care resources in order to identify and remedy problems with access to alternative care options for Medicaid recipients before imposing co-payments for non-emergency care furnished by emergency rooms.

As for future policy-making and conducting a national initiative to identify creative solutions to the lack of accessible routine medical services for the poor, Section 6043 of the DRA of 2005 provides for $50 million in grant funding to States to provide for the establishment of alternative non-emergency service providers or networks of such providers to address primary care access. CMS recently awarded the grant funding to 20 States to help in addressing this issue. State programs include providing education to beneficiaries on the benefits of a medical home, establishment of additional Federally qualified health centers in the State to provide for additional primary care access for beneficiaries, and extending the hours of operation of currently established Federally qualified health centers to include evenings and weekends when Medicaid beneficiaries are more prone to presenting in the emergency room with a non-emergent condition.

We are always interested in working with States on initiatives to improve the delivery of services under the Medicaid program and better provide health care services to our nation's low-income populations. We have approved a number of demonstration projects under the authority of section 1115 of the Social Security Act for this purpose. In addition, we have worked with States to improve access to care through flexibility in payment methods.

Comment: One commenter believes that a thorough analysis of the actual impact of cost sharing on Medicaid recipients and State revenues should be conducted before adoption of this rule.

Response: This rule incorporates options for States that are contained in statutory provisions currently in effect. There is no basis to unduly delay issuance of this rule which could provide guidance on implementing these statutory provisions. Moreover, while we can make some estimates as to the impact, those estimates are speculative. We are required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)) to conduct a regulatory analysis of the impact of any regulatory revision to the Medicare, Medicaid, and/or SCHIP programs before adoption of any rule. We direct the commenter to the Regulatory Impact Analysis included in this rule. Specifically, we estimate that this rule is ''economically significant.'' The Regulatory Impact Analysis presents the estimated costs and benefits of the rulemaking. In the Regulatory Impact Analysis, CMS estimates the anticipated effects of this rule.

Comment: Several commenters stated that the specifics of the statutory language have provided fairly narrow opportunities for implementing many of the new provisions. That is, many high cost populations are excluded from the flexible provisions, and the greatest flexibility is often targeted to higher income populations, which do not make up the bulk of Medicaid consumers in most States.

Response: We agree. This rule provides some operational guidance in implementing the statutory provisions, but those provisions established a relatively comprehensive framework for State flexibility in premiums and cost sharing.

Comment: One commenter indicated the belief that cost sharing, while one of several avenues provided to modernize Medicaid, can be used by the States in conjunction with other alternatives, such as flexibility in benefit packages, to be more cost effective. The commenter also recommended that this rule be revised to ensure that State election of alternative cost sharing would be cost-effective by itself.

Response: We wish to clarify that Medicaid modernization options, such as alternative premiums and cost sharing, can be used separately, and do not have to be used jointly with benefit flexibility. States are in the best position to determine whether alternative cost sharing would be cost effective and whether it is appropriate to provide for alternative cost sharing in modernizing their Medicaid and SCHIP programs.

Comment: Several commenters stated that imposing premiums and cost sharing on Medicaid services acts as a deterrent to individuals receiving care, including children. The commenters stated that imposing premiums and cost sharing could lead to higher costs overall, poorer health outcomes for beneficiaries, barriers to access and care, shifts in costs to providers, and higher rates of uninsured.

In addition, commenters stated that individuals with low incomes will be faced with unreasonable financial burdens and are likely to forgo needed treatment. Several commenters stated that our most vulnerable populations, those with chronic medical needs and those below the poverty line, will be required to choose to provide for their basic needs like food and shelter rather than obtain necessary medical health care because of the rigor created by following a private health insurance model of premiums and co-pays.

Commenters also stated that people with very low incomes will be required to pay more for their care. The commenters are concerned that individuals will be unable to pay premiums to enroll in Medicaid coverage, or that providers will deny necessary care to those who cannot afford to pay cost sharing. The commenters stated that this situation will invariably lead to increases in emergency room visits and hospitals, and should not be allowed within a program created to serve our country's neediest residents. The commenters also stated that any cost savings are outweighed because people who go without needed care will eventually present in the emergency room with complicated, costly conditions that could have been prevented with earlier medical attention.

Several commenters also stated that any new premiums and cost sharing imposed on Medicaid recipients would result in negative consequences for the recipients who are the poorest individuals and families in this country, the providers of Medicaid services, and the Medicaid program. Cost sharing results in insurance coverage for fewer needy individuals and families. Further, the failure by Medicaid recipients to access care and prescription drugs in the community due to their inability to afford deductibles and co-payments could result in serious health problems and the need for costlier services (for example, hospitalization). The commenters further stated that, in turn, this could result in eventual higher expenditures by Medicaid and, for dually eligible individuals, by Medicare.

Some commenters stated that other costs, which are more difficult to quantify, for example, school absences for children and missed work for parents when children are sick as well

as the adverse consequences of delayed treatment are also likely.

Response: We acknowledge the commenters' concerns that the imposition of premiums and cost sharing can lead to individuals delaying or forgoing care and to higher costs in the long-term if individuals delay care and therefore, become sicker and costlier to treat. We assume that Congress considered these concerns when it passed the statutory provisions for alternative premiums and cost sharing at State option. Indeed, the statute seems to indicate these considerations when it provides protections for certain populations and income groups.

The statutory framework appears to reflect the principle that States are in the best position to weigh the commenters' concerns and determine the appropriate levels and scope of alternative cost sharing. States have the statutory authority and option to impose lower cost sharing than the maximum levels permitted, or to exempt additional classes of individuals or additional items or services from cost sharing.

In section V of this final rule, we recognized, among other possibilities, that increased cost sharing could result in declines in utilization as some enrollees subject to new cost sharing requirements choose to decrease their use of services.

Comment: Several commenters stated that the cost sharing proposed rule would have a negative impact on community-based services. These individuals receiving community-based services require a multitude of services, including frequent physician visits, laboratory testing on a regular basis, medical equipment and supplies, and numerous prescription drugs in addition to their home health services. Although cost sharing for services would be limited to 5 percent of total family income, these individuals are disproportionately affected by the cost sharing and have other costs associated with their illness that are not reflected in Medicaid covered services. For example, many are prescribed special diets that carry with them higher food costs. Another example is the additional expenses they must incur for transportation to medical appointments. Elderly and severely disabled individuals with bowel and bladder problems require incontinence products that are not covered by Medicare or many Medicaid programs.

Response: As indicated in the last response, the statutory framework appears to reflect the principle that States are in the best position to weigh the commenters' concerns and determine the appropriate levels and scope of alternative cost sharing. For community-based services, States have the option to impose lower cost sharing than the maximum levels permitted, or to exempt additional classes of individuals or additional items or services from alternative premiums or cost sharing.

Comment: Some commenters stated that dual eligible consumers should be exempt from premium and cost sharing requirements. Without excluding dual eligible consumers from the premium protected lists, the commenters indicated that barriers to care would be established.

Response: Dual eligible individuals (individuals eligible for both Medicare and Medicaid) are not a group specifically exempted by statute from alternative cost sharing. If States determine that this group should be exempted or protected from alternative premiums or cost sharing, States have the authority and the option to impose lower cost sharing than the maximum levels permitted, or to exempt the class of individuals from alternative premiums or cost sharing.

Comment: Many commenters stated that each of these areas of the proposed rule has the potential to become the behavioral healthcare Medicaid Trojan horse: It appears harmless but it will reverse hard-fought progress won over years of struggle that brought about equitable, decent care for Medicaid recipients experiencing mental illness or who have a developmental disability. They fear that these rules will have costlier results—and not the desired economizing—while also negatively impacting peoples' lives, their well-being and care, and our society.

Response: These concerns should be raised with States for consideration in designing their programs. If States determine that a group should be exempted or protected from alternative premiums or services exempted from cost sharing requirements, States have the option to impose lower cost sharing than the maximum levels permitted, or to exempt a class of individuals from alternative premiums or cost sharing.

Comment: One commenter stated that health centers such as Federally Qualified Health Centers (FQHCs) or other health care centers (that is, title X family planning clinics) are statutorily required to care for patients who visit the health center regardless of their ability to pay. In addition, the commenter stated that any decrease in Medicaid coverage only results in increasing health centers' already growing population of uninsured. The commenter indicated that cost sharing should not apply to FQHC services or other health care centers (that is, title X family planning clinics) and should not affect health center reimbursements or their ability to provide quality care to their patients.

Response: We note that this is a concern that should be raised with States. The Federal statute does not provide for any specific treatment of these health centers or their patients.

Comment: One commenter stated that the proposed rule read together with other CMS rules (for example, the citizenship documentation requirement and the State Health Officials of August 17, 2007) create major barriers to access to health care. In addition, the commenter stated that the proposed rule has a devastating impact on the low income population who cannot afford cost sharing.

Response: The citizenship and documentation requirements are part of the DRA but are not part of this rule. The August 17 State Health Officials letter is also not part of this rule.

Comment: Many commenters stated that providing for new or increased cost sharing was a bad policy. They referred to the Congressional Budget Office analysis indicating that some 13 million people—a third of them children who could face new or increased cost sharing over the first 10 years the provision is in effect—and that 80 percent of the savings expected to result from the new cost sharing would be due to decreased use of services and/or because individuals are unable to pay the new premiums. In that analysis, some who were expected to lose coverage are children.

Several commenters refer to recent experience with section 1115 Medicaid waivers and the finding that premiums and cost sharing can create barriers to obtaining or maintaining coverage, increase the number of uninsured, reduce use of essential services, and increase financial strains on families who already devote a significant share of their incomes to out of pocket medical expenses. Some commenters cited studies that show that health insurance participation steadily declines when premiums are imposed, particularly at low levels of income and providers often faced additional administrative burdens related to attempts to collect co-payments and a reduction in payment levels if they were unable to do so.

Response: We assume that Congress considered these concerns when it passed the statutory provisions for alternative premiums and cost sharing at State option. The materials cited by

the commenters were available to Congress at the time. Indeed, the statute appears to reflect such consideration when it provides specific protections for certain populations and income groups.

The statutory framework appears to reflect the principle that States are in the best position to weigh the commenters' concerns and determine the appropriate levels and scope of alternative cost sharing. States have the discretion under the statute and the option to impose lower cost sharing than the maximum levels permitted, or to exempt additional classes of individuals and/or additional items or services from cost sharing.

Comment: Several commenters stated that the accelerated pace of this short comment period, given the broad implications, would lead to a short-sighted, onerous rule that has dangerous health impacts for the poor. The commenters stated that this proposed rule was published in the **Federal Register** on February 22, 2008 and the deadline for submission of comments was March 24, 2008. The commenter indicated that other rulemaking has taken a longer period and that given the impact of the discussion in this rule, a longer comment period is warranted.

Response: We disagree with the commenters suggesting that 30 days is too short of a time period to respond to the regulation. Neither section 553(c) of the Administrative Procedures Act nor the Social Security Act specify a time period for submission of comments. (While section 1871(b) of the Act requires a 60-day comment period for Medicare proposed rules, there is no specified time period for Medicaid rules.) Thus, for Medicaid rules, we allow 30 days or 60 days based on the complexity and size of the rule, or the need to publish the final rule quickly. Since the statute was fairly prescriptive and the proposed rule contains little policy interpretation, we have chosen a 30-day comment period in the interest of quickly getting guidance to States on the DRA flexibilities contained herein. Moreover, none of the commenters identified any specific inability to effectively comment on the proposed rule in the 30-day time period.

Comment: Several comments were provided by organizations that have an interest in how the premiums and cost sharing impact American Indians and Alaskan Natives (AI/ANs). They believe they are like other low-income groups; cost sharing requirements serve as a substantial barrier to AI/AN enrollment in the Medicaid program. Because of the Federal government's trust responsibility to provide health care to AI/ANs, cost sharing requirements have specific tribal implications that have not been addressed in this rule.

Several commenters believe that the imposition by States of cost sharing requirements on Medicaid beneficiaries would have serious adverse consequences on Indian Health Service and tribally operated health programs in at least three ways: (1) An AI/AN beneficiary who is eligible to enroll in Medicaid may be dissuaded from doing so where a cost is imposed on him or her for such enrollment; (2) the Indian Health Service or tribal operated health program who services an AI/AN patient would lose Medicaid reimbursement for that patient; and (3) even if the eligible AI/AN does enroll in Medicaid, the Indian Health Service or tribally operated health program would have to use scarce IHS-appropriated funds to pay the cost share amount.

Response: We recognize that AI/ANs may have special concerns because of their eligibility for services through the Indian Health Service (IHS) or tribal health programs without charge. In addition, IHS and tribal providers may have special concerns. Nevertheless, the statute does not provide for special treatment of this group and these concerns should be raised to States for consideration in designing their programs. We encourage States to consider these issues fully when they design their programs.

Comment: Several commenters believe that AI/ANs should be exempt from premiums and cost sharing requirements entirely.

Response: We are not aware of any provision in the Medicaid statute that authorizes CMS to adopt a position providing for special treatment of AI/AN individuals. In contrast, section 2103(b)(3)(D) of the SCHIP statute provides for special treatment of such individuals, when it requires procedures to ensure that AI/AN targeted low-income children receive child health assistance. We have interpreted that SCHIP requirement to authorize the position at § 457.535 requiring exemption of AI/AN children from premiums, deductibles, coinsurance, co-payments, or any other cost sharing charges. In light of the absence of a similar statutory authorization, we are unable to adopt a similar policy under Medicaid.

Comment: One commenter indicated that according to the DRA, AI/ANs are required to prove both citizenship and identity in order to obtain Medicaid services. The commenter stated that Native Americans have been told that tribal documentation is insufficient to prove eligibility for Medicaid services. The commenters also stated that many Navajo elders were born at home and do not have birth certificates and it is a substantial burden to obtain birth certificates in this situation. Hence, this new rule limits the Navajo elders ability to access Medicaid. Further, the commenter stated that CMS issued the August 17 State Officials letter that restricts States from requesting health care expansions for SCHIP up to 250 percent limit until the State can prove enrollment of 95 percent of children under the 200 percent of the poverty line. The August 17 directive is unrealistic in obtaining this type of proof of participation. All of these CMS efforts have the collective effect of limiting health care for the poor and AI/AN populations, and present barriers to receiving health care.

Response: The citizenship documentation and identity requirements and the August 17 State Health Officials letter are not part of this rule.

Comment: Several commenters stated that this rule is contrary to the Department of Health and Human Services Tribal Consultation policy since CMS did not consult with Tribes in the development of these regulations before they were promulgated. The commenters indicated that CMS did not obtain advice and input from the CMS Tribal Technical Advisory Group (TTAG) even though the TTAG meets on a monthly basis via conference calls and holds quarterly face to face meetings. In addition, the commenter stated that CMS did not consult with the CMS TTAG Policy Subcommittee which was specifically established by CMS for the very purpose of obtaining advice and input in the development of policy guidance and regulations.

Furthermore the commenter stated that the proposed rule does not contain a Tribal summary impact statement describing the extent of the tribal consultation or lack thereof; or an explanation of how the concerns of Tribal officials have been met. Several commenters request that these regulations not be made applicable to AI/AN Medicaid beneficiaries until Tribal consultation is conducted.

Response: We follow the Department of Health and Human Services' Tribal Consultation Policy. The Departmental guidelines provide for determination of critical events that require special consultation efforts. This action was not considered as a critical event under the Departmental guidelines and thus special consultation efforts were not undertaken. Tribes have had an opportunity to review the proposed rule and submit comments either directly or through the CMS TTAG that has been

established to facilitate consultation. We are currently developing our own consultation guidelines to better serve its tribal stakeholders, consistent with the Departmental guidelines. Even under those draft CMS consultation guidelines, we would not routinely require consultation before notice and comment rulemaking on policies that do not specifically refer to AI/ANs, or tribes. In this instance, it appears that tribes are not directly affected by the provisions of greater flexibility to States, but only by the manner in which individual States choose to exercise that flexibility. We encourage States which decided to implement alternative premiums and cost sharing to consult with tribes and notify them whenever possible on implementation policies that will directly affect the Tribes.

Comment: Several commenters indicated that in the event CMS proceeds to make these regulations effective on Indian tribes, the CMS TTAG should strongly encourage that the proposed rule be modified to require State Medicaid programs to consult with Indian Tribes before the development of any policy that would impose any premium or cost sharing requirements on AI/ANs served by Indian Health Service or tribal health programs similar to the way consultation takes place with Indian Tribes in the development of waiver proposals.

Response: This rule is not ''effective on Indian tribes''. The rule will implement a statutory provision that affects federal review of State Medicaid plans. While we recognize that the resulting changes in State Medicaid programs may have an impact on Indian tribes, we believe these concerns should be raised on a State level. The statutory framework appears to reflect the principle that States are in the best position to weigh the commenters' concerns and determine the appropriate levels and scope of alternative cost sharing. States have the option to impose lower cost sharing than the maximum levels permitted, and/or to exempt additional classes of individuals or additional items or services from cost sharing.

Comment: One commenter stated that it is laudable that the proposed rule would not affect existing waiver authority with respect to premiums and cost sharing but, in the interest of consistency, using similar methodologies under waivers and the State plan should be allowable. For automated eligibility systems and tracking purposes, having one method of charging and defining co-payments would simplify the process for all providers.

Response: We agree that similar methodologies for calculating premiums and cost sharing should be allowable. For example, States can use similar methodologies for determining family income and eligibility. States can use similar methodologies for tracking cost sharing as under approved waivers, or can use the methods that SCHIP programs use to track cost sharing. States can program their automated systems to track and compute recipients' cost sharing.

We note that the DRA provides States with flexibility to choose not to use the same methodologies in determining family income and eligibility. It is up to the States to determine what methodologies work best for them in providing health care coverage to their Medicaid beneficiaries and in imposing alternative premiums and cost sharing. The DRA provisions provide States with unprecedented flexibilities and we have maintained that flexibility in promulgating this rule.

Comment: One commenter appreciates and supports making explicit the Secretary's authority to waive the limitations on premiums and cost sharing.

Response: The DRA did not expand or contract the Secretary's waiver authority with respect to premiums and cost sharing. We note that States may no longer need waivers from the Secretary for certain programmatic options. This could be particularly advantageous for States since waivers need to be periodically renewed.

Comment: One commenter stated that the collection of co-payments and deductibles is especially problematic when health care services (for example, home health) are delivered in the community. The barriers that exist to the collection of fees by clinicians during home visits are the potential negative impact on the clinician/patient relationship and safety concerns for clinicians collecting and transporting cash, despite the fact that the amounts may be small.

Several commenters stated that States would experience increased costs because States would be required to develop new accounting systems in order to reflect cost sharing payments timely, disenroll recipients for failure to pay premiums, identify and transfer individuals in and out of exception groups, and hear and adjudicate exception eligibility decisions. In addition, several commenters stated that cost sharing responsibilities that are shifted to the provider of service may discourage participation, thereby increasing access problems.

Response: In response to the burden to develop systems to track premiums and cost sharing, we are not requiring that States develop electronic or new accounting systems to track Medicaid beneficiaries' cost sharing obligations. We only require that States indicate the method they will use in tracking cost sharing. We believe that using electronic systems to comply with the requirement is ideal, however, it is not a requirement under this rule.

We note that this provision is at the State option. States are not required to impose premiums and cost sharing on Medicaid beneficiaries and providers have the statutory authority under 1916A(d)(2) of the Act to waive or reduce cost sharing if they believe imposing cost sharing produces a negative relationship between providers and clients. Safety for providers collecting co-payments should be a consideration by States before choosing to adopt the flexibilities outlined in this rule.

3. Alternative Premiums, Enrollment Fees, or Similar Fees: State Plan Requirements (§ 447.64)

Section 1916A(a)(1) of the Act requires that the State plan specify the group or groups of individuals upon which it will impose alternate premiums. In accordance with the statute, at § 447.64(a), we proposed that the State plan describe the group or groups of individuals that may be subject to such premiums, enrollment fees, or similar charges. We further proposed in § 447.64(b) that the State plan must include a schedule of the premiums, enrollment fees, or similar charges and the process for informing recipients, applicants, providers, and the public of the schedule. States may vary the premiums, enrollment fees, or similar charges among the groups of individuals.

Section 1916A(b)(4) of the Act requires that the State plan specify the manner and the period for which the State determines family income. In accordance with the statute, at § 447.64(c), we proposed that the State plan describe the methodology used to determine family income, including the period and periodicity of those determinations. We also proposed in § 447.64(d) that the State plan describe the methodology the State would use to ensure that the aggregate amount of premiums and cost sharing imposed for all individuals in the family does not exceed 5 percent of family income as applied during the monthly or quarterly period specified by the State.

Section 1916A(d)(1) of the Act requires that the State specify the group

or group of individuals for whom payment of premiums is a condition of eligibility. In accordance with the statute, at § 447.64(e), we proposed that the State plan list the group or groups of individuals. We further propose in § 447.64(f) that the State plan describe the premium payment terms for the group or groups.

Specific comments on this section and our responses to those comments are as follows:

Comment: One commenter stated that States should be required to notify pharmacists, providers, recipients, and the public no later than 60 days before the effective date of any changes in cost sharing requirements under the State plan.

Response: We proposed at § 447.76 to require issuance of a public schedule that includes current cost sharing requirements. We required contemporaneous but not advance notice of any change in that schedule. As we discuss below, we have revised the proposed provision to require at least 1 month before notice of any change in premiums or cost sharing, to permit individuals and providers an opportunity to plan for the increased financial responsibility.

Comment: Several commenters stated that States should be required to include in their State plan amendment a schedule of prescription drug cost sharing for the various covered populations and indicate in this schedule whether these cost sharing amounts must be paid by the Medicaid patient in order to receive the prescription. The commenters stated that the schedule should be posted to the State Medicaid program Web site and to the CMS Web site. This information should be distributed to patients and include a statement regarding the expectation that patients would pay the cost sharing amounts. Other commenters stated that the State plans should indicate how the State would communicate to providers that some individuals are exempt from co-payment obligations.

Response: We agree that any changes to cost sharing should be made available to pharmacists, providers, recipients, and the general public. Section 447.76 requires that a public schedule be prepared and made available that includes a current listing of cost sharing charges. We also require that the public schedule be made available to recipients, at the time of enrollment and reenrollment, and when charges are revised.

We plan to include an assurance concerning the public schedule requirement in the State plan.

In terms of the commenter's recommendation to post the public schedule to the State Web site and the CMS Web site, we have not prescribed that public schedules or State plans be posted to the State Web site or CMS Web site because we wish to maintain State flexibility in this regard.

Comment: Several commenters complained that the proposed rule contained no requirement that the State facilitate pharmacy providers' attempts at point-of-sale to determine whether specific patients are subject to cost sharing for a transaction at hand. Some commenters stated that it is necessary for States to set up systems for tracking and computing recipients' co-payments at point-of-sale and to adopt policies that support electronic identification of non-preferred drugs to minimize confusion for recipients and providers. The commenters stated that the information should include the level of cost sharing imposed, whether the recipient has met his or her aggregate limit for the month or quarter, and whether the co-payment is enforceable.

Response: Section 447.68(d) requires that the State plan must specify the method for tracking cost sharing. If the state is tracking cost sharing electronically, cost sharing information regarding the appropriate levels, whether the beneficiary has met his or her 5 percent aggregate cap and whether the co-payment is enforceable could all be available. However, States can use other methods to track cost sharing; thus, information at point-of-sale may not be available in all States.

4. General Alternative Premium Protections (§ 447.66)

Section 1916A(b)(3)(A) of the Act specifies that the State plan may not impose premiums on certain groups. In accordance with § 447.66(a), we proposed that the State exclude these classes of individuals from the imposition of premiums.

Section 1916A(b)(3)(C) of the Act clarifies that a State may exempt additional classes of individuals from premiums. We proposed to implement this provision at § 447.66(b).

Specific comments on this section and our responses to those comments are as follows:

Comment: One commenter requests clarification of proposed § 447.66, which States that premiums cannot be imposed on disabled children who are receiving medical assistance because of the Family Opportunity Act. The commenter questioned at what age premiums can be imposed upon these children.

Response: We clarify that in § 447.66, we specified that disabled children who are receiving medical assistance because of the Family Opportunity Act (sections 1902(a)(10)(A)(ii)(XIX) and 1902(cc) of the Act) cannot have alternative premiums nor cost sharing imposed upon them under section 1916A of the Act. Neither the Family Opportunity Act nor the DRA specify an age for children. The age for qualification as a child is determined by each State individually, thus it would vary as to when premiums could be imposed under the authority of the Family Opportunity Act.

Comment: One commenter indicated that women who choose to delay or prevent pregnancy should be exempt from premiums, regardless of their ability to pay a premium, just like pregnant women are exempt. Additionally, the commenter stated that CMS should exempt individuals eligible for family planning services pursuant to a section 1115 family planning waiver from the imposition of premiums.

Response: Section 1916A(b)(3)(A)(ii) of the Act provides that pregnant women are exempt from premiums, but there is no statutory exemption for women who choose to receive family planning supplies to prevent unintended pregnancies, nor individuals who receive family planning services pursuant to a section 1115 demonstration explicitly exempt from premiums. While States may elect to exempt such groups in designing alternative cost sharing, the regulations do not require States to do so, which is consistent with the DRA statutory language.

5. Alternative Copayments, Coinsurance, Deductibles, or Similar Cost Sharing Charges: State Plan Requirements (§ 447.68)

Section 1916A(a)(1) of the Act requires that the State plan specify the group or groups of individuals upon which it opts to impose cost sharing. In accordance with the statute, at § 447.68(a), we proposed that the State plan describe the group or groups of individuals that may be subject to cost sharing. We further proposed that the State plan must include a schedule of the copayments, coinsurance, deductibles, or similar cost sharing charges, the items or services for which the charges apply, and the process for informing recipients, applicants, providers, and the public of the schedule. We note that States may vary cost sharing among the types of items and services.

Section 1916A(b)(4) of the Act requires that the State plan specify the

manner and the period for which the State determines family income. In accordance with the statute, at § 447.68(b), we proposed that the State plan describe the methodology used to determine family income, including the period and periodicity of these determinations.

We also proposed that the State plan describe the methodology the State would use to ensure that the aggregate amount of premiums and cost sharing imposed for all individuals in the family does not exceed 5 percent of family income as applied during the monthly or quarterly period specified by the State. We further proposed that the State plan describe the State's methods for tracking cost sharing charges, informing recipients and providers of their liability, and notifying recipients and providers when individual recipients have reached their aggregate limit on premiums and cost sharing. States can use the same methods that SCHIP programs use to track cost sharing. For example, States can program their automated systems to track and compute recipients' cost sharing.

Finally, we proposed that the State plan specify whether the State permits a provider participating under the State plan, to require payment of authorized cost sharing as a condition for the provision of covered care, items, or services.

Specific comments on this section and our responses to those comments are as follows:

Comment: One commenter expressed concern that States would be unable to identify transition Medicaid recipients who develop a terminal illness in a timely manner to ensure that they are exempted from premiums and co-payments when they access hospice services.

The commenter also stated that States should be required to institute expedited processes for transition of recipients that have been diagnosed as having a terminal illness to the exclusion group.

Response: We agree with the commenter's suggestion that it is important that individuals who have been diagnosed with a terminal illness should not have to worry about premiums and co-payments and States should promptly identify these individuals as exempt from these obligations. Congress clearly identified in section 1916A(b)(3) of the Act individuals with a terminal illness receiving hospice care as individuals exempt from premiums and cost sharing. We included these exemptions in § 447.66—General Premium Protections and § 447.70—General Cost Sharing Protections.

Beyond the State plan requirements required by this section, we believe it is important to provide flexibility to States and therefore, have not prescribed methods for States to follow to ensure that exempted individuals are not charged premiums and/or cost sharing. If an individual is part of a population for which no premiums and/or cost sharing can be imposed, it is incumbent upon the State to ensure that procedures are in place so that there is no routine reliance on a refund for overpayments. If premiums or co-payments are imposed in error on these individuals, the State should take prompt corrective action to ensure full and continuing compliance with applicable requirements.

Comment: One commenter stated that co-payments should apply to broader coverage groups and was concerned that this would not be possible because a significant number of Medicaid recipients, cutting across usual coverage groups are still exempt from cost sharing.

Response: This rule reflects statutory exemptions and exclusions, and does not expand or contract the list of items or services for which no cost sharing can be imposed, the level of cost sharing that could be imposed, the premiums that could be imposed, the populations for which premiums and cost sharing could be imposed, or the enforceability of premiums and/or cost sharing.

Even though a significant number of Medicaid recipients are protected from alternate premiums and cost sharing, there are still important opportunities for States to exercise flexibility in this area. Also, while some of the groups cut across traditional Medicaid eligibility groups (that is, there could be terminally ill individuals accessing hospice care in almost any traditional Medicaid eligibility group), States can implement systems to identify these exempt individuals.

6. General Alternative Cost Sharing Protections (§ 447.70)

Section 1916A(b)(3)(B) of the Act specifies that the State plan may not impose alternative cost sharing under 1916A(a) of the Act for certain services including emergency services and family planning services. We proposed to implement this provision at § 447.70(a)(1).

In addition, section 1916A(c)(1)(B) of the Act prohibits the State plan from imposing otherwise applicable cost sharing for preferred drugs for individuals ''for whom cost sharing may not otherwise be imposed under subsection (a) due to the application of 1916A(b)(3)(B) of the Act.'' Therefore, in accordance with the statute, at § 447.70(a)(1)(x), we proposed that the State plan exclude these classes of individuals from the imposition of cost sharing for preferred drugs within a class.

Section 1916A(b)(3)(C) of the Act clarifies that a State may exempt additional individuals or services from cost sharing. We proposed to implement this provision at § 447.70(c).

Finally, section 1916A(c)(3) of the Act requires a State to charge cost sharing applicable to a preferred drug in the case of a non-preferred drug if the prescribing physician determines that the preferred drug would not be as effective for the individual or would have adverse effects for the individual or both. We proposed to implement this section at § 447.70(b). We further proposed at § 447.70(b) that the overrides meet State criteria for prior authorization and be approved through the State before the authorization process.

Specific comments on this section and our responses to those comments are as follows:

Comment: Several commenters stated that family planning services and supplies should be exempt from cost sharing entirely. Other commenters stated that family planning services and supplies have consistently been treated as a package, and have been exempt from cost sharing entirely. Futhermore, commenters stated that CMS' own guidelines including the State Medicaid Manual and the title XIX Financial Management Review Guide confirm this.

Commenters also stated that the DRA expanded State authority to impose cost sharing for non-preferred prescription drugs, limiting cost sharing to nominal amounts for a clearly defined list of services and recipients, including family planning services and supplies. In addition, some commenters expressed that States may interpret the provisions of the DRA to permit some cost sharing for non-preferred drugs and may interpret this as cost sharing for oral contraceptives. The commenters stated that if this were an acceptable interpretation, the statute would require that cost sharing be limited to no more than a nominal amount and the rule should be revised accordingly.

Response: Family planning services and supplies are exempt from cost sharing, except that States have the option under 1916A(c) of the Act to impose nominal cost sharing on non-preferred drugs, including contraceptive drugs. Congress was clear to indicate

that family planning services and supplies were exempt from alternate cost sharing as a service (see section 1916A(b)(3)(B)(vii) of the Act), and Congress clarified in section 405(a)(2) of TRHCA that this exemption extends to preferred prescription drugs within a class of drugs. Nominal cost sharing for non-preferred drugs, including contraceptive drugs, is permitted subject to the limitations by income group and the aggregate cap. In this rule, we neither expand nor contract these protections.

Comment: One commenter requested clarification of proposed §§ 447.70 and 447.71 in which cost sharing for non-emergency use of the hospital emergency room can be imposed. The commenter indicated that these proposed sections read as if emergency room physicians cannot impose co-payments against any beneficiary at or below 100 percent, or over 100 percent of the Federal poverty level, unless the regular outpatient provider charges no cost sharing payment for the same service in the same geographic area.

The commenter also asked that we clarify how a State can ensure compliance with this particular requirement and what mechanism a State would use to demonstrate such compliance.

Response: We agree that clarification is needed in terms of cost sharing for non-emergency use of the hospital emergency room, and we have revised this final rule accordingly. Specifically, as directed by the DRA for individuals with family incomes at or below 100 percent of the Federal poverty line (FPL), cost sharing for non-emergency use of the hospital emergency room can be imposed at nominal amounts only so long as no cost sharing is imposed to receive the same services from an alternate outpatient provider in the same geographic area. For individuals with family incomes from 100 to 150 percent of the FPL, cost sharing can be imposed at up to two times the nominal amount. For individuals with family incomes that exceed 150 percent of the FPL cost sharing there is no limit as to the amount of cost sharing that can be imposed; however, States must ensure that cost sharing does not exceed the 5 percent total aggregate cap. The 5 percent total aggregate cap also applies to individuals with incomes at or below 100 percent of the FPL and to individuals with family incomes from 100 to at or below 150 percent of the FPL.

The limitation that cost sharing may be imposed only so long as no other cost sharing has been imposed in the same geographic area applies only to individuals with family incomes at or below 100 percent of poverty and to individuals exempt from cost sharing.

In response to the request for clarification as to how States can comply with this limitation, we believe that the hospital will need to document that it has provided a referral to an alternate provider who can provide the services without imposition of such cost sharing.

Comment: Some commenters stated that in considering the experience of a large majority of emergency physicians, imposing cash co-payments on many Medicaid recipients in the emergency department is just not practical. The commenters noted that medical conditions are not easy to ascertain in an episodic setting when doctors have little or no knowledge of the patient. The commenters also asserted that emergency rooms do not typically have separate ''screening services'' and ''management/treatment service.'' The commenters further asserted that by the time the emergency physician and the emergency department team have completed the EMTALA-required medical screening examination, 90 percent of the resources are expended and most of the work is complete. The commenters thought it would be unpalatable to many doctors to inform the patient that his or her condition is not emergent and he or she has to make a payment before receiving a prescription or some minor additional treatment. The commenters indicated that it is unethical to withhold treatment while the patient is in front of them and even harder to justify when the potential financial gain is so tiny. Commenters also stated that these new requirements would put an excessive burden on hospitals and would be extremely costly to States, with little apparent benefit if any at all.

Response: Section 1916A(e) of the Act, as amended by the DRA, provided a State option to impose higher cost sharing for non-emergency care furnished in a hospital emergency department without a waiver. If such cost-sharing is imposed, providers also have the option to waive or reduce cost sharing on a case-by-case basis in accordance with section 1916A(d)(2) of the Act.

The EMTALA screening is an existing statutory requirement and is not particular to this rule.

Comment: Several commenters stated that hospitals would have to compile an ever changing roster of available medical care sites that would not charge co-payments. In addition, they stated that it is not clear how the terms in the proposed rule, ''available and accessible,'' would be defined in order to quantify time and distance. They further stated that it would be nearly impossible for hospitals to keep up-to-date records on these providers.

Response: The statute provides that the hospital is responsible for providing a referral to such a provider. We are leaving to States flexibility to determine whether each hospital must maintain a list of available providers, or whether the State or other governmental entity assists in this responsibility.

Comment: Several commenters stated that none of these requirements do anything to address the real problem, which is that a significant amount of those that utilize the emergency department are chronically ill patients with poor control of their illness(es)—individuals who will benefit most by having a medical home. The commenters also stated that a State's ability to impose cost sharing amounts for non-emergency services provided in an emergency department merely shifts financial burdens to hospitals and would not address the problem of access to a regular source of care. They also stated that this should be addressed by broadening health care coverage and access to needed services. Furthermore, they stated that to date, the systems designed to increase access to urgent, episodic care have only addressed the systems of the ''illness'' of an increasingly inadequate primary care system in which there is a growing number of physicians who do not take Medicaid patients because of inadequate payment. They believe that the hospital emergency departments serve as the ''safety net'' and are often the only source of primary medical care for Medicaid beneficiaries. They also stated that imposing further burdens on the safety net is not the solution.

Response: We agree that there is a need to address the problem that some individuals may use the hospital emergency room as their primary care provider and that these individuals will benefit most from a medical home. The DRA provided for $50 million in grant funding to States to establish alternative non-emergency service providers or networks of these providers. CMS recently awarded the grant funding to 20 States for projects that include innovative programs for providing primary care access to Medicaid beneficiaries. Many of the States' projects include components that will focus on educating beneficiaries on the benefits of care coordination and of having a medical home. Many also focus on case management strategies and disease management. We require, as part of the State applications, a plan for

sustainability so that these State projects for alternative providers and primary care access will continue well into the future.

Comment: Several commenters questioned the logic of the prescription drug co-payment structure for patients with income from 100 to 150 percent of the Federal poverty level. They stated that the proposed rule provided that cost sharing for this group cannot exceed 10 percent of the payment the agency makes for the service, but cannot exceed the nominal amounts for non-preferred drugs. They also stated that given that the average Medicaid reimbursement for a brand name drug is $155, the proposed rule appears to allow the State to charge up to almost $16 for a preferred brand name drug (10 percent of the payment) but only $3.30 for a non-preferred brand name drug (which is the maximum nominal co-payment amount). The commenters stated that this appears to encourage the use of non-preferred drugs rather than preferred drugs.

Response: This comment is based on a misunderstanding of the cost sharing which may be imposed on ''preferred drugs.'' Section 1916A(c) of the Act provides authority for alternate cost sharing (other than the level permitted under section 1916 of the Act) only for non-preferred drugs. There is no provision in section 1916A(c) of the Act authorizing cost sharing for preferred drugs that would exceed the nominal levels that could be permitted under section 1916 of the Act. In the example given, cost sharing for the preferred drug would be at or below nominal levels, and there would be no financial disincentive for use of the preferred drug.

Comment: Commenters stated that the cost sharing permitted for higher income individuals would be excessive. For individuals with incomes above 150 percent of the Federal poverty level, the cost sharing amount would increase to 20 percent, potentially increasing the cost of a medication to $32, some or all of which the pharmacy would have to absorb if the State doesn't condition payment on the cost of the service, and the patient cannot pay.

Response: The statutory framework appears to reflect that States are in the best position to weigh the commenters' concerns and determine the appropriate levels and scope of alternative cost sharing. States have the option to impose lower cost sharing than the maximum levels permitted by the statute, or to exempt additional classes of individuals or additional items or services from cost sharing.

Comment: Some commenters stated that the proposed requirement at § 447.70(c)(2) for requesting prior authorization as a condition for an exception to non-preferred drug cost sharing exceeds the scope of the statute and CMS should delete this requirement. Other commenters stated that the prior authorization process should be at the State option, rather than a requirement.

Response: We disagree with the commenter that the prior authorization requirement should be deleted. The DRA indicates that a prescribing physician can impose cost sharing for non-preferred drugs at the level of a preferred drug if it is determined that the non-preferred drug would better meet the needs of the beneficiary (that is, a preferred drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual or both). We have further required that this activity be part of the prior authorization process since States should be aware of these determinations and be part of the approval process. States are responsible for administering their Medicaid programs.

Comment: One commenter stated that given the proposed rule would not mandate that the Medicaid patient pay the cost sharing, even for non-preferred drugs, it does not appear that physicians would have incentives to obtain prior authorization for the non-preferred drugs if the patient can simply say they cannot afford the cost sharing on the non-preferred drug.

Response: In terms of incentives to obtain prior authorization for non-preferred drugs even if the patient cannot afford cost sharing on the non-preferred drug, the DRA specifies that a physician can impose cost sharing at the level of a preferred drug on a non-preferred drug if it is determined that the non-preferred drug would be more effective in the treatment of the condition and that the non-preferred drug prevents adverse effects for the beneficiary. We require that this process conform to the States' prior authorization process. We note that an incentive exists for beneficiaries since cost sharing can be imposed at the level of the preferred drug. For individuals exempt from cost sharing, this level is $0; therefore, the beneficiary would be required to pay no cost sharing for the non-preferred drug.

Comment: One commenter stated that States should be given the option to allow physicians to use a ''dispense as written'' process to reduce cost sharing for certain non-preferred drugs.

Response: Our proposed rule did not preclude a State from accepting a process to document a physician's finding that the preferred drug would be less effective or would have adverse effects for the individual or both, (the statutory standard). In addition, our proposed rule did not preclude a State from requiring compliance with a prior authorization process, or a more detailed documentation process.

Comment: Several commenters request that CMS require States to publish the preferred drug list, just as they are required to make available a public schedule for other cost sharing information. The commenters recommended this requirement since lists are not easily available in a logical section on the State or plan's Web site and it is difficult to access particularly when there are multiple formularies by different managed care plans.

Response: We interpreted the proposed rule at § 447.76 requiring States to publish a public schedule of cost sharing charges to implicitly include a reference to schedules of preferred drugs. We envisioned the preferred drug schedule as part of, or as a supplement to, the required public schedule. In response to the comment, we are including in this final rule an express requirement to make available either the preferred drug list itself, or a method to obtain the list upon request.

Comment: Several commenters want CMS to define preventive services, well child care, and immunizations and what qualifies as a preventive service under proposed § 447.70. They also stated that this section fails to define terms and provides no other reference to services found in the statute or the proposed rule. In addition, commenters stated that the Bright Futures guidelines, which provide an explanation of the AAP-recommended periodicity schedule for preventive visits and appropriate immunizations should be the appropriate reference and should be included in the rule as the standard by which preventive services should be judged.

One commenter recommended that CMS add a definition for medically frail.

Response: We wish to maintain the flexibilities Congress granted in the DRA. We have not defined these terms or what qualifies as a preventive service under § 447.70. States may choose to use the Bright Futures guidelines as a reference, which provide an explanation of the American Academy of Pediatrics-recommended periodicity schedule for preventive visits and appropriate immunizations. We note that we find the States' use of these guidelines to be appropriate. These guidelines are used

as guidelines for well baby and well child care services in the SCHIP program.

7. Alternative Premium and Cost Sharing Exemptions and Protections for Individuals With Family Income At or Below 100 Percent of the FPL (§ 447.71)

Under section 1916A(a)(2)(A) of the Act, the State plan may not impose premiums on individuals whose family income is at or below 100 percent of the FPL. In accordance with the statute, at § 447.71(a) we proposed that the State plan exclude these individuals from the imposition of premiums.

Under section 1916A(a)(2)(A) of the Act, the State plan may not impose cost sharing on individuals whose family income is at or below 100 percent of the FPL, with the exception of cost sharing for non-preferred drugs and for non-emergency services furnished in a hospital emergency department. However, section 1916A(c)(2)(A)(i) of the Act prohibits a State from imposing, with respect to a non-preferred drug, cost sharing that exceeds the nominal amount as otherwise determined under section 1916 of the Act and described at § 447.54(a)(3) or § 447.54(4) for those individuals. In addition, section 1916A(e)(2)(B) of the Act prohibits a State from imposing, with respect to non-emergency services furnished in a hospital emergency department, cost sharing that exceeds the nominal amount as otherwise determined under section 1916 of the Act and described at § 447.54(a)(3) or § 447.54(4). Furthermore, a State may only impose nominal cost sharing with respect to non-emergency services as long as no cost sharing is imposed to receive such care through an outpatient department or other alternative health care provider in the geographic area of the hospital emergency department involved.

In accordance with the statute, we proposed at § 447.71(b)(1), (now § 447.71(b)(2)) that cost sharing for non-preferred drugs for those individuals not exceed the nominal cost sharing amount. In addition, we proposed at § 447.71(b)(2), (now § 447.71(b)(3)) that cost sharing for non-emergency services furnished in a hospital emergency department for those individuals not exceed the nominal cost sharing amount and be imposed only as long as no cost sharing is imposed on those individuals to receive care through an outpatient department or other alternative non-emergency services provider in the geographic area of the hospital emergency department involved.

Section 1916A(a)(2)(B) of the Act provides that the total aggregate amount of cost sharing imposed under sections 1916A(c), 1916A(e), and/or 1916 of the Act upon individuals whose family income is at or below 100 percent of the FPL may not exceed 5 percent of the family income of the family involved, as applied on a quarterly or monthly basis as specified by the State. In accordance with the statute, we proposed at § 447.71(c) that aggregate cost sharing for individuals whose family income is at or below 100 percent of the FPL applicable to a family of the size involved not exceed the maximum permitted under § 447.78(b). At § 447.78(b), we proposed that the total aggregate amount of cost sharing may not exceed 5 percent of such family's income for the monthly or quarterly period, as specified in the State plan.

A comment on this section and our response to the comment is as follows:

Comment: Commenters stated that the matrix of cost-sharing is complex and request clarifying information on cost sharing requirements, limitation, and exemptions, as well as cost sharing for non-preferred and preferred prescription drugs, and for non-emergency use of the hospital emergency room.

Response: In considering the complexity of the cost-sharing limitations and requirements, we are clarifying that in § 447.71, we indicated in the proposed rule that individuals with family incomes at or below 100 percent of the poverty line were exempt from cost sharing. The Tax Relief and Health Care Act amended the DRA and indicated that for individuals with family incomes at or below 100 percent of the FPL cost sharing cannot be imposed under section 1916A(a) of the Act but can be imposed at nominal amounts under section 1916 of the Act. Consequently, we are updating § 447.71 to insert a new paragraph (b)(1) indicating that the State may impose cost-sharing under the State plan on individuals whose family income is at or below 100 percent of the FPL under the authority provided in section 1916 of the Act and consistent with such section. We are also redesignating § 447.71(b)(1) as § 447.71(b)(2) and § 447.71(b)(2) as § 447.71(b)(3).

This completes the specific comments submitted to this section in terms of cost sharing imposed upon individuals at or below 100 percent of the Federal poverty level. We note, that we did receive comments on prescription drugs and non-emergency use of the hospital emergency room which we addressed in § 447.70—General alternative cost sharing protections.

8. Alternative Premium and Cost Sharing Exemptions and Protections for Individuals With Family Income Is Above 100 Percent but At or Below 150 Percent of the FPL (§ 447.72)

Under section 1916A(b)(1)(A) of the Act, the State plan may not impose premiums on individuals whose family income exceeds 100 percent, but does not exceed 150 percent of the FPL applicable to a family of the size involved. In accordance with the statute, at § 447.72(a), we proposed that the State plan exclude these individuals from the imposition of premiums.

Section 1916A(b)(1)(B)(i) of the Act provides that, in the case of individuals whose family income exceeds 100 percent, but does not exceed 150 percent of the FPL applicable to a family of the size involved, cost sharing imposed under the State plan may not exceed 10 percent of the cost of such item or service. However, section 1916A(c)(2)(A)(i) of the Act prohibits a State from imposing, with respect to a non-preferred drug, cost sharing that exceeds the nominal amount as otherwise determined under section 1916 of the Act and described at § 447.54(a)(3) for those individuals. In addition, section 1916A(e)(2)(A) of the Act prohibits a State from imposing, with respect to non-emergency services furnished in a hospital emergency department, cost sharing that exceeds twice the nominal amount as otherwise determined under section 1916 of the Act and described at § 447.54(a)(3) for those individuals.

Therefore, in accordance with the statute, we proposed at § 447.72(b) that cost sharing for those individuals under the State plan not exceed 10 percent of the payment the agency makes for that item or service, with the exception that it not exceed the nominal cost sharing amount for non-preferred drugs or twice the nominal cost sharing amount for non-emergency services furnished in a hospital emergency department. In the case of States that do not have fee-for-service payment rates, we proposed that any copayment that the State imposes for services provided by an MCO may not exceed $5.20 for FY 2007. Thereafter, any copayment that the State imposes for services provided by an MCO may not exceed this amount as updated each October 1 by the percentage increase in the medical care component of the CPI–U for the period of September to September ending in the preceding calendar year and then rounded to the next highest 10-cent increment.

Section 1916A(b)(1)(B)(ii) of the Act provides that the total aggregate amount

of cost sharing imposed under section 1916 and 1916A of the Act may not exceed 5 percent of the family income of the family involved, as applied on a quarterly or monthly basis as specified by the State. In accordance with the statute, we proposed at § 447.72(c) that aggregate cost sharing for individuals whose family income exceeds 100 percent, but does not exceed 150 percent of the FPL applicable to a family of the size involved, not exceed the maximum permitted under § 447.78(a). At § 447.78(a), we proposed that the total aggregate amount of cost sharing may not exceed 5 percent of such family's income for the monthly or quarterly period, as specified in the State plan.

We did not receive any specific comments on this proposal as it relates to cost sharing imposed upon individuals with incomes from 100 to 150 percent of the Federal poverty level, therefore, we are adopting it in this final rule. We note that we have revised the copayment that the State may impose for services by an MCO not to exceed from $5.20 per visit for FY 2007 to $3.15 for FY 2007, to $3.25 for FY 2008, and $3.40 for FY 2009. However, we received comments on the rounding up the nominal amounts by the next highest 10-cent increment, the managed care maximum amount, and the cost sharing that can be imposed for prescription drugs and non-emergency use of the hospital emergency room. For comments related to the 10-cent increment and the managed care maximum, we addressed these in § 447.54 in the preamble of this final rule. As noted earlier, for comments related to cost sharing for prescription drugs and non-emergency use of the hospital emergency room, we addressed these in § 447.70 in the preamble of this final rule.

9. Alternative, Premium and Cost Sharing Protections for Individuals With Family Income Above 150 Percent of the FPL (§ 447.74)

Under section 1916A(b)(2) of the Act, the State plan may impose premiums upon individuals whose family income exceeds 150 percent of the FPL applicable to a family of the size involved provided that, as described at section 1916A(b)(2)(A) of the Act, the total aggregate amount of premiums and cost sharing imposed under section 1916 and 1916A of the Act not exceed 5 percent of the family income. In accordance with the statute, at § 447.74(a), we proposed that the State plan can impose premiums upon individuals with family income above 150 percent of the FPL subject to the aggregate limit on premiums and cost sharing.

Section 1916A(b)(2)(B) of the Act provides that, in the case of individuals whose family income exceeds 150 percent of the FPL applicable to a family of the size involved, cost sharing imposed under the State plan may not exceed 20 percent of the cost of that item (including a non-preferred drug) or service. Therefore, in accordance with the statute, we proposed at § 447.74(b) that cost sharing for those individuals under the State plan not exceed 20 percent of the payment the agency makes for that item or service. In the case of States that do not have fee-for-service payment rates, we proposed that any copayment that the State imposes for services provided by an MCO may not exceed $5.20 for FY 2007. This proposal would provide greater flexibility to State Medicaid programs consistent with that provided to State SCHIP programs. Thereafter, any copayment that the State imposes for services provided by an MCO may not exceed this amount as updated each October 1 by the percentage increase in the medical care component of the CPI–U for the period of September to September ending in the preceding calendar year and then rounded to the next highest 10-cent increment.

Section 1916A(b)(2)(A) of the Act provides that the total aggregate amount of cost sharing imposed under section 1916 and 1916A of the Act may not exceed 5 percent of the family income of the family involved, as applied on a quarterly or monthly basis as specified by the State. In accordance with the statute, we proposed at § 447.74(c) that aggregate cost sharing for individuals whose family income exceeds 150 percent of the FPL applicable to a family of the size involved, not exceed the maximum permitted under § 447.78(a). At § 447.78(a), we proposed that the total aggregate amount of premiums and cost sharing may not exceed 5 percent of the family's income for the monthly or quarterly period, as specified in the State plan.

We did not receive any specific comments on this proposal; therefore, we are adopting it in this final rule, without change. We note that we did receive comments on rounding up the nominal amounts by the next highest 10-cent increment, the managed care maximum amount and the cost sharing that can be imposed for prescription drugs and non-emergency use of the hospital emergency room. For comments related to the 10-cent increment and the managed care maximum, we addressed these in § 447.54 in this preamble. As noted earlier, for comments related to cost sharing for prescription drugs and non-emergency use of the hospital emergency room, we addressed these in § 447.70 in this preamble. We note that we revised the copayment that the state may impose for services provided by on MCO not to exceed from $5.20 per visit for FY 2007 to $3.15 for FY 2007, $3.25 for FY 2008 and $3.40 for FY 2009.

10. Public Schedule (§ 447.76)

As previously discussed, section 1916 and 1916A of the Act provides authority for States to impose premiums and cost sharing for items and services, including prescription drugs and non-emergency use of a hospital emergency department. In addition, it requires a group or groups of individuals to make payment as a condition of eligibility or of receiving that item or service. In § 447.76(a), we proposed that State plans provide for schedules of premiums and cost sharing. In § 447.76(a), we proposed that the public schedule contain the following information: (1) Current premiums, enrollment fees, or similar fees; (2) current cost sharing charges; (3) the aggregate limits on premiums and cost sharing or only cost sharing; (4) mechanisms for making payments for required premiums and charges; (5) the consequences for an applicant or recipient who does not pay a premium or charge; and (6) a list of hospitals charging alternative cost sharing for non-emergency use of the emergency department. In addition, at § 447.76(b), we proposed that the State make the public schedule available to recipients, at the time of enrollment and reenrollment and when charges are revised, to applicants, all participating providers, and the general public.

Specific comments on this section and our responses to those comments are as follows:

Comment: One commenter requested that CMS provide for adequate notice to providers and beneficiaries.

Response: We agree with the commenter that adequate notice should be provided to providers and beneficiaries. We note that § 447.76 requires that the State make available to recipients, applicants, all participating providers, and the general public, a public schedule that includes, for example, the groups for which premiums and cost sharing will apply, the levels of current cost sharing and the populations for which cost sharing and premiums will be enforceable.

Comment: Several commenters believe that education would be imperative for Medicaid beneficiaries. The commenters stated that Medicaid patients are not accustomed to yearly

changes in their co-payments, and it is incumbent upon State Medicaid agencies and providers to educate beneficiaries so that the Medicaid patients know the co-payment amounts that should be paid.

Response: In terms of education to beneficiaries, we agree that it is important for individuals to be educated and informed as to the yearly changes and the premiums and cost sharing amounts they could be obligated to pay. In § 447.76 in this final rule, we require that States make available to recipients, applicants, all participating providers, and the general public, among other things, the current premiums, enrollment fees, or similar fees and the current cost sharing charges.

11. Aggregate Limits on Alternative Premiums and Cost Sharing (§ 447.78)

Section 1916A(b)(1)(B)(ii) of the Act provides that the total aggregate amount of cost sharing imposed under section 1916 and 1916A of the Act upon individuals with family income above 100 percent but at or below 150 percent of the FPL may not exceed 5 percent of the family income, as applied on a quarterly or monthly basis as specified by the State. Section 1916A(c)(2)(C) of the Act reiterates that this aggregate limit includes cost sharing for prescription drugs and section 1916A(e)(2)(C) of the Act reiterates that this aggregate limit includes cost sharing for non-emergency use of a hospital emergency department. Section 1916A(b)(2)(A) of the Act provides that the total aggregate amount of premiums and cost sharing imposed under section 1916 and 1916A of the Act upon individuals with family income above 150 percent of the FPL may not exceed 5 percent of the family income, as applied on a quarterly or monthly basis as specified by the State. Again, section 1916A(c)(2)(C) of the Act reiterates that this aggregate limit includes cost sharing for prescription drugs, and section 1916A(e)(2)(C) of the Act reiterates that this aggregate limit includes cost sharing for non-emergency use of a hospital emergency department. Finally, section 1916A(a)(2)(B) of the Act provides that to the extent that cost sharing under section 1916A(c) of the Act for prescription drugs, cost sharing under section 1916A(e) of the Act for non-emergency use of a hospital emergency department, and/or cost sharing under section 1916 of the Act is imposed upon individuals whose family income is at or below 100 percent of the FPL, the total aggregate amount of premiums and cost sharing imposed may not exceed 5 percent of the family income.

In accordance with these provisions, at § 447.78(a), we proposed that for individuals with family income above 100 percent of the FPL the aggregate amount of premiums (when applicable) and cost sharing under section 1916 and 1916A of the Act not exceed 5 percent of a family's income for the monthly or quarterly period, as specified by the State in the State plan. At § 447.78(b), we proposed that for individuals whose family income is at or below 100 percent of the FPL the aggregate amount of cost sharing under sections 1916, 1916A(c), and/or 1916A(e) of the Act not exceed 5 percent of a family's income for the monthly or quarterly period, as specified by the State in the State plan. We also proposed at § 447.78(c) that family income shall be determined in a manner and for that period as specified by the State in the State plan. We clarified that States may use gross income to compute family income and that they may use a different methodology for computing family income for purposes of determining the aggregate limits than for determining income eligibility.

Specific comments on this section and our responses to those comments are as follows:

Comment: Several commenters stated that Medicaid patients may not be able to track their cost sharing spending and premiums for a month, and it should not be the responsibility of the pharmacy or provider to have to keep track. The commenters stated that Medicaid patients may not use the same pharmacy and other non-pharmacy Medicaid cost sharing applies to the limits. They further indicated that most States require families in SCHIP to track their own out of pocket spending to prove they have met the 5 percent income limit. Presumably States would also use this ''shoebox'' method with any Medicaid cost sharing changes. Therefore, the commenters stated that States should be required to track out of pocket spending for families, who will already be under enough burden having to come up with the additional money for cost sharing and premiums.

Response: We agree with the commenter's suggestion that States should be required to track premiums and cost sharing. We do not prescribe the way States ensure that the total aggregate amount of premiums and cost sharing for all individuals in the family does not exceed 5 percent of the family income as applied during the monthly or quarterly period specified by the State. We have maintained the flexibility granted to States by the DRA. However, we require at § 447.68 that the State plan describe the methodology the State will use to ensure that the aggregate amount of premiums and cost sharing imposed for individuals does not exceed 5 percent of the family income. We also require that the State plan describe the State's methods for tracking cost sharing charges, informing recipients and providers of their liability, and notifying recipients and providers when individual recipients have reached their aggregate limit on premiums and cost sharing. States have the flexibility to use the ''shoebox'' method for tracking the aggregate 5 percent cap. This would require a collection of receipts by beneficiaries and a validation process by the State to ensure that individuals have met their aggregate limits. States may use any other method to track the aggregate 5 percent cap (that is, States can program their automated systems to track and compute recipients' cost sharing).

Comment: Several commenters stated that CMS should provide for enhanced administrative match available to States that implement a system to track cost sharing. Commenters believe that CMS should offer states Federal financial participation at the 90/10 match rate to implement Medicaid Management Information System (MMIS) modifications/enhancements to accommodate the tracking of cost sharing.

Response: For modifications/enhancements to the MMIS to accommodate the tracking of cost sharing are eligible for MMIS rates 90 percent Federal financial participation (FFP) for design, development and installation of the enhancements, and 75 percent FFP for operation of the system are currently available. The approach States choose to track these costs is left to each State's discretion. Should they elect to make changes to their MMIS, the previously mentioned rates are applicable. Other electronic solutions outside of the MMIS are eligible for a 50 percent FFP administrative match.

Comment: Other commenters feel that this information can be generated electronically and should be an important element in the Federal government's efforts to make patient records, e-prescribing, and claims billing inter-operative electronically.

Response: States should have systems that best meet their needs in terms of electronic billing, electronic patient records and electronic prescribing for prescription drugs and States are in the best position to determine what best meets their needs. We note that the Federal government is also interested in ways to improve the Medicaid program and Congress provided for $150 million in grant funds to be awarded to States

for Medicaid transformation. We awarded the funds in 2007 for projects which presented innovative ideas in operating their Medicaid programs and provided for replication and sustainability well into the future. Several of these projects include health information technology components; for example, e-prescribing, electronic patient health records and Web-based patient information for clients that emphasize interoperability. We are not aware of State components that specifically address electronically tracking premiums and cost sharing, however, this activity is not precluded from either the grant awards or as a result of the requirements in the rule at § 447.68.

Comment: Some commenters believe that States should not seek to collect payments from pharmacists or providers that provided items and services in good faith if the provider believes that the patient has not yet met their monthly or quarterly aggregate cap. Since States use varying methods to calculate family income and the resulting cost sharing obligations, beneficiaries should not be expected to track their expenses. Individuals with such low incomes should not be expected to recoup money later because it will be very burdensome to them. Commenters stated that this requirement places a large burden on low income families. In addition, it places a burden on Medicaid providers which will need to rely on self-reporting by Medicaid beneficiaries to determine whether to charge a co-payment.

Response: We are not attempting to prescribe the way in which States administer their Medicaid programs. However, if overpayments have been made because individuals have reached their 5 percent aggregate cap, and/or co-payments have been collected in error, States are responsible for ensuring that individuals are made whole. As mentioned previously, we require in § 447.68 that States describe the method that will be used for tracking cost sharing and for notifying recipients and providers when individual recipients have reached their 5 percent aggregate cap.

Comment: One commenter requests clarification of the total aggregate amount of cost sharing and the provider's discretion to waive or reduce the cost sharing. The commenter stated that § 447.80 in the proposed rule indicates that a provider may waive or reduce cost sharing imposed under section 1916A of the Act on a case-by-case basis. The commenter wonders how or if the waived or reduced co-payment will be factored or counted towards the 5 percent family income cap even though it was waived. Many commenters agree that providers should be able to decide when to reduce or waive cost sharing on a case-by-case basis.

Response: In terms of providers waiving or reducing cost sharing and the calculation of the 5 percent aggregate cap, we note that in order to meet the 5 percent aggregate cap, individuals must have out of pocket spending. If a co-payment is waived, there is no out of pocket spending. In tracking the cost sharing, if a provider chooses to waive the cost sharing obligation, there is no receipt—no payment has been made; thus, the 5 percent cap remains constant and no cost sharing is applied to the cap.

Again, the ability to waive or reduce cost sharing is at provider discretion on a case-by-case basis.

Comment: One commenter stated that the proposed rule would implement aggregate cost sharing restrictions by placing percentage-of-income caps ''on the total aggregate amount of premiums and cost sharing under section 1916, 1916A(c), or 1916A(e) of the Act.'' The commenter stated that the language should be revised to include cost sharing that may apply under any provision of law, including those imposed by a State benchmark or benchmark-equivalent plan adopted under section 1937 of the Act.

Response: We agree with the commenter recommending that the cost sharing permissible by the DRA should also apply to the benchmark flexibility also added by the DRA.

We promulgated a proposed rule for State Flexibility for Medicaid Benefit Packages (73 FR 9714 through 9727). The proposed rule was published on February 22, 2008 and, similar to this rule, comments were due on March 24, 2008. In that proposed rule, we require that if premiums and/or cost sharing are imposed under one of the benchmark or benchmark-equivalent plans authorized by the DRA, cost sharing and premiums for recipients may not exceed cost sharing limits under the State's plan with respect to Sections 1916 and/or 1916A of the Act.

Comment: In determining family income and the resulting cost sharing obligations, commenters believe that the proposed rule encourages States to use gross income standards or methods which will result in more cost sharing. The DRA specifies that ''family income shall be determined in a manner specified by the State * * *, including the use of such disregards as the State may provide.'' Commenters stated that Congress intended that States could be more generous and apply additional disregards for calculating income to lessen the amount of income and the aggregate level of permissible cost sharing. The commenters stated that CMS should allow States to use the same methodology that States use in determining family income for purposes of determining Medicaid eligibility (including the use of disregards) or a different methodology that results in more disregards, and therefore, less cost sharing for Medicaid beneficiaries.

Response: States should have the flexibility to use the same methodology in determining family income as they do in determining eligibility or a different methodology that results in more disregards. We specify in § 447.78 that family income shall be determined in a manner and for the period specified by the State in the State plan, including the use of such disregards as the State may provide. In addition, we specifically provided that States may use gross income or any other methodology to compute family income.

We note that two different tests have been set out in law. For cost sharing, the law provides that family income shall be determined in a manner specified by the State (including the use of State-specified disregards) for purposes of the cost sharing provision. The State is entitled by law to determine family income using a methodology other than the one it uses for eligibility purposes, and the use of disregards is a State option. In this respect, the rule reflects the law and does not contain new discretionary policy. For eligibility determinations, there is a more specific test in Section 1902(r)(2) of the Act which provides that income eligibility for purposes of determining eligibility shall be no more restrictive than the methodologies used by the cash assistance programs (primary SSI for the aged, blind, and disabled, and AFDC for families and children). The use of methodologies that are no more restrictive than cash assistance methodologies (including the cash assistance disregards) is a mandatory requirement under title XIX of the Act and is not at State discretion.

The DRA does not tie the cost sharing family income determinations to the mandatory statutory requirements for determining Medicaid eligibility.

In practice, the impact to beneficiaries for eligibility purposes is in applying a methodology for determining eligibility based on income and the use of income disregards (that is, individuals that may not have previously been determined eligible for Medicaid may now be determined eligible). The impact to beneficiaries for cost sharing purposes is dependent upon how the State exercises

the flexibility the law provides to determine income for purposes of cost sharing. If income disregards are used, the cost sharing amounts would be computed based on a lower income threshold, and, therefore, individuals would pay less cost sharing relative to their total income. If income disregards are not used, individuals are paying cost sharing amounts that are consistent with total income. The DRA does not provide the authority to mandate the use of the eligibility methodologies for determining family income for cost sharing. We note that States have the option to use the same methodologies for determining family income as they do for determining eligibility or to use a different methodology.

We believe it would have been an intrusion on the flexibility given to States for cost sharing to tie the methodologies for determining family income to the eligibility methodologies.

12. Enforceability of Alternative Premiums and Cost Sharing (§ 447.80)

Section 1916A(d)(1) of the Act permits a State to condition Medicaid eligibility upon the prepayment of premiums imposed under section 1916A of the Act or to terminate Medicaid eligibility for the failure to pay a premium for 60 days or more.

In accordance with the statute, we proposed at § 447.80(a), to permit a State to condition eligibility for a group or group of individuals upon prepayment of premiums, to terminate the eligibility of an individual from a group or groups of individuals for failure to pay for 60 days or more, and to waive payment in any case where requiring the payment would create undue hardship.

Section 1916A(d)(2) of the Act permits a State to allow a provider to require that an individual, as a condition of receiving an item or service, pay the cost sharing charge imposed under section 1916A of the Act. The provider is not prohibited by this authority from choosing to reduce or waive cost sharing on a case-by-case basis. However, section 1916A(a)(2)(A) of the Act specifies that section 1916A(d)(2) of the Act shall not apply in the case of an individual whose family income does not exceed 100 percent of the FPL applicable to a family of the size involved.

In accordance with the statute, at § 447.80(b), we proposed that a State may permit a provider, including a pharmacy, to require an individual to pay cost sharing imposed under section 1916A of the Act as a condition of receiving an item or service. However, at § 447.80(b)(1), we specified that a provider, including a pharmacy or hospital, may not require an individual whose family income is at or below 100 percent of the FPL to pay the cost sharing charge as a condition of receiving the item or service. In addition, at § 447.80(b)(2), we proposed that a hospital that has determined after an appropriate medical screening under section 1867 of the Act that an individual does not have an emergency medical condition must first provide the name and location of an available and accessible alternate non-emergency services provider, the fact that the alternate provider can provide the services without the imposition of that cost sharing, and a referral to coordinate scheduling of treatment before it can require payment of the cost sharing. Finally, at § 447.80(b)(3), we proposed that a provider may reduce or waive cost sharing imposed under section 1916A of the Act on a case-by-case basis.

Specific comments on this section and our responses to those comments are as follows:

Comment: Several commenters stated that increasing cost sharing amounts without making them enforceable does little to encourage the use of more cost-effective medications, but potentially shifts the economic burden to the pharmacy.

Response: To the extent that pharmacies are precluded from conditioning services on the payment of cost sharing for individuals with family incomes at or below 100 percent of the FPL, this rule reflects the unambiguous provisions of the statute. Congress was clear to protect certain Medicaid beneficiaries from enforceability of premiums and cost sharing. We believe Congress intended to protect our Nation's most vulnerable low-income beneficiaries. For higher income individuals, the law and as specified in this final rule, gives States and providers new tools to enforce cost sharing obligations.

Comment: Some commenters request clarification as to whether the refusal of service to individuals who do not pay co-payments also apply to SCHIP and Medicaid managed care enrollees.

Response: The only revision to the SCHIP program made by this rule is to update the nominal amounts and the maximum allowable charges imposed (see § 457.555). We do not address the SCHIP program in any other way. If any provision regarding enforceability exists, it would be as a result of the SCHIP statutory and regulatory provisions and not as part of this rule.

Since Medicaid managed care enrollees are participants in the Medicaid program and these rules apply to Medicaid programs, the enforceability provisions will apply. The specific enforceability provisions apply to beneficiaries enrolled in Medicaid managed plans with family incomes above 100 percent of the FPL if the State has opted to apply the enforceability provisions under section 1916A of the Act.

13. Restrictions on Payments to Providers (§ 447.82)

Proposed § 447.82 requires States to reduce the amount of State payments to providers by the amount of recipients' cost sharing obligations under section 1916A of the Act. However, States have the ability to increase total State plan rates to providers to maintain the same level of State payment when cost sharing is introduced.

Specific comments on this section and our responses to those comments are as follows:

Comment: Some commenters stated that CMS has exceeded its authority by interpreting the DRA to mean that States *must* reduce provider reimbursement rates irrespective of whether the provider has successfully collected the co-payments. The commenters indicated that the statute does not suggest that Congress intended to mandate how states set their reimbursement rates. They also indicated that the statutory provision could set a dangerous precedent, the proposed § 447.82 creates an additional, unnecessary barrier to beneficiary access to services. In addition, they indicated that this provision would require States to reduce their provider reimbursement rates by co-payment amounts, irrespective of whether the co-payments were actually collected by the provider. This would severely impact providers' ability to limit cost sharing and ensure that Medicaid beneficiaries receive needed drugs and services.

Some commenters stated that this section should be completely removed from the proposed rule.

Other commenters stated that because of § 447.82, the possibility of providers waiving or reducing the required co-payment is minor since any unpaid amounts would ultimately be borne by the provider. The commenters stated that this is essentially a shift from the States to our nation's safety net providers (including health centers, title X family planning clinics, home health agencies, home and community based service providers), many of whom are already struggling to make ends meet with inadequate Medicaid payment rates. These providers should not be financially penalized further because of

an inability to collect a co-payment from the neediest of patients.

One commenter also stated that, to require States to cut reimbursement rates by cost sharing amounts, but allow them to increase their overall reimbursement rate to providers to offset the cut is insufficient in alleviating the harm to providers as states facing their own budget constraints would unlikely provide an overall rate increase.

Response: We disagree that this section of the rule should be deleted in its entirety. We are not intending to prescribe the way States set their provider rates. However, we are ensuring that duplicate payment is not made (that is, Medicaid should not be responsible for paying amounts for which the beneficiary is liable). We have always required in regulations that provider rates, in considering cost sharing obligations, are net of the cost sharing obligations of Medicaid beneficiaries.

C. SCHIP Regulations

1. Maximum Allowable Cost Sharing Charges on Targeted Low-Income Children in Families With Incomes From 101 to 150 Percent of the FPL (§ 457.555)

We proposed in § 457.555, to update the existing ''nominal'' SCHIP cost sharing amounts, specifically the copayment amounts described at § 457.555(a)(1) and (2), (c), and (d) and the deductible amount described at § 447.555(a)(4). In the proposed rule, we discussed in detail the statutory basis and the proposed methodology for updating the nominal amounts (73 FR 9727 through 9740). Based on this methodology, we proposed the following copayment maximum amounts:

Total cost of services * * *	Maximum amount * * *
$15.00 or less	$1.10
$15.01 to $40	2.10
$40.01 to $80	3.20
$80.01 or more	5.20

We also proposed that the copayments for services provided by an MCO and for emergency services provided by an institution not exceed $5.20 per visit and that the copayment for non-emergency services furnished in a hospital emergency room to targeted low-income children with family income from 101 to 150 percent of the FPL not exceed $10.40. Finally, we proposed that a deductible not exceed $3.20 per family per month.

We proposed that States should use these updated nominal amounts during FY 2007. Thereafter, we proposed to update these amounts each October 1 by the percentage increase in the medical care component of the CPI–U for the period of September to September ending in the preceding calendar year and then rounding to the next higher 10-cent increment.

CMS received comments regarding the updating of the nominal amounts for both Medicaid and SCHIP by the MCPI–U and addressed the issues related to both Medicaid and the specific updates to the SCHIP regulations in our discussion above related to § 447.54. As discussed in that section, in response to comments, we have revised our rounding increment to the next higher 5-cent increment.

III. Provisions of the Final Rule

In this final rule, we are adopting the proposed provisions as set forth in the February 22, 2008, proposed rule, subject to the following changes.

Section 447.54—Maximum Allowable and Nominal Charges by—

+ Revised paragraph (a)(1) by updating the nominal deductible amount for Federal FY 2009 to not exceed $2.30 per month per family for each period of Medicaid eligibility. We also updated the nominal amounts for Medicaid, rounded to the next highest 5-cent increment rather than 10 cents to be consistent with the Medicare Part D program.

+ Revised paragraph (a)(3)(i) by updating the maximum copayments for FY 2009 that are imposed under a fee-for-service delivery system, rounded to the next highest 5-cent increment rather than 10 cents to be consistent with the Medicare Part D program. The copayments will not exceed the amounts specified in the table below.

State payment for the service	Maximum copayment
$10 or less	$ 0.60
$10.01 to $25	1.15
$25.01 to $50	2.30
$50.01 or more	3.40

+ Revised paragraph (a)(3)(ii) to clarify that in updating the nominal amounts for Medicaid, we rounded to the next highest 5-cent increment rather than 10 cents to be consistent with the Medicare Part D program. In addition, we clarify that we calculate the update each year without considering any rounding adjustment made in the previous year.

+ Added a new paragraph (a)(4) to update the Federal FY 2009 maximum Medicaid managed care amount to be aligned with the Medicaid fee-for-service amount and the Federal FY 2009 maximum Medicaid expansion SCHIP managed care amount to be aligned with the SCHIP fee-for-service amount. We note that paragraph (a)(4) now reads: ''For Federal FY2009, any copayment for services provided by an MCO may not exceed the copayment permitted under subparagraph (3)(i) for comparable services under a fee-for-service delivery system, except as provided in this paragraph. When there is no fee-for-service delivery system, the copayment may not exceed $3.40 per visit or for individuals referenced in an approved State child health plan under title XXI of the Act pursuant to § 457.70(c), $5.70 per visit. In succeeding years * * * ending in the preceding calendar year and then rounded to the next higher 5-cent increment''.

Section 447.71—Alternative Premium and Cost-Sharing Exemptions and Protections for Individuals With Family Income At or Below 100 Percent of the FPL

+ Redesignated paragraph (b)(1) as paragraph (b)(2), and paragraph (b)(2) as paragraph (b)(3).

+ Added a new paragraph (b)(1) to clarify that States may impose cost sharing under the State plan on individuals whose family income is at or below 100 percent of the FPL in accordance with section 1916 of the Act and consistent with § 447.54.

Section 447.72—Alternative Premium and Cost Sharing Exemptions and Protections for Individuals With Family Incomes Above 100 Percent but At or Below 150 Percent of the FPL

+ Revised paragraph (b)(3) by updating the copayment amount to not exceed $3.40 per visit for Federal FY 2009. We also state that individuals referenced in an approved State child health plan under title XXI of the Act in accordance with § 457.70(c), the copayment is not to exceed $5.70 per visit for Federal FY 2009. In addition, we updated the nominal amounts for Medicaid, rounded to the next highest 5-cent increment rather than 10 cents to be consistent with the Medicare Part D program.

Section 447.74—Alternative Premium and Cost Sharing Protections for Individuals With Family Incomes Above 150 Percent of the FPL

+ Revised paragraph (b) by updating the copayment amount to not exceed $3.40 per visit for Federal FY 2009. We also stated that individuals referenced

in an approved State child health plan under title XXI of the Act pursuant to § 457.70(c), the copayment is not to exceed $5.70 for Federal FY 2009. In addition, we updated the nominal amounts for Medicaid, rounded to the next highest 5-cent increment rather than 10 cents to be consistent with the Medicare Part D program.

Section 447.76—Public Schedule

Added a new paragraph (a)(7) to specify that the State must make available a public schedule that contains either a list of preferred drugs or a method to obtain such a list upon request.

Section 447.78—Aggregate Limits on Alternative Premiums and Cost Sharing

Added to the end of paragraph (c) of this section the phrase, ''* * * including the use of such disregards as the State may provide.''

Section 457.555—Maximum Allowable Cost Sharing Charges on Targeted Low-Income Children in Families With Income From 101 To 150 Percent of the FPL

+ Revised paragraph (a)(1)(i) by updating the copayment amounts for Federal FY 2009. Any copayment or similar charge the State imposes under a fee-for-service delivery system may not exceed the following amounts:

Total cost	Maximum amount
$15 or less	$1.15
$15.01 to $40	2.30
$40.01 to $80	3.40
$80.01 or more	5.70

+ Revised paragraph (a)(1)(ii) by updating the nominal amounts for Medicaid, rounded to the next highest 5-cent increment rather than 10 cents to be consistent with the Medicare Part D program.

+ Revised paragraph (a)(2) by updating the copayment amount to not exceed $5.70 per visit for Federal FY 2009. We also updated the nominal amounts for Medicaid, rounded to the next highest 5-cent increment rather than 10 cents to be consistent with the Medicare Part D program.

+ Revised paragraph (a)(4) by updating the deductible amount to not exceed $3.40 per month, per family for each period of eligibility for Federal FY 2009. We also updated the nominal amounts for Medicaid, rounded to the next highest 5-cent increment rather than 10 cents to be consistent with the Medicare Part D program.

+ Revised paragraph (c) ''Institutional emergency services,'' by updating the copayment amount to not exceed $5.70 for Federal FY 2009. We also updated the nominal amounts for Medicaid, rounded to the next highest 5-cent increment rather than 10 cents to be consistent with the Medicare Part D program.

+ Revised paragraph (d) ''Non-emergency use of the emergency room,'' by updating the maximum amount that the State can charge for non-institutional services to $11.35 for Federal FY 2009. We also updated the nominal amounts for Medicaid, rounded to the next highest 5-cent increment rather than 10 cents to be consistent with the Medicare Part D program.

VI. Collection of Information Requirements

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 the Office of Management and Budget (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.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements:

Section 447.64 Premiums, Enrollment Fees, or Similar Fees: State Plan Requirements

Section 447.64 requires a State imposing premiums, enrollment fees, or similar fees on individuals to describe in the State plan:

- The group or groups of individuals that may be subject to the premiums, enrollment fees, or similar charges.
- The schedule of the premiums, enrollment fees, or similar fees imposed.
- The methodology used to determine family income for purposes of the limitations related to family income level that are described below, including the period and periodicity of those determinations.
- The methodology used to ensure compliance with the requirements of § 447.78 that the aggregate amount of premiums and cost sharing imposed for all individuals in the family does not exceed 5 percent of the family income of the family involved.
- The process for informing the recipients, applicants, providers, and the public of the schedule of premiums, enrollment fees, or similar fees for a group or groups of individuals in accordance with § 447.76.
- The notice of, timeframe for, and manner of required premium payments for a group or groups of individuals and the consequences for an individual who does not pay.

The burden associated with this requirement is the time and effort it would take for a State to include this detailed description in the State plan. We estimate it would take one State approximately 20 minutes to incorporate this information in their plan. We believe 56 States will be affected by this requirement for a total annual burden of 18.67 hours.

Section 447.68 Copayments, Coinsurance, Deductibles, or Similar Cost Sharing Charges: State Plan Requirements

Section 447.68 requires a State imposing copayments, coinsurance, deductibles, or similar cost sharing charges on individuals to describe in the State plan:

- The group or groups of individuals that may be subject to the cost sharing charge.
- The methodology used to determine family income, for purposes of the limitations on cost sharing related to family income that are described below, including the period and periodicity of those determinations.
- The item or service for which the charge is imposed.
- The methods, such as the use of integrated automated systems, for tracking cost sharing charges, informing recipients and providers of their liability, and notifying recipients and providers when individual recipients have paid the maximum cost sharing charges permitted for the period of time.
- The process for informing recipients, applicants, providers, and the public of the schedule of cost sharing charges for specific items and services for a group or groups of individuals in accordance with § 447.76.
- The methodology used to ensure that:
  - The aggregate amount of premiums and cost sharing imposed for all individuals with family income above 100 percent of the FPL does not exceed 5 percent of the family income of the family involved.

○ The aggregate amount of cost sharing under sections 1916, 1916A(c), and/or 1916A(e) of the Act for individuals with family income at or below 100 percent of the FPL does not exceed 5 percent of the family income of the family involved.

○ The notice of, timeframe for, and manner of required cost sharing and the consequences for failure to pay.

The burden associated with this requirement is the time and effort it would take for a State to include this detailed description in the State plan. We estimate it would take one State approximately 20 minutes to incorporate this information in their plan. We believe 56 States will be affected by this requirement for a total annual burden of 18.67 hours.

Comment: Some commenters stated that this regulation poses a much greater administrative burden than that estimated by CMS and believe that the State plan requirements are quite burdensome and CMS' estimate of 20 minutes per state is inaccurate. Among other things, States would need to change State law, State policy would need to be changed, systems would need to be changed, workers would need to be trained, providers would need to be notified, and most importantly, beneficiaries and their families, caretakers, and advocates would need to be informed. The commenter also indicated that the Regulatory Impact Analysis section of the proposed rule makes no reference to such costs on the States. In fact, the only estimate of the administrative burden on the States is in the Collection of Information Requirements where CMS estimates that it will take 20 minutes for a State to incorporate these requirements into a Medicaid State Plan. The commenters strongly disagree with this estimated time. The extensiveness of the requirements means that whenever a state might wish to change even a small portion of its plan, then a State Plan Amendment (SPA) would be required. This would be excessively burdensome on the States. Even with a State plan ''pre-print'' each State has unique processes for considering and requesting SPAs. In addition, each SPA must be accompanied by a CMS 179. The commenter also stated that CMS often asks one or more round of questions or requests more information, requiring additional State time and resources. Thus CMS' 20 minute estimate is in reality almost always more like tens of hours of staff time.

Response: In terms of the commenter's suggestion that the State plan requirements are quite burdensome and the estimate of 20 minutes per State is inaccurate, we considered these comments and believe that the estimate is accurate. In order to minimize the amount of time needed to complete a SPA imposing alternative premiums and cost sharing, we provided guidance to States in two State Medicaid Director's letters and we designed three State plan preprints that allow States to complete almost all of the sections by checking a box next to each answer. We expect that before completing the CMS 179 and State plan preprint, a State will have fully developed the information that describes the way in which States will provide for alternative premiums and cost sharing and can insert or attach this information to the preprint. With that assumption in mind, we estimated that it would take no more than 20 minutes to check off the appropriate boxes and to insert or attach any already created information concerning the imposition of premiums and cost sharing that is necessary to the completion of the State plan amendment. In this regard, we have made no revisions to the regulatory impact analysis.

Comment: Several commenters stated that Medicaid providers would be required to assume a large administrative burden to collect co-payments from Medicaid beneficiaries or take a financial loss if they choose to forgo collection of cost sharing. Hospitals would be placed in a situation in which the hospital must pursue patients for small, unpaid amounts, and at the same time, face lower payments by the State Medicaid program because the state assumes that the hospital has collected the co-payments. Ultimately, hospitals would be forced to write-off these uncollected co-payments as bad debt.

Response: We disagree that there will be additional administrative burden and administrative costs associated with imposing premiums and cost sharing. Prior to the DRA, section 1916 of the Act authorized the imposition of premiums and cost sharing and Federal rules on this subject have been in existence since 1974. Several States have already taken advantage of the premiums and cost sharing provision outlined in Section 1916 of the Act. States and providers are already aware of the effort to implement and impose premiums and cost sharing for Medicaid beneficiaries. In fact, we recognize in the regulatory impact analysis that savings will occur because we believe that States that already impose cost sharing will opt to impose the alternative cost sharing permitted under this rule. Thus, no additional administrative costs will be borne. If additional States choose to implement this option, more savings can accrue. We provide in Federal regulations that administrative costs are matched at 50 percent.

Section 447.76 Public schedule

Section 447.76(a) requires States to make available to the groups in paragraph (b) of § 447.76 a public schedule that contains the following information:

- Current premiums, enrollment fees, or similar fees.
- Current cost sharing charges.
- The aggregate limit on premiums and cost sharing.
- Mechanisms for making payments for required premiums and charges.
- The consequences for an applicant or recipient who does not pay a premium or charge.
- A list of hospitals charging alternative cost sharing for non-emergency use of the emergency department.

The burden associated with this requirement is the time and effort it would take the State to prepare and make available to appropriate parties a public schedule. We estimate that it would take 20 minutes per State. We believe 56 States will be affected by this requirement for an annual burden of 18.67 hours.

Section 447.80 Enforceability of premiums and cost sharing

Section 447.80(b)(2) states that a hospital that has determined after an appropriate medical screening pursuant to § 489.24, that an individual does not have an emergency medical condition before imposing cost sharing on an individual must provide the name and location of an available and accessible alternate non-emergency services provider as defined in section 1916A(e)(4)(B) of the Act, the fact that the alternate provider can provide the services with the imposition of a lesser cost sharing amount or no cost sharing, and a referral to coordinate scheduling of treatment by this provider before requiring payment of cost sharing.

The burden associated with this requirement is the time and effort it would take for a hospital to provide the name and location of an alternate provider who can provide services of a lesser cost sharing amount or no cost sharing and a referral. We estimate the burden on a hospital to be 30 minutes. We believe the number of hospital visits will be 4 million; therefore, the total annual burden is 2 million hours.

Specific comments on the burden associated with this requirement, and

our responses to those comments are as follows.

Comment: Several commenters stated that the Department has determined that this rule would not have a significant impact on the operations of a substantial number of small rural hospitals. Commenters stated the Department is plainly mistaken and that an impact analysis must be performed. Under proposed § 447.80, if a State imposes a co-payment for a beneficiary's non-emergency use of the hospital emergency room, the hospital must ''provide the beneficiary the name and location of an available and accessible alternate non-emergency services provider'', inform the beneficiary ''that the alternate provider can provide the services with the imposition of a lesser cost sharing amount or no cost sharing,'' and provide ''a referral to coordinate scheduling of treatment by'' the non-emergency care provider. Presumably, a State may withhold payment from or otherwise penalize a hospital that fails to take these steps. The Department recognizes the requirement would impose a ''burden'' on hospitals because CMS estimates the burden on a hospital to be 30 minutes. CMS estimated the response burden for these information requirements to be 2 million hours.

One commenter stated that in a hospital emergency room, anything that requires an additional 30 minutes of staff time per patient and that implicates compliance with Medicaid rules would almost certainly have a significant impact on the hospital's operations.

Response: We are required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)) to conduct a regulatory analysis of the impact of any regulatory revision to the Medicare, Medicaid, and/or the SCHIP program before adoption of any rule. A Regulatory Impact Analysis was completed for this rule and estimates in the proposed rule that 2 million hours will be the annual burden in considering cost sharing for non-emergency use of the hospital emergency room.

We agree that the initial estimate of 30 minutes in the proposed rule is incorrect. Upon further review, we have determined that on average, it is estimated that for each patient triaged at the hospital emergency room and found by the hospital emergency room physician to have a non-emergency medical condition which does not require emergency room treatment or stabilization, approximately five additional minutes will be required by staff to properly implement the requirements included in this rule. Our justification is that it will take no additional time for the emergency room physician or other health care provider to inform the beneficiary that he or she does not have an emergency medical condition which requires (further) care or stabilization in the hospital emergency room. The EMTALA legislation currently includes language that requires that individuals who present to the emergency room are screened for an emergency medical condition. Thus, this information is currently being conveyed to patients.

Since the State plan requirements under § 447.76 provide that the State must have, and make available, a public schedule that includes a listing of hospitals that charge alternative cost sharing for non-emergency use of the hospital emergency room and the current cost sharing charges, we believe hospitals will have the information available to inform Medicaid beneficiaries. We agree that it will not take 30 minutes to provide this information, but rather closer to five additional minutes. This information can and should be provided by the hospital emergency room registrar (that is, the person responsible for taking the information needed from patients to be seen in the emergency room) to inform the beneficiary that because the emergency room physician did not find that the patient has an emergency medical condition which requires (further) treatment (or stabilization) in the hospital emergency room and because the patient is a Medicaid beneficiary, the individual has a choice to go to a nearby alternate Medicaid provider or to receive treatment for the non-emergency medical condition at the emergency room but a higher co-pay can be imposed.

Consequently, we update the Collection of Information Requirements to indicate a revision in the annual burden from 2 million hours to approximately 300,000 hours. In considering this revision, we continue to believe that there is no significant impact on small rural hospitals.

We have updated the Collection of Information Requirements as follows:

Section 447.80 Enforceability of Premiums and Cost Sharing

Section 447.80(b)(2) states that a hospital that has determined after an appropriate medical screening pursuant to § 489.24, that an individual does not have an emergency medical condition before imposing cost sharing on an individual must provide: The name and location of an available and accessible alternate non-emergency services provider as defined in section 1916A(e)(4)(B) of the Act; the fact that the alternate provider can provide the services with the imposition of a lesser cost sharing amount or no cost sharing; and a referral to coordinate scheduling of treatment by this provider before requiring payment of cost sharing.

The burden associated with this requirement is the time and effort it would take for a hospital to provide the name and location of an alternate provider who can provide services of a lesser cost sharing amount or no cost sharing and a referral. We estimate the burden on a hospital to be 5 minutes. We believe the number of hospital visits will be 4,077,000; therefore, the total annual burden is 339,750 hours.

We have submitted a copy of this final rule to OMB for its review of the information collection requirements described above. These requirements are currently approved under OMB number 0938–0993.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this rule; or

2. Mail copies to the address specified in the **ADDRESSES** section of this rule and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, *Attn:*, CMS Desk Officer, *CMS–4064–F@omb.eop.gov.* Fax (202) 395–6974.

Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this final rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 (as amended by Executive Order 13258), directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential

economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimated that this rule is ''economically significant'' as measured by the $100 million threshold, and hence is also a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking.

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration definition of a small business (having revenues of less than $6.5 million to $31.5 million in any 1 year). Individuals and States are not included in the definition of a small entity. We have determined, and the Secretary certifies, that this rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Core-Based Statistical Area and has fewer than 100 beds. We have determined, and the Secretary certifies, that this rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million in 1995, updated annually for inflation. In 2008, that threshold level is approximately $130 million. We have determined that this rule would likely result in new spending by Medicaid enrollees in excess of the threshold. Table 2 outlines the total increase to Medicaid enrollees cost sharing as a result of all the provisions of the DRA. This includes an estimated cost increase to Medicaid recipients of $105 million in 2007, $155 million in 2008, $255 million in 2009, $375 million in 2010, and $455 million in 2011.

Executive Order 13132 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. We have determined that this rule would not impose substantial direct requirement costs on State and local governments.

B. Anticipated Effects

The following chart summarizes our estimate of the anticipated effects of this final rule.

TABLE 1—ESTIMATED SAVINGS OF THE COST SHARING PROVISIONS OF THE DEFICIT REDUCTION ACT (DRA) OF 2005

	Savings in millions of dollars					Total savings over 5 year period
	2007	2008	2009	2010	2011	
Federal Share						
Sec. 6041 Optional alternative premiums/ cost sharing	65	85	135	190	220	695
Sec. 6042 Cost sharing for prescription drugs	40	65	120	185	240	650
Sec. 6043(a) Copays for non-emergency care in ER	5	10	15	20	25	75
State Share						
Sec. 6041 Optional alternative premiums/ cost sharing	50	65	105	145	165	530
Sec. 6042 Cost sharing for prescription drugs	30	50	90	140	180	490
Sec. 6043(a) Copays for non-emergency care in ER	5	5	10	15	20	55

TABLE 2—MEDICAID ENROLLEES COST SHARING IMPACT AS A RESULT OF THE PROVISIONS OF THE DEFICIT REDUCTION ACT (DRA) OF 2005

	Costs in millions of dollars					Total increase in cost sharing over 5 year period
	2007	2008	2009	2010	2011	
Medicaid Enrollee Share						
Total increase in Medicaid enrollee cost sharing for all provisions	105	155	255	375	455	1345

These estimates are based on data regarding copayments in the Medicaid program derived from a 2004 Kaiser Family Foundation survey, and data on premiums from a 2004 report by the U.S. Government Accountability Office. In addition, we have used enrollment data from the Medicaid Statistical Information System and utilization data from the 2002 Medicaid Expenditure Panel Survey conducted by the Agency for Healthcare Research and Quality.

We assume that only states that currently charge copayments and/or premiums for some groups will take advantage of the option to expand the use of premiums and copayments under the DRA provisions. States now charging copayments are assumed to increase them on average to 75 percent of maximum possible levels by 2011, and States currently charging premiums are assumed to add premium requirements for some groups not currently allowed, also reaching 75 percent of the maximum possible by 2011.

In addition to direct savings from increased cost sharing, we assume there would be declines in utilization as some enrollees subject to new cost sharing requirements choose to decrease their use of services. The decline is assumed to create additional savings of 75 percent of direct savings for physician and outpatient hospital services, 100 percent for drugs, and 125 percent for dental services. These additional savings are assumed to be reduced somewhat as a result of some providers failing to collect copayments. Savings are split between Federal and State governments using an average matching rate of 57 percent.

Table 2 illustrates that the estimated impact for Medicaid enrollees as a result of all of the cost sharing provisions of the DRA are $105 million for 2007, $155 million for 2008, $255 million for 2009, $375 million for 2010, and $455 million for 2011. Although these estimates reflect an increase of costs to beneficiaries, we do not believe this will pose a barrier to accessing health care. The law provides that States can impose alternative cost sharing. We believe through the use of alternative cost sharing, States will help recipients become more educated and efficient health care consumers.

We did not receive any comments on this section.

C. Alternatives Considered

This final rule is necessary to implement section 1916A of the Social Security Act, which was established by the Deficit Reduction Act of 2005 (DRA) and amended by the Tax Relief and Health Care Act of 2006 (TRHCA). Therefore, we were not able to consider any alternatives.

D. Accounting Statement and Table

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in the table below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this rule. This table provides our best estimate of the decrease in Medicaid payment as a result of the changes presented in this final rule. All savings are classified as transfers to the Federal government.

TABLE 2—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM FY 2007 TO FY 2011

[In millions]

Category	TRANSFERS				
Annualized Monetized Transfers	3% Units Discount Rate $278.2			7% Units Discount Rate $270.7	
From Whom To Whom?	Beneficiaries to Federal Government				
Category	TRANSFERS				
Year	2007	2008	2009	2010	2011
Annualized Monetized Transfers	$110	$160	$270	$395	$485
From Whom to Whom?	Beneficiaries to Federal Government				
Category	TRANSFERS				
Annualized Monetized Transfers	3% Units Discount Rate $210.6			7% Units Discount Rate $205.0	
From Whom To Whom?	Beneficiaries to State Governments				
Category	TRANSFERS				
Year	2007	2008	2009	2010	2011
Annualized Monetized Transfers	$85	$120	$205	$300	$365
From Whom to Whom?	Beneficiaries to State Governments				

E. Conclusion

We expect that this final rule will promote the modernization of the Medicaid program. This final rule will also provide a new option to States to create programs that are aligned with today's Medicaid populations and the health care environment. Through alternative cost sharing, States will help recipients become more educated and efficient health care consumers.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs—

health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

42 CFR Part 457

Administrative practice and procedure, Grant programs—health, Health insurance, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 447—PAYMENTS FOR SERVICES

■ 1. The authority citation for part 447 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

■ 2. Section 447.54 is amended by—
■ A. Revising the section heading.
■ B. Adding a new introductory text.
■ C. Revising paragraph (a) introductory text.
■ D. Revising paragraph (a)(1) and paragraph (a)(3).
■ E. Adding a new paragraph (a)(4).

The additions and revisions read as follows.

§ 447.54 Maximum allowable and nominal charges.

Except as provided at §§ 447.62 through 447.82 of this part, the following requirements must be met:

(a) *Non-institutional services.* Except as specified in paragraph (b) of this section, for non-institutional services, the plan must provide that the following requirements are met:

(1) For Federal FY 2009, any deductible it imposes does not exceed $2.30 per month per family for each period of Medicaid eligibility. For example, if Medicaid eligibility is certified for a 3-month period, the maximum deductible which may be imposed on a family is $6.90. Thereafter, any deductible should not exceed these amounts as updated each October 1 by the percentage increase in the medical care component of the CPI–U for the period of September to September ending in the preceding calendar year, and then rounded to the next higher 5-cent increment.

* * * * *

(3)(i) For Federal FY 2009, any co-payments it imposes under a fee-for-service delivery system do not exceed the amounts shown in the following table:

State payment for the service	Maximum copayment
$10 or less	$0.60
$10.01 to $25	1.15
$25.01 to $50	2.30
$50.01 or more	3.40

(ii) Thereafter, any copayments should not exceed these amounts as updated each October 1 by the percentage increase in the medical care component of the CPI–U for the period of September to September ending in the preceding calendar year and then rounded to the next higher 5-cent increment.

(4) For Federal FY 2009, any copayment for services provided by an MCO may not exceed the copayment permitted under paragraph (a)(3)(i) of this section for comparable services under a fee-for-service delivery system, except as provided in this paragraph. When there is no fee-for-service delivery system, the copayment may not exceed $3.40 per visit or for individuals referenced in an approved State child health plan under title XXI pursuant to § 457.70(c), $5.70 per visit. In succeeding years, any copayment should not exceed these amounts as updated each October 1 by the percentage increase in the medical care component of the CPI–U for the period of September to September ending in the preceding calendar year and then rounded to the next higher 5-cent increment.

* * * * *

■ 3. Section 447.55 is amended by revising paragraph (b) to read as follows:

§ 447.55 Standard co-payment.

* * * * *

(b) This standard copayment amount for any service may be determined by applying the maximum copayment amounts specified in § 447.54(a) and (b) to the agency's average or typical payment for that service. For example, if the agency's typical payment for prescribed drugs is $4 to $5 per prescription, the agency might set a standard copayment of $.60 per prescription. This standard copayment may be adjusted based on updated copayments as permitted under § 447.54(a)(3).

■ 4. Add a new undesignated center heading immediately following § 447.60 and add new §§ 447.62, 447.64, 447.66, 447.68, 447.71, 447.72, 447.74, 447.76, 447.78, 447.80, and 447.82 to read as follows:

* * * * *

Sec.

Alternative Premiums and Cost Sharing Under Section 1916A

* * * * *

Alternative Premiums and Cost Sharing Under Section 1916A

§ 447.62 Alternative premiums and cost sharing: Basis, purpose and scope.

(a) Section 1916A of the Act sets forth options for alternative premiums and cost sharing, which are premiums and cost sharing that are not subject to the limitations under section 1916 of the Act as described in §§ 447.51 through 447.56. For States that impose alternative premiums, §§ 447.64 through 447.66, 447.72, 447.74, 447.78, and 447.80 prescribe State plan requirements and options for alternative premiums and the standards and conditions under which States may impose them. For States that impose alternative cost sharing, §§ 447.68 through 447.72, 447.74, 447.78, and 447.80 prescribe State plan requirements and options for alternative cost sharing and the standards and conditions under which States may impose alternative cost sharing. For other individuals, premiums and cost sharing must comply with the requirements described in §§ 447.50 through 447.60.

(b) Neither section 1916A of the Act nor the regulations referenced in paragraph (a) of this section affect the following:

(1) The Secretary's authority to waive limitations on premiums and cost sharing under this subpart.

(2) Existing waivers with regard to the imposition of premiums and cost sharing.

§ 447.64 Alternative premiums, enrollment fees, or similar fees: State plan requirements.

When a State imposes alternative premiums, enrollment fees, or similar fees on individuals, the State plan must describe the following:

(a) The group or groups of individuals that may be subject to the premiums, enrollment fees, or similar charges.

(b) The schedule of the premiums, enrollment fees, or similar fees imposed.

(c) The methodology used to determine family income for purposes of the limitations related to family income level that are described below, including the period and periodicity of those determinations.

(d) The methodology used to ensure compliance with the requirements of § 447.78 that the aggregate amount of premiums and cost sharing imposed for all individuals in the family do not exceed 5 percent of the family income of the family involved.

(e) The process for informing the recipients, applicants, providers, and the public of the schedule of premiums, enrollment fees, or similar fees for a group or groups of individuals in accordance with § 447.76.

(f) The notice of, time frame for, and manner of required premium payments for a group or groups of individuals and the consequences for an individual who does not pay.

§ 447.66 General alternative premium protections.

(a) States may not impose alternative premiums upon the following individuals:

(1) Individuals under 18 years of age that are required to be provided medical assistance under section 1902(a)(10)(A)(i) of the Act, and including individuals with respect to whom child welfare services are made available under Part B of title IV of the Act on the basis of being a child in foster care and individuals with respect to whom adoption or foster care assistance is made available under Part E of that title, without regard to age.

(2) Pregnant women.

(3) Any terminally ill individual receiving hospice care, as defined in section 1905(o) of the Act.

(4) Any individual who is an inpatient in a hospital, nursing facility, intermediate care facility, or other medical institution, if the individual is required, as a condition of receiving services in that institution under the State plan, to spend for costs of medical care all but a minimal amount of the individual's income required for personal needs.

(5) Women who are receiving Medicaid on the basis of the breast or cervical cancer eligibility group under sections 1902(a)(10)(A)(ii)(XVIII) and 1902(aa) of the Act.

(6) Disabled children who are receiving medical assistance by virtue of the application of sections 1902(a)(10)(A)(ii)(XIX) and 1902(cc) of the Act.

(b) States may exempt additional classes of individuals from premiums.

§ 447.68 Alternative copayments, coinsurance, deductibles, or similar cost sharing charges: State plan requirements.

When a State imposes alternative copayments, coinsurance, deductibles, or similar cost sharing charges on individuals, the State plan must describe the following:

(a) The group or groups of individuals that may be subject to the cost sharing charge.

(b) The methodology used to determine family income, for purposes of the limitations on cost sharing related to family income that are described below, including the period and periodicity of those determinations.

(c) The item or service for which the charge is imposed.

(d) The methods, such as the use of integrated automated systems, for tracking cost sharing charges, informing recipients and providers of their liability, and notifying recipients and providers when individual recipients have paid the maximum cost sharing charges permitted for the period of time.

(e) The process for informing recipients, applicants, providers, and the public of the schedule of cost sharing charges for specific items and services for a group or groups of individuals in accordance with § 447.76.

(f) The methodology used to ensure that:

(1) The aggregate amount of premiums and cost sharing imposed under section 1916 or section 1916A of the Act for individuals with family income above 100 percent of the FPL does not exceed 5 percent of the family income of the family involved.

(2) The aggregate amount of cost sharing under sections 1916, 1916A(c), and/or 1916A(e) of the Act for individuals with family income at or below 100 percent of the FPL does not exceed 5 percent of the family income of the family involved.

(g) The notice of, time frame for, and manner of required cost sharing and the consequences for failure to *pay*.

§ 447.70 General alternative cost sharing protections.

(a)(1) States may not impose alternative cost sharing for the following items or services. Except as indicated, these limits do not apply to alternative cost sharing for non-preferred prescription drugs within a class of such drugs or non-emergency use of the emergency room.

(i) Services furnished to individuals under 18 years of age who are required to be provided Medicaid under section 1902(a)(10)(A)(i) of the Act, and including services furnished to individuals with respect to whom child welfare services are made available under Part B of title IV of the Act on the basis of being a child in foster care and individuals with respect to whom adoption or foster care assistance is made available under Part E of that title, without regard to age.

(ii) Preventive services (for example, well baby and well child care and immunizations) provided to children under 18 years of age regardless of family income.

(iii) Services furnished to pregnant women, if those services relate to pregnancy or to any other medical condition which may complicate the pregnancy.

(iv) Services furnished to a terminally ill individual who is receiving hospice care (as defined in section 1905(o) of the Act).

(v) Services furnished to any individual who is an inpatient in a hospital, nursing facility, intermediate care facility for the mentally retarded, or other medical institution, if the individual is required, as a condition of receiving services in that institution under the State plan, to spend for costs of medical care all but a minimal amount of the individual's income required for personal needs.

(vi) Emergency services as defined at § 447.53(b)(4), except charges for services furnished after the hospital has determined, based on the screening and any other services required under § 489.24 of this chapter, that the individual does not have an emergency medical condition consistent with the requirements of paragraph (a)(2) of this section and § 447.80(b)(1).

(vii) Family planning services and supplies described in section 1905(a)(4)(C) of the Act.

(viii) Services furnished to women who are receiving medical assistance by virtue of the application of sections 1902(a)(10)(A)(ii)(XVIII) and 1902(aa) of the Act (breast or cervical cancer provisions).

(ix) Services furnished to disabled children who are receiving medical

assistance by virtue of the application of sections 1902(a)(10)(A)(ii)(XIX) and 1902(cc) of the Act.

(x) Preferred drugs within a class for individuals for whom cost sharing may not otherwise be imposed as described in paragraphs (a)(1)(i) through (ix) of this section.

(2) A State may impose nominal cost sharing as defined in § 447.54 for services furnished in a hospital emergency department, other than those required under § 489.24 of this chapter, if the hospital has determined based on the screening required under § 489.24 that the individual does not have an emergency medical condition, the requirements of § 447.80(b)(1) are met, and no cost sharing is imposed to receive the care through an outpatient department or another alternative health care provider in the geographic area of the hospital emergency department involved.

(b) In the case of a drug that is a preferred drug within a class, cost sharing may not exceed the levels permitted under section 1916 of the Act. Cost sharing can be imposed that exceeds section 1916 of the Act levels only for drugs that are not preferred drugs within a class in accordance with section 1916A(c) of the Act.

(c) In the case of a drug that is not a preferred drug, the cost sharing is limited to the amount imposed for a preferred drug if the following conditions are met:

(1) The prescribing physician determines that the preferred drug would be less effective or would have adverse effects for the individual or both.

(2) State criteria for prior authorization, if any, are met.

(d) States may exempt additional individuals, items, or services from cost sharing.

§ 447.71 Alternative premium and cost sharing exemptions and protections for individuals with family incomes at or below 100 percent of the FPL.

(a) The State may not impose premiums under the State plan on individuals whose family income is at or below 100 percent of the FPL.

(b) The State may not impose cost sharing under the State plan on individuals whose family income is at or below 100 percent of the FPL, with the following exceptions:

(1) The State may impose cost sharing under the State plan on individuals whose family income is at or below 100 percent of the FPL under authority provided under section 1916 of the Act and consistent with the levels described in such section and § 447.54.

(2) The State may impose cost sharing for non-preferred drugs that does not exceed the nominal amount as defined in § 447.54.

(3) The State may impose cost sharing for non-emergency services furnished in a hospital emergency department that does not exceed the nominal amount as defined in § 447.54 as long as no cost sharing is imposed to receive such care through an outpatient department or other alternative non-emergency services provider in the geographic area of the hospital emergency department involved.

(c) Aggregate cost sharing of the family under sections 1916, 1916A(c), and/or 1916A(e) of the Act may not exceed the maximum permitted under § 447.78(b).

§ 447.72 Alternative premium and cost sharing exemptions and protections for individuals with family incomes above 100 percent but at or below 150 percent of the FPL.

(a) The State may not impose premiums under the State plan on individuals whose family income exceeds 100 percent, but does not exceed 150 percent, of the FPL.

(b) Cost sharing may not exceed 10 percent of the payment the agency makes for the item or service, with the following exceptions:

(1) Cost sharing for non-preferred drugs cannot exceed the nominal amount as defined in § 447.54.

(2) Cost sharing for non-emergency services furnished in the hospital emergency department cannot exceed twice the nominal amount as defined in § 447.54. A hospital must meet the requirements described at § 447.80 before the cost sharing can be imposed.

(3) In the case of States that do not have fee-for-service payment rates, any copayment that the State imposes for services provided by an MCO may not exceed $3.40 per visit for Federal FY 2009 or for individuals referenced in an approved State child health plan under title XXI of the Act pursuant to § 457.70(c), $5.70 per visit for Federal FY 2009. Thereafter, any copayment may not exceed this amount as updated each October 1 by the percentage increase in the medical care component of the CPI-U for the period of September to September ending in the preceding calendar year and then rounded to the next highest 5-cent increment.

(c) Aggregate cost sharing of the family may not exceed the maximum permitted under § 447.78(a).

§ 447.74 Alternative premium and cost sharing protections for individuals with family incomes above 150 percent of the FPL.

(a) States may impose premiums consistent with the aggregate limits set forth in § 447.78(a).

(b) Cost sharing may not exceed 20 percent of the payment the agency makes for the item (including a non-preferred drug) or service, with the following exception: In the case of States that do not have fee-for-service payment rates, any copayment that the State imposes for services provided by an MCO may not exceed $3.40 per visit for Federal FY 2009 or for individuals referenced in an approved State child health plan under title XXI of the Act pursuant to § 457.70(c), $5.70 for Federal FY 2009. Thereafter, any copayment may not exceed this amount as updated each October 1 by the percentage increase in the medical care component of the CPI-U for the period of September to September ending in the preceding calendar year and then rounded to the next highest 5-cent increment.

(c) Aggregate premiums and cost sharing of the family may not exceed the maximum permitted under § 447.78(a).

§ 447.76 Public schedule.

(a) The State must make available to the groups in paragraph (b) of this section a public schedule that contains the following information:

(1) Current premiums, enrollment fees, or similar fees.

(2) Current cost sharing charges.

(3) The aggregate limit on premiums and cost sharing or just cost sharing.

(4) Mechanisms for making payments for required premiums and charges.

(5) The consequences for an applicant or recipient who does not pay a premium or charge.

(6) A list of hospitals charging alternative cost sharing for non-emergency use of the emergency department.

(7) Either a list of preferred drugs or a method to obtain such a list upon request.

(b) The State must make the public schedule available to the following:

(1) Recipients, at the time of their enrollment and reenrollment after a redetermination of eligibility, and when premiums, cost sharing charges, and the aggregate limits are revised.

(2) Applicants, at the time of application.

(3) All participating providers.

(4) The general public.

§ 447.78 Aggregate limits on alternative premiums and cost sharing.

(a) If a State imposes alternative premiums or cost sharing, the total aggregate amount of premiums and cost sharing under section 1916, 1916A(a), 1916A(c) or 1916A(e) of the Act for individuals with family income above 100 percent of the FPL may not exceed 5 percent of the family's income for the monthly or quarterly period, as specified by the State in the State plan.

(b) The total aggregate amount of cost sharing under sections 1916, 1916A(c), and/or 1916A(e) of the Act for individuals with family income at or below 100 percent of the FPL may not exceed 5 percent of the family's income for the monthly or quarterly period, as specified in the State plan.

(c) Family income shall be determined in a manner and for that period as specified by the State in the State plan including the use of such disregards as the State may provide.

(1) States may use gross income or any other methodology.

(2) States may use a different methodology for determining the aggregate limits than they do for determining income eligibility.

§ 447.80 Enforceability of alternative premiums and cost sharing.

(a) With respect to alternative premiums, a State may do the following:

(1) Require a group or groups of individuals to prepay.

(2) Terminate an individual from medical assistance on the basis of failure to pay for 60 days or more.

(3) Waive payment of a premium in any case where it determines that requiring the payment would create an undue hardship.

(b) With respect to alternative cost sharing, a State may permit a provider, including a pharmacy to require an individual, as a condition for receiving the item or service, to pay the cost sharing charge, except as specified in paragraphs (b)(1) through (3) of this section.

(1) A provider, including a pharmacy and a hospital, may not require an individual whose family income is at or below 100 percent of the FPL to pay the cost sharing charge as a condition of receiving the service.

(2) A hospital that has determined after an appropriate medical screening pursuant to § 489.24, that an individual does not have an emergency medical condition, before imposing cost sharing on an individual, must provide the name and location of an available and accessible alternate non-emergency services provider as defined in section 1916A(e)(4)(B) of the Act, the fact that the alternate provider can provide the services with the imposition of a lesser cost sharing amount or no cost sharing, and a referral to coordinate scheduling of treatment by this provider before requiring payment of cost sharing.

(3) The provider is not prohibited by this authority from choosing to reduce or waive cost sharing on a case-by-case basis.

§ 447.82 Restrictions on payments to providers.

The plan must provide that the agency reduces the payment it makes to any provider by the amount of a recipient's cost sharing obligation, regardless of whether the provider successfully collects the cost sharing.

PART 457—ALLOTMENTS AND GRANTS TO STATES

■ 5. The authority citation for part 457 continues to read as follows:

Authority: Section 1102 of the Social Security Act (42 U.S.C. 1302).

■ 6. Section 457.555 is amended by—

■ A. Revising paragraphs (a) introductory text, and (a)(1), (2), and (4).

■ B. Revising paragraph (c).

■ C. Revising paragraph (d).

The revisions read as follows:

§ 457.555 Maximum allowable cost sharing charges on targeted low-income children in families with income from 101 to 150 percent of the FPL.

(a) *Non-institutional services.* For targeted low-income children whose family income is from 101 to 150 percent of the FPL, the State plan must provide that for non-institutional services, including emergency services, the following requirements must be met:

(1)(i) For Federal FY 2009, any co-payment or similar charge the State imposes under a fee-for-service delivery system may not exceed the following amounts:

Total cost	Maximum amount
$15 or less	$1.15
$15.01 to $40	2.30
$40.01 to $80	3.40
$80.01 or more	5.70

(ii) Thereafter, any copayments may not exceed these amounts as updated each October 1 by the percentage increase in the medical care component of the CPI–U for the period of September to September ending in the preceding calendar year and then rounded to the next higher 5-cent increment.

(2) For Federal FY 2009, any co-payment that the State imposes for services provided by a managed care organization may not exceed $5.70 per visit. Thereafter, any copayment may not exceed this amount as updated each October 1 by the percentage increase in the medical care component of the CPI–U for the period of September to September ending in the preceding calendar year and then rounded to the next higher 5-cent increment.

* * * * *

(4) For Federal FY 2009, any deductible the State imposes may not exceed $3.40 per month, per family for each period of eligibility. Thereafter, any deductible may not exceed this amount as updated each October 1 by the percentage increase in the medical care component of the CPI–U for the period of September to September ending in the preceding calendar year and then rounded to the next higher 5-cent increment.

* * * * *

(c) *Institutional emergency services.* For Federal FY 2009, any copayment that the State imposes on emergency services provided by an institution may not exceed $5.70. Thereafter, any copayment may not exceed this amount as updated each October 1 by the percentage increase in the medical care component of the CPI–U for the period of September to September ending in the preceding calendar year and then rounded to the next higher 5-cent increment.

(d) *Non-emergency use of the emergency room.* For Federal FY 2009, for targeted low-income children whose family income is from 101 to 150 percent of the FPL, the State may charge up to twice the charge for non-institutional services, up to a maximum amount of $11.35 for services furnished in a hospital emergency room if those services are not emergency services as defined in § 457.10. Thereafter, any charge may not exceed this amount as updated each October 1 by the percentage increase in the medical care component of the CPI–U for the period of September to September ending in the preceding calendar year and then rounded to the next higher 5-cent increment.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: July 24, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: August 25, 2008.

Michael O. Leavitt,

Secretary.

Editorial Note: This document was received in the Office of the Federal Register on November 18, 2008.

[FR Doc. E8–27717 Filed 11–19–08; 11:15 am]

BILLING CODE 4120–01–P