

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 447 and 457

[CMS–2244–FC]

RIN 0938–AP73

Medicaid Program; Premiums and Cost Sharing

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

ACTION: Final rule with comment period.

SUMMARY: This final rule revises the November 25, 2008 final rule entitled, “Medicaid Programs; Premiums and Cost Sharing (73 FR 71828),” to address public comments received during reopened comment periods, and to reflect relevant statutory changes made in section 5006(a) of the American Recovery and Reinvestment Act of 2009 (the Recovery Act). This revised final rule implements and interprets section 1916A of the Social Security Act (the Act), which was added by sections 6041, 6042, and 6043 of the Deficit Reduction Act of 2005 (DRA), amended by section 405(a)(1) of the Tax Relief and Health Care Act of 2006 (TRHCA) and further amended by section 5006(a) of the American Recovery and Reinvestment Act of 2009 (the Recovery Act). These provisions increase State flexibility to impose premiums and cost sharing for coverage of certain individuals whose family income exceeds specified levels. This revised rule also provides a further opportunity for public comment on revisions made to implement and interpret section 5006(a) of the Recovery Act. The Recovery Act prohibits States from charging premiums and cost sharing under Medicaid to Indians furnished items or services directly by the Indian Health Service, Indian Tribes, Tribal Organizations, or Urban Indian Organizations or through referral under contract health services.

DATES:

Effective Date: These regulations are effective on July 1, 2010.

Comment Date: To be assured of consideration, comments limited to the implementation of section 5006(a) of the Recovery Act must be received at one of the addresses provided below, no later than 5 p.m. on July 27, 2010.

ADDRESSES: In commenting, please refer to file code CMS–2244–FC.

You may submit comments in one of four ways (please choose only one of the ways listed). We cannot accept

comments by facsimile (FAX) transmission.

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the “More Search Options” tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2244–FC, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2244–FC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document’s paperwork requirements by following the instructions at the end of the

“Collection of Information Requirements” section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Christine Gerhardt, (410) 786–0693.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

A. Statutory Authority

The Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171) was enacted on February 8, 2006. 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. 109–432, enacted on December 20, 2006). Section 1916A of the Act sets forth State 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 adopt certain rules with respect to the nonpayment and 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 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 of the Act (per the Emergency Medical Treatment and Active Labor 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 and that an available and accessible alternate non-emergency services provider can provide the services in a timely manner without the imposition of the same cost sharing, before providing the non-emergency services and imposing cost sharing, it must inform the individual of the availability of such services from the accessible non-emergency services provider and coordinate a referral to that provider. After notice is given, the hospital may require payment of the cost sharing before providing non-emergency services, if the individual elects to receive the non-emergency services from the hospital. The cost sharing cannot be imposed if no available alternative non-emergency service provider exists.

Section 5006(a) of the American Recovery and Reinvestment Act of 2009

(the Recovery Act) (Pub. L. 111–5, enacted on February 17, 2009) amended sections 1916 and 1916A of the Act effective July 1, 2009. Specifically, Section 5006(a)(1)(A) of the Recovery Act amended section 1916 of the Act to add a new subsection (j), which prohibits premiums and cost sharing for Indians who are provided services or items covered under the Medicaid State plan by Indian health care providers or through referral under contract health services. Section 5006(a)(2) of the Recovery Act amended section 1916A(b)(3)(A) of the Act to add a new clause prohibiting premiums on an Indian furnished an item or service directly by Indian health care providers or through referral under contract health services, and also added a clause to 1916A(b)(3)(B) prohibiting cost sharing for that population. In addition, section 5006(a)(1)(B) of the Recovery Act amended section 1916 of the Act to specify that payments to Indian health care providers or to a health care provider through referral under contract health services for Medicaid services or items furnished to Indians cannot be reduced by the amount of any enrollment fee, premium, or cost sharing that otherwise would be due from the individual.

We also acknowledge the importance of providing adequate mental health benefits and will be separately addressing how the laws following the DRA, including the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (Pub. L. 110–343), relate to the Medicaid program regarding the treatment of beneficiary cost sharing.

B. Regulatory History

On February 22, 2008, we published a proposed rule in the **Federal Register** (73 FR 9727) that proposed to implement and interpret the provisions of sections 6041, 6042, and 6043 of the DRA. A final rule entitled “Medicaid Program; Premiums and Cost Sharing” was published in the **Federal Register** on November 25, 2008 (73 FR 71828).

On January 27, 2009, prior to the effective date of the November 25, 2008 final rule, we published a final rule in the **Federal Register** (74 FR 4888) that temporarily delayed for 60 days the effective date of the November 25, 2008 final rule and reopened the comment period on the policies set out in the November 25, 2008 final rule.

On March 27, 2009, we published a second final rule in the **Federal Register** (74 FR 13346) that further delayed the effective date of the November 25, 2008 final rule until December 31, 2009. We stated that the delay was needed

because our initial review had indicated that substantial revisions to the final rule would be needed. Also, the comment period was again reopened, for two purposes: for additional comments on the policies set forth in the November 25, 2008 final rule, and for comments on revisions needed to reflect section 5006(a) of the Recovery Act (related to the exclusion of Indians from payment of premiums and cost sharing).

On October 30, 2009, we published a proposed rule in the **Federal Register** (74 FR 56151) to delay further the effective date of the November 25, 2008 final rule until July 1, 2010. Upon review and consideration of the public comments received and the provisions of the Recovery Act, we determined that we needed more time to review and revise the November 25, 2008 final rule. On November 30, 2009, we published a third final rule in the **Federal Register** (74 FR 62501) that delayed the effective date of the November 25, 2008 final rule until July 1, 2010.

II. Provisions of the November 25, 2008 Final Rule and the Extended Comment Period and Analysis of and Response to Public Comments

A. Public Comments

We received approximately 50 timely items of correspondence during the public comment period for the February 22, 2008 proposed rule, which we addressed in the November 25, 2008 final rule. We received approximately 5 timely items of correspondence (including 20 specific comments) in response to the January 27, 2009 reopening of the comment period. In addition, we received approximately 10 timely items of correspondence (including 36 specific comments) in response to the March 27, 2009 reopening of the comment period. Summaries of those public comments and our responses are set forth in the various sections of this final rule under the appropriate heading.

B. General Comments

A majority of the public comments received for the January 27, 2009 and March 27, 2009 extended comment periods were similar to comments received on the February 22, 2008 proposed rule, which we addressed in the November 25, 2008 final rule. In light of the continued concerns reflected by these comments, and additional review of available research, State practice, and changes in overall economic circumstances throughout the country, we have reconsidered our responses to these comments. In

particular, we have given greater weight to concerns about maintaining access to services for needy families. A summary of the general comments received and our responses are as follows:

Comment: Several commenters stated that the rule would significantly reduce affordability of care and patients' access to adequate care, and would result in decreased utilization of essential health care services, increased adverse events, and worsened health status due to less use of health care characterized as "effective" and subsequent use of more costly care. These commenters requested that the final rule reflect the need for caution and care when imposing premiums and cost sharing charges on low-income Medicaid beneficiaries. These commenters asserted that the November 25, 2008 final rule would allow States to increase health care expenses for vulnerable citizens, result in more crisis situations that lead to more expensive hospitalizations, limit access to basic health care, and force out people who need services most. These commenters argued that increased flexibility for States to impose premiums or cost sharing is detrimental to low-income populations, unless there are explicit restrictions on maximum premium and cost sharing levels.

One commenter described her personal situation that she would have inadequate money for food or rent if her copayments were increased.

Response: We appreciate the significant concerns expressed in these comments and agree that there is ample evidence that cost is a significant barrier to people accessing coverage and care, particularly for those with low or moderate incomes. These are important issues with which States must contend when they determine whether to impose premiums and cost sharing for their Medicaid and Children's Health Insurance Program (CHIP) populations and as they design and implement these provisions. CMS also must be mindful of these issues as we promulgate rules and oversee the operation of Medicaid and CHIP. However, to the extent that these comments reflect fundamental disagreements with the statutory flexibility and requirements enacted in sections 1916 and 1916A of the Act, we note that CMS is charged with implementing applicable statutory provisions.

We have developed the revised final rule in accordance with the provisions set forth at sections 1916 and 1916A of the Act. This regulation is consistent with the statute and reflects little interpretive policy by CMS; therefore, we are unable to change major aspects

of the revised final rule based on these comments.

In light of public comments, we have, however, reconsidered some of our prior responses to comments on specific interpretive issues, in order to increase the protections for vulnerable populations to the extent consistent with the statutory requirements. As we discuss in greater detail in responding to specific public comments on each issue below, in this revised rule we are:

- Reducing the maximum copayment amount from \$5.70 (the maximum copayment amount for children in separate CHIP programs) to \$3.40 per visit in fiscal year 2009 (which is then adjusted for inflation annually) for Medicaid expansion optional targeted low income children enrolled in managed care organizations, when a State does not have a fee-for-service system.

- Specifying that a State that adopts cost sharing rules that could result in aggregate costs to the family that exceed five percent of the family's income must: (1) Describe in its Medicaid State plan the methodology it will use to identify beneficiaries who are subject to premiums or cost sharing for specific items or services; and (2) track beneficiaries' incurred premiums and cost sharing through a mechanism developed by the State that does not rely on beneficiaries. These requirements are imposed so that the State is able to inform beneficiaries and providers of beneficiaries' liability and notify beneficiaries and providers when individual beneficiaries have reached the five percent limit on family out-of-pocket expenses and so are no longer subject to further cost sharing for the remainder of the family's current monthly or quarterly cap period. Ideally, for ease of administration and accuracy, States will use automated systems to track these cost sharing amounts.

- Specifying that a State must describe in its Medicaid State plan how the State identifies for providers, ideally through the use of automated systems, whether cost sharing for a specific item or service may be imposed on an individual beneficiary and whether the provider may require the beneficiary, as a condition for receiving the item or service, to pay the cost sharing charge.

- Specifying at a minimum the services listed at § 457.520 as the preventive services that must be excluded from cost sharing for children younger than age 18, which reflect the well baby and well child care and immunizations described by the Bright Futures guidelines of the American Academy of Pediatrics.

- Requiring States to describe in their Medicaid State plan their process for beneficiaries to request a reassessment of the family's aggregate limit for premiums and cost sharing if the family's income is reduced or if eligibility is being terminated due to nonpayment of premiums.

- Clarifying that the statutory exclusion of family planning services and supplies from cost sharing encompasses the entire range of such services for which the State claims or could claim the enhanced Federal matching rate for family planning services and supplies under section 1903(a)(5) of the Act, including contraceptives and other pharmaceuticals.

- Clarifying that the statutory exclusion of certain populations and services from cost sharing exceeding a nominal amount means that drugs not identified by a State as non-preferred drugs within a class of pharmaceuticals are subject to the same exclusions from cost sharing as preferred drugs.

- Requiring States to submit documentation with a State plan amendment proposing to establish or substantially modify alternative premiums or cost sharing under section 1916A of the Act that the State provided the public with advance notice of the amendment and reasonable opportunity for comment in a form and manner provided under applicable State law.

CMS will continue to carefully review State plan amendments submitted to implement or modify premiums or cost sharing to ensure that the processes described adhere to the statutory and regulatory requirements.

We further note that the concerns expressed by the commenters may be widely shared. To date, only 8 States have approved State plan amendments for alternative premiums and/or cost sharing under section 1916A of the Act. These provisions are usually applied to narrowly defined, higher income populations and/or to limited services, such as premiums for specific expansion populations or slightly more than nominal pharmacy copayments.

Comment: We also received a recommendation that the rule should reflect the change in course signaled by the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) to strengthen quality of care, ensure the availability of preventive services, and enhance access to needed services to improve health outcomes. The commenter also recommended that rigorous data collection accompany any enhanced cost sharing, to determine whether higher co-payment requirements present a greater access

barrier to people with disabilities. The commenter further recommended that providers report to States and that States report to CMS at least a sample of the race and ethnicity of individuals for whom providers approved a waiver from mandatory co-payments on a case-by-case basis, in order to demonstrate that the waiver does not have a disparate effect on people of color or non-English-speaking individuals.

Response: While we agree with the commenter's overall sentiments, we believe it is important to consider these kinds of recommended information collection and reporting requirements separately, in conjunction with other similar potential information collection and reporting requirements. CMS has broad authority under section 1902(a)(6) of the Act to require States to report any needed information, but it is important to carefully consider such reporting requirements and ensure that they can be integrated with existing State responsibilities and are not overly burdensome. Because providers are not required to report on their claims for Medicaid reimbursement whether the provider collected a mandatory copayment, requiring providers to obtain and submit information about the race and ethnicity of individuals for whom the provider waived a copayment would be burdensome and costly for all involved, even for a sample of claims.

C. General Comments on the Exemption of Indians From Premiums and Cost Sharing

We received the following general comments concerning the exemption of Indians furnished items or services directly by an Indian health care provider (the Indian Health Service (IHS), an Indian Tribe, a Tribal Organization, or an Urban Indian Organization) or through referral under contract health services from payment of premiums and cost sharing effective July 1, 2009, in accordance with the section 5006(a) of the Recovery Act.

Comment: Several commenters urged CMS to fulfill its responsibilities for early Tribal consultation, which did not occur with the original cost-sharing rule.

Response: CMS believes that it is in compliance with applicable Tribal consultation responsibilities, but notes that considerable additional consultation was undertaken since the original cost sharing rule was published. Further, we are open to specific suggestions as to how to maximize the effectiveness of Tribal consultation. In our March 27, 2009 final rule, we specifically requested public comment on the new provisions exempting

Indians from premiums and cost sharing, and we believe that there has been a full opportunity for Tribes to raise issues of concern. Moreover, the Recovery Act contains expanded consultation responsibilities for States in implementing options under the Federal Medicaid and CHIP statutes.

In keeping with the Department's Tribal consultation policy and the new provisions in the Recovery Act, CMS collaborated and consulted with the Tribal Technical Advisory Group (TTAG) and the IHS to solicit advice on implementing these provisions. The Tribal Affairs Group and the Center for Medicaid, CHIP and Survey and Certification within CMS jointly hosted two All Tribes Calls on June 5 and 12, 2009, to consult on implementation of section 5006 of the Recovery Act. Two face-to-face consultation meetings were held in Denver on July 8 and 10, 2009, to solicit advice and input on these provisions from federally-recognized Tribes, Indian health care providers, and Urban Indian Organizations. An All-States Call was held on June 10, 2009, with the State Medicaid and CHIP programs, to describe the CMS Tribal consultation process and the Recovery Act provisions and to solicit feedback and questions from States.

Comment: A commenter asserted that CMS should adopt the TTAG recommendation to adopt an interim rule to implement section 5006(a) of the Recovery Act by July 1, 2009, because, otherwise, violations of the new provision could occur and go undetected. The commenter stated that it is important for CMS to assure that mechanisms are put in place timely at the State level, to assure compliance with this new provision as of the effective date of July 1, 2009.

Response: The requirements of section 5006(a) of the Recovery Act were effective as of July 1, 2009, and CMS intends to work with States to implement the statutory requirements through its compliance reviews and reviews of State plan amendments. CMS issued a letter to State Medicaid Directors and State Health Officials on January 22, 2010 (SMDL# 10-001/ARRA# 6), providing guidance on implementation of section 5006 of the Recovery Act.

The Congress did not expressly provide authority for interim final rulemaking authority under the Recovery Act. In light of the strong public interest in timely protection of the exempt Indian populations, we provided the interim guidance to States described above and have diligently pursued the rulemaking process.

Comment: A commenter asked that CMS establish effective procedures to properly enforce this provision, including a new audit element to quickly detect any prohibited reductions in providers' payments or other violations. The commenter asserted that States must make supplemental payments to providers for any prohibited reductions in payment.

Response: Congress did not provide for any new enforcement mechanism for these provisions, and it is not clear that existing enforcement mechanisms are inadequate. All States have an appeal process through which beneficiaries and providers can appeal State determinations concerning the amount of medical assistance. CMS involvement is primarily through the State plan approval process. In addition, CMS has authority to initiate compliance actions under section 1904 of the Act in the event of systemic noncompliance by a State.

Comment: Another commenter recommended that CMS include requirements for administrative simplicity in the implementation of the Recovery Act's new exclusion of Native Americans from cost-sharing, including ease of tribal membership documentation.

Response: We agree that administrative simplicity is very important. Therefore, we have defined the term "Indian" for purposes of the exemption from premiums and cost sharing in broad terms that indicate the kinds of documentation that could support the application of the exception.

Specifically, *Indian* means any individual defined at 25 USC 1603(c), 1603(f), or 1679(b), or who has been determined eligible as an Indian, pursuant to 42 CFR 136.12. This means the individual:

- (1) Is a member of a Federally-recognized Indian tribe;
- (2) resides in an urban center and meets one or more of the four criteria:
 - (a) Is a member of a tribe, band, or other organized group of Indians, including those tribes, bands, or groups terminated since 1940 and those recognized now or in the future by the State in which they reside, or who is a descendant, in the first or second degree, of any such member;
 - (b) is an Eskimo or Aleut or other Alaska Native;
 - (c) is considered by the Secretary of the Interior to be an Indian for any purpose;
 - or (d) is determined to be an Indian under regulations promulgated by the Secretary;
- (3) is considered by the Secretary of the Interior to be an Indian for any purpose; or

(4) is considered by the Secretary of Health and Human Services to be an Indian for purposes of eligibility for Indian health care services, including as a California Indian, Eskimo, Aleut, or other Alaska Native.

Documentation that an individual is an Indian could include Tribal enrollment and membership cards, a certificate of degree of Indian blood issued by the Bureau of Indian Affairs, a Tribal census document, or a document issued by a Tribe indicating an individual's affiliation with the Tribe. The Indian health care programs and urban Indian health programs are responsible for determining who is eligible to receive an item or service furnished by their programs and so a medical record card or similar documentation that specifies an individual is an Indian as defined above could suffice as appropriate documentation. These documents are examples of documents that may be used, but do not constitute an all-inclusive list of such documents.

Comment: A commenter also stated that Tribal leaders are not cognizant of all the impacts that these changes will have on the elderly Indian populations enrolled in Medicaid. The commenter stated that none of this information has been provided by CMS or the IHS.

Response: As described above, CMS has engaged in an extensive Tribal consultation process, providing information to the Tribes, soliciting their input, and incorporating changes into this revised rule based on that input.

Comment: A commenter stated that for Indians who use the IHS system, Medicaid is considered the primary payer, and IHS is considered the payer of last resort according to 42 CFR 136.61. Therefore, the commenter asserted that a conflict exists between section 5006 of the Recovery Act specifying circumstances under which Indians may not be charged cost-sharing (and so defining when they may be charged cost sharing) and the IHS payer of last resort policy, as well as Federal responsibility in providing health care for Native Americans.

Response: We do not see any conflict between the exclusion of Indians from Medicaid premiums and cost sharing and the IHS payer of last resort rule, which was included in section 2901 of the Patient Protection and Affordable Care Act of 2010, Public Law 111-148. We also do not see any conflict with overall Federal responsibilities toward Indian health care. Indeed, we believe that these policies are consistent and ensure that Medicaid programs will pay for health care coverage of Medicaid

items and services primary to both IHS and to individual Indians.

Comment: A commenter expressed concern that CMS seems to feel that the statutory framework for the cost sharing rule reflects the principle that States are in the best position to weigh the Tribes' concerns, as Sovereign Nations, and that the States alone are to determine the appropriate levels and scope of alternative cost sharing. The commenter noted that the Tribes' poorest people who are on Medicaid cannot afford even the smallest cost sharing, and the commenter was concerned that CMS ensure that States follow requirements to consult with Tribes prior to implementing cost sharing that will directly affect the Tribes and indigent patients.

Response: We agree that there are special concerns about cost sharing for Indians, and we believe that Congress recognized these concerns in enacting the Recovery Act protections for Indians from cost sharing that are being implemented in this revised final rule, and the new requirements for CMS to maintain the TTAG and for States to engage in tribal consultation under section 5006(e) of the Recovery Act. We will continue to monitor State compliance with tribal consultation requirements in all aspects of the Medicaid program.

D. Comments From the January 27, 2009 and March 27, 2009 Extended Comment Periods on the November 25, 2008 Final Rule

Following is a summary of each provision in the February 22, 2008 proposed rule entitled "Medicaid Programs: Premiums and Cost Sharing" that was addressed in a public comment. We include a background summary of any changes included in the final rule published on November 25, 2008 based on comments received during the initial comment period; and then a summary of the additional comments on the final rule that were received during the reopened comment periods beginning on January 27 and March 27, 2009; and responses to those additional comments.

Maximum Allowable and Nominal Charges (§ 447.54)

Under DRA § 6041(b)(2), adding § 1916(h) to the Social Security Act, the Secretary was authorized to adjust the regulatory definition of nominal charges. In reviewing those definitions, we also addressed the issue of maximum charges by managed care organizations (MCO). CMS had previously, in interpreting regulatory provisions that addressed maximum

charges only under fee-for-service systems, limited MCO charges to an estimate of the charges that would have been allowed under a fee-for-service system. In the February 22, 2008 proposed rule, we proposed to revise § 447.54 to provide updates for Federal fiscal year (FY) 2007 to 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) by applying an inflation factor, and described a methodology for future inflation-based updates that included rounding the maximum copayment amounts to the next highest 10-cent increment. We also proposed to add a new § 447.54(a)(4) to establish a maximum copayment amount for Federal FY 2007 for services provided by an MCO, in light of the difficulty in determining comparable fee-for-service charges. We noted that a similar MCO limit was applied under the CHIP program.

In the November 25, 2008 final rule, we updated the maximum nominal copayments to reflect amounts for Federal FY 2009. The amounts were rounded to the next highest 5-cent increment rather than 10-cent increment, to be consistent with the Medicare Part D program. In addition, we clarified that we would calculate the update each year without considering any rounding adjustment made in the previous year. A new paragraph (a)(4) was added to specify that the copayment amount for services provided by an MCO may not exceed the copayment amount for comparable services under a fee-for-service delivery system. In the circumstance when there is no fee-for-service delivery system under the plan, we specified that the copayment amount for services furnished by an MCO may not exceed the maximum copayment amount under a fee-for-service delivery system, which was \$3.40 per visit for Federal FY 2009 (based on the maximum fee-for-service copayment under Medicaid), or for individuals referenced in an approved State child health plan under title XXI of the Act, a higher different maximum MCO copayment amount of \$5.70 per visit (based on the maximum fee-for-service amount for children enrolled in separate CHIP programs under title XXI of the Act).

Specific comments to this section submitted during the reopened comment periods and our responses to those additional comments are as follows:

Comment: Several commenters recommended deletion of the \$5.70 per

visit maximum Medicaid copayment specifically for children in CHIP-related Medicaid expansions under managed care plans when a State does not have a fee-for-service system. This amount was added in the final rule published on November 25, 2008.

Response: We agree with the underlying concern that copayments for such children would exceed levels otherwise considered nominal under the Medicaid program. Therefore, in this revised final rule, we have deleted the higher maximum copayment amount for Medicaid expansion children enrolled with MCOs. The same maximum copayment of \$3.40 per visit for Federal FY 2009 will be applied for Medicaid expansion children as for all other Medicaid beneficiaries enrolled in MCOs. While our intent had been to align the Medicaid and CHIP programs by permitting the same copayment levels under either program, we have been convinced by the commenters that the status of the children under the Medicaid program should be of primary importance, because it indicates a State's determination that the children should be entitled to all the benefits and protections of the Medicaid program. We have always applied Medicaid-specific rules to Medicaid expansion programs, even if those rules vary from the rules applicable to separate CHIP programs. The importance of ensuring coverage for children and reducing barriers to such coverage has been affirmed generally by Congress in CHIPRA, which expanded and improved the CHIP program while maintaining the option of using CHIP funding for serving children through the Medicaid program.

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

In the February 22, 2008 proposed rule, we proposed to implement the flexibility for States to impose alternative premiums and cost sharing with 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 limited to prescription drugs and non-emergency services furnished in a hospital emergency room.

In the November 25, 2008 final rule, we accepted the provisions of the proposed rule without change but added a provision that clarified that individuals with family income at or below 100 percent of the FPL could be charged nominal copayments to the extent consistent with section 1916 of the Act.

Specific comments on this section received during the reopened comment period, and our responses to those additional comments, are as follows:

Comment: Several commenters recommended that the alternative premium and cost sharing rules be simplified and clarified as much as possible, such as the different requirements based on the family's income level, because neither the State nor providers have the resources to implement these complex rules.

Response: We agree that the regulatory presentation of the statutory limitations on alternative premiums and cost sharing may have been confusing. In this revised final rule at § 447.62(a) and (b)(1), we have attempted to clarify the regulatory provisions to better ensure consistency with the statutory requirements in sections 1916 and 1916A of the Act. The basic provisions of this section, such as the different exclusions and limits based on a family's income level, are defined in statute and are by nature complex. We have attempted to describe these complex exclusions and limits in the simplest and most straightforward manner possible in this revised rule.

Comment: A commenter recommended that the rule be revised to make it clear that the Secretary of Health and Human Services' (HHS) authority to waive cost sharing provisions under section 1916A of the Act is limited in accordance with section 1916(f) of the Act.

Response: In this revised final rule, we included language in § 447.62(b) to clarify the text, taking into account the amendment to section 1916(f) of the Act made by section 6041(b)(1) of the DRA. In light of section 1916A of the Act and the provision of the DRA that applies section 1916(f) to 1916A of the Act, we are reviewing our policies under section 1115 of the Social Security Act.

Comment: Several commenters advised that giving States the flexibility to exclude additional groups of individuals from payment of premiums or cost sharing should not have the effect of discriminating against individuals on the basis of race, color, national origin, or disability (title VI of the Civil Rights Act of 1964, Americans with Disabilities Act (ADA), 42 CFR 430.2(b), 45 CFR Part 80).

Response: We agree. Existing HHS regulations under these civil rights and other statutes, including section 504 of the Rehabilitation Act, already prohibit both States and entities that receive Federal Medicaid funding from taking discriminatory actions. The HHS Office for Civil Rights (responsible for Departmental enforcement of most civil

rights laws) and the Department of Justice (which also has responsibility for enforcement of certain civil rights laws, including the Americans with Disabilities Act), are available to investigate any questions or complaints as to illegal discrimination under these statutes and the implementing regulations.

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

We proposed at § 447.64(a), 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 include a schedule of the premiums, enrollment fees, or similar charges. 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. In addition, at § 447.64(e), we proposed that the State plan specify the process for informing beneficiaries, applicants, providers, and the public of the schedule. We further proposed in § 447.64(f) that the State plan describe the premium payment terms for the group or groups and the consequences for an individual who does not pay.

In the November 25, 2008 final rule, we accepted the provisions of the proposed rule with no substantive changes.

Specific comments to this section submitted during the reopened comment periods and our responses to those additional comments are as follows:

Comment: Several commenters requested that the State agency, rather than beneficiaries or managed care organizations, be required to track each beneficiary's aggregate incurred premiums and cost sharing, to assure that a beneficiary's aggregate limit is not exceeded.

Response: We agree with the commenters' request because we are concerned that it would be overly burdensome for beneficiaries to track aggregate incurred cost sharing that may have been made in small cash transactions when such information can be more efficiently tracked through the State's eligibility, enrollment, and claims processing systems. In this

revised final rule, we have modified paragraph (d) of § 447.64 to specify that if a State chooses to charge premiums and cost sharing that could result in aggregate costs to a family that exceed 5 percent of the family's income, the State must develop a tracking mechanism and not rely on the so-called "shoebox" method that puts the burden on families to track cost sharing. Specifically, a State must describe in its Medicaid State plan the methodology it will use to identify beneficiaries who are subject to premiums or cost sharing for specific items or services and track their incurred premiums and cost sharing, in order to inform beneficiaries and providers of beneficiaries' liability and notify beneficiaries and providers when individual beneficiaries have incurred the 5 percent limit on family out-of-pocket expenses and are no longer subject to further cost sharing for the remainder of the family's current monthly or quarterly cap period. Such methods must assure that families' cost sharing will not exceed the statutory limits. Ideally, for ease of administration and accuracy, States will use automated systems to track these cost sharing amounts.

We encourage States to track such costs through their Medicaid Management Information System (MMIS). Some States already use MMIS for this purpose. To the extent that they do so, enhanced Federal funding is available for development and operation of system improvements.

As part of our review of State plan amendments and our ongoing reviews and audits of State Medicaid programs, we will review how States that impose costs that could exceed the 5 percent limit meet these requirements, to assure their compliance with the statutory and regulatory requirements. We will also share best practices among States to promote effective and efficient tracking systems. We note that States that design their cost sharing rules so that costs cannot exceed the 5 percent limit need not develop a tracking system.

General Alternative Premium Protections (§ 447.66)

In the February 22, 2008 proposed rule at § 447.66(a), we proposed to implement statutory requirements of section 1916A(b)(3)(A) of the Act that limit the application of alternative premiums under section 1916A by requiring that States exclude certain classes of individuals from the imposition of premiums. In addition, we proposed at § 447.66(b) that a State may exempt additional classes of individuals from premiums.

In the November 25, 2008 final rule, we accepted the provisions of the proposed rule without change.

Specific comments to this section submitted during the reopened comment periods and our responses to those additional comments are as follows:

Comment: Several commenters requested that the Recovery Act's exclusion of premiums and cost sharing for Indians under certain circumstances be broadened to exclude from premiums and cost-sharing all Indians receiving any Medicaid service from any Medicaid provider.

Response: The Recovery Act specifies under what circumstances States are required to exclude Indians from payments of premiums and cost sharing under sections 1916 and 1916A of the Act, and we are not authorized to expand on these statutory circumstances. In this revised final rule at § 447.66(a)(7), we are specifying that States may not impose alternative premiums upon an Indian who is eligible to receive or has received an item or service furnished by an Indian health care provider or through referral under contract health services under authorities for serving Indians. This language would not preclude States from excluding from premiums individuals based on other criteria that could have the effect of broadening the circumstances in which Indian populations would be exempt from premiums. We add at § 447.66(c) to clarify that nothing in this subsection shall be construed as restricting the application of any other limitations on the imposition of premiums that may apply to an individual receiving Medicaid who is an Indian. And, at § 447.70(e) we specify that States may exempt additional individuals, items, or services from cost sharing. We anticipate that additional exemptions, if needed to protect Indian populations, will be an issue raised in the tribal consultation process.

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

In the February 22, 2008 proposed rule at § 447.68(a), we proposed that the State plan describe the group or groups of individuals that may be subject to such cost sharing. We further proposed in § 447.68(b) that the State plan must describe the methodology used to determine family income, including the period and periodicity of those determinations. We also proposed in § 447.68(c) that the State plan describe the item or service for which the charge

is imposed. In § 447.68(d), we proposed that the State plan must describe methods, such as the use of integrated automated systems, for tracking cost sharing charges, informing beneficiaries and providers of the beneficiary's liability, and notifying them when a beneficiary has reached the aggregate maximum for a period. In § 447.68(e), we proposed that the State plan must specify the process of publicizing the schedule of cost sharing charges. In § 447.68(f), we proposed that the State plan must explain 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 as applied during the monthly or quarterly period specified by the State. In addition, at § 447.68(g), we proposed that the State plan specify how notice is provided of the time frame and manner of required cost sharing and the consequences for an individual who does not pay.

In the November 25, 2008 final rule, we accepted the provisions of the proposed rule without any substantive change.

Specific comments to this section submitted during the reopened comment periods and our responses to those additional comments are as follows:

Comment: Several commenters requested that States be required to describe in their State plans a method by which States identify for Medicaid providers which beneficiaries, services, and items are exempted from cost sharing, in accordance with § 447.70 and § 447.71. Commenters also stated that States should be required to provide accurate and updated information to providers about appropriate cost sharing for each beneficiary. One commenter stated that States should be required to demonstrate, before implementing alternative premiums and cost sharing, that adequate State administrative systems are in place to protect families from exceeding the cost sharing limits. Other commenters requested that States, rather than beneficiaries or managed care organizations, be required to track beneficiaries' aggregate premiums and cost sharing, to assure that 5 percent of a family's income is not exceeded. Another commenter stated that CMS should require States to implement automated systems to support the tracking and computing of beneficiaries' copayments at the point-of-sale and to adopt policies that support electronic identification of non-preferred drugs. The commenter also stated that States must be required to make information

electronically available at the point-of-sale regarding a beneficiary's required cost sharing and whether the beneficiary's family has met its applicable monthly or quarterly aggregate limit. In addition, the commenter stated that CMS should make an enhanced 90 percent administrative match available to States that implement such a system.

Response: We agree with many of these comments that beneficiaries should not bear the full burden of accounting for aggregate cost sharing maximums. In this revised final rule, we have thus revised paragraph (d) of § 447.68 to specify that a State must describe in its Medicaid State plan the methodology it will use to identify beneficiaries who are subject to premiums or to cost sharing for specific items or services and, if cost sharing could exceed 5 percent of family income, to track beneficiaries' incurred premiums and cost sharing in order to inform beneficiaries and providers of beneficiaries' liability and to notify beneficiaries and providers when individual beneficiaries have reached the five percent limit on family out-of-pocket expenses to assure that costs do not exceed the 5 percent statutory limit. Also, a State is required to describe in its State plan the State's methods for assuring that providers and beneficiaries are effectively informed of cost sharing requirements in the State plan, in accordance with § 447.68(d). States must be mindful of the need for clear, non-technical explanations and that accommodations must be made for individuals for whom English is not the first language.

For example, one State informs providers and members (beneficiaries) of allowable cost sharing amounts via provider updates and a member Enrollment and Benefits booklet. Another State conducts public meetings and sends a letter to each beneficiary for whom cost sharing is applicable.

While this rule requires States imposing cost sharing that could exceed the 5 percent statutory cap to have a methodology to track costs and to assure that costs do not exceed the 5 percent limit, the rule does not require one particular system for tracking. Some of the methods that States are using to track families' incurred premiums and cost sharing and to assure that they do not exceed the aggregate maximum of 5 percent of the family's income include:

- One State has its premium collection vendor track premium payments. Its MCPs track enrollees' copayments. If a family reaches its aggregate maximum, the premium vendor will waive premiums and suspend invoicing for the

remainder of the benefit period. The MCOs will notify their pharmacy and ambulance transportation providers to waive the family's copayments through a specified date.

- Another State uses MMIS to track and enforce cost sharing limits. The system calculates a family's quarterly out-of-pocket maximum based on the family's income, and tracks the family's cost sharing payments associated with submitted claims. If a family's maximum is reached, an indicator is changed in MMIS and providers are alerted as part of eligibility verification that the family is not subject to copayments.

- Another State calculates each family's cost sharing limit as part of the eligibility determination process, records this information in the eligibility system, copies the State's benefits administrator, and informs the family of the limit in the eligibility approval notice. It encourages families to track their payments, but it also has the benefits administrator track families' payments and notify the State if a family reaches its maximum. Families can also call the State to check on the amount of out-of-pocket expenses they have incurred. If the maximum is reached, the State moves the family to a no-cost benefits plan for the remainder of their plan year and notifies the family of this change in writing.

- Another State has its eligibility and enrollment broker inform families of their out-of-pocket limits in the letter notifying them of enrollment in a health plan. It also notifies the health plan. The health plan tracks families' cost sharing payments. If the limit is reached, the health plan notifies the family by letter and annotates the family's file in the electronic claims system in order to notify providers that no further cost sharing is required.

- Another State has its system track families' out-of-pocket payments, and stops deducting the copayment amount from the allowed amount on a provider's claim if a family reaches its limit. The system notes on an Explanation of Benefits (EOB) when a family reaches its maximum, and families may share the EOB with providers. Such a notice is also included in the point-of-sale system used by pharmacists. Monthly reports are generated to track copayments.

We are requiring that States describe their method of tracking when they impose cost sharing that could exceed the 5 percent statutory limit, and are recommending that, whenever possible, they employ automated systems to do so. The Health Insurance Portability and Accountability Act of 1996 (HIPAA)

governs the contents and format of electronic transactions providing information from a State's MMIS, including an electronic transaction sent by a State Medicaid program in response to an enrolled provider's electronic request for information related to a beneficiary's Medicaid eligibility (for example, information about a beneficiary's cost sharing responsibilities and payments). MMIS system changes and operations are subject to an enhanced Federal matching rate. As part of our review of State plan amendments and our ongoing reviews and audits of State Medicaid programs, we will review how States meet the premium and cost sharing requirements, to assure their compliance with the statutory and regulatory requirements. We will also share best practices to help other States learn about effective and efficient ways to track cost sharing.

General Alternative Cost Sharing Protections (§ 447.70)

In the February 22, 2008 proposed rule, we proposed that State plans may not impose alternative cost sharing under section 1916A(a) of the Act for certain services including emergency services and family planning services and supplies. We also proposed that State plans could not impose cost sharing for preferred drugs within a class for the same categories of individuals. We proposed that the State may exempt additional individuals or services from cost sharing. Also, we proposed that cost sharing applicable to a preferred drug be charged for 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 further proposed that such overrides meet the State's criteria for prior authorization and be approved through the State's prior authorization process.

In the November 25, 2008 final rule, we accepted the provisions of the proposed rule without substantive changes.

Specific comments to this section submitted during the reopened comment periods and our responses to those additional comments are as follows:

Comment: One commenter recommended that the rule define the preventive services which are excluded from alternative cost-sharing (see § 447.70(a)(2)), such as by using the definition in the American Academy of Pediatrics Bright Futures guidelines.

Response: We agree. In this revised final rule, we revised § 447.70(a)(2) to

specify that, at the minimum, the preventive services listed at § 457.520 must be excluded from cost sharing for children younger than 18 years old, which reflect the well baby and well child care and immunizations described by the Bright Futures guidelines of the American Academy of Pediatrics. These guidelines are used for well baby and well child care services in the CHIP program. They provide an explanation of the periodicity schedule recommended by the American Academy of Pediatrics for preventive visits and appropriate immunizations for children. The referencing of such a schedule allows for flexibility in the definition of preventive services to reflect the most current medical practice standards. States are permitted to exempt preventive services beyond those described in the Bright Futures guidelines.

Comment: Several commenters recommended that the entire package of family planning services and supplies described and mandated at section 1905(a)(4)(C) of the Act be excluded from cost sharing, as required by sections 1916A(b)(3)(B)(vii) and 1916(a)(2)(D) of the Act, so that even nominal cost sharing is not permitted for non-preferred family planning drugs (for example, contraceptive drugs not on a State's preferred drug list) and cost sharing does not otherwise distinguish between family planning methods.

Response: While we agree with the concerns of commenters, we are not authorized by the statute to generally preclude alternate cost sharing under section 1916A(c) of the Act for family planning drugs. The protections under section 1916A(b)(3)(B)(vii) of the Act are "subject to the succeeding provisions of this section" which include the special provisions concerning alternate cost sharing under section 1916A(c) of the Act. But we believe it is reasonable to require that States have a consistent treatment of family planning drugs. In this revised final rule, we have revised § 447.70(a)(7) to clarify that the exclusion for family planning services and supplies encompasses contraceptives and other prescription drugs for which the State claims or could claim the Federal matching rate available under section 1903(a)(5) of the Act for family planning services and supplies.

Comment: Several commenters requested that the rule be made consistent with section 1916A(c)(2)(B) of the Act by limiting alternative cost sharing for non-preferred prescription drugs for the items or services listed at § 447.70(a) to no more than the nominal

amount, in order to protect vulnerable populations such as pregnant women.

Response: While we understand the underlying concerns of commenters, we are not authorized by the statute to generally preclude alternate cost sharing under section 1916A(c) of the Act for the services listed at § 447.70(a). The protections under section 1916A(b)(3)(B)(vii) of the Act are "subject to the succeeding provisions of this section" which include the special provisions concerning alternate cost sharing under section 1916A(c) of the Act. As a result of our review of these comments, however, we realized that we had not integrated the protections at section 1916A(c)(3) of the Act into these regulations, and thus we have integrated into the revised final rule at § 447.70(d) the provision that drugs identified as non-preferred drugs are subject to the same exclusions and limits for cost-sharing as preferred drugs if the individual's prescribing physician determines that the preferred drug for treatment of the same condition either would be less effective for the individual or would have adverse effects for the individual or both. We deleted as unnecessary the additional requirement that the State's criteria for prior authorization, if any, must be met.

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 (§ 447.72)

In the February 22, 2008 proposed rule, we proposed at § 447.72(a) that the State plan exclude individuals with family incomes above 100 percent but at or below 150 percent of the FPL from the imposition of premiums. We also proposed at § 447.72(b) that cost sharing for those individuals under the State plan not exceed 10 percent of the payment the State Medicaid agency makes for that item or service, with the exception that cost sharing 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 imposed by a State for services provided by an MCO may not exceed \$5.20 for FY 2007. In addition, we proposed at § 447.72(c) that aggregate premiums and cost sharing for individuals whose family income exceeds 100 percent, but does not exceed 150 percent of the FPL, not exceed the 5 percent aggregate maximum permitted under § 447.78(a).

In the November 25, 2008 final rule, we revised § 447.74(b) to specify that the copayment amount for services provided by an MCO may not exceed \$3.40 per visit for Federal FY 2009 when the State does not have a comparable fee-for-service system. We added a higher copayment limit of \$5.70 for Federal FY 2009 for services provided by an MCO for Medicaid expansion optional targeted low-income children in that circumstance. In addition, we revised the methodology for updating the maximum nominal amounts for Medicaid each October 1 by rounding to the next highest 5-cent increment rather than 10-cent increment, to be consistent with the Medicare Part D program.

Specific comments to this section submitted during the reopened comment periods and our responses to those additional comments are as follows:

Comment: As we discussed above, several commenters recommended that the separate \$5.70 per visit maximum co-payment added in the final rule published on November 25, 2008, be deleted for Medicaid expansion optional targeted low income children in managed care plans when a State does not have a fee-for-service system.

Response: We are accepting this comment for the reasons discussed above. The result is that the same per visit maximum will apply to all Medicaid managed care enrollees when the State does not have a fee-for-service system.

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

In the February 22, 2008 proposed rule at § 447.74(a), we proposed that a State plan may impose premiums upon individuals with family income above 150 percent of the FPL, subject to the aggregate limit on premiums and cost sharing at § 447.78. We also proposed at § 447.74(b) that cost sharing for those individuals under the State plan not exceed 20 percent of the payment the State Medicaid 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. In addition, we proposed at § 447.74(c) that aggregate cost sharing for individuals whose family income exceeds 150 percent of the FPL not exceed the maximum permitted under § 447.78(a).

In the November 25, 2008 final rule, we revised § 447.74(b) to specify that

the copayment amount for services provided by an MCO may not exceed \$3.40 per visit for Federal FY 2009. We added a higher limit for Medicaid expansion optional targeted low-income children of \$5.70 for Federal FY 2009. In addition, we revised the methodology for updating the nominal amounts for Medicaid each October 1 by rounding to the next highest 5-cent increment rather than 10-cent increment, to be consistent with the Medicare Part D program.

Specific comments to this section submitted during the reopened comment periods and our responses to those additional comments are as follows:

Comment: One commenter stated that the cost sharing permitted for higher income individuals would be excessive. The commenter stated that for individuals with incomes above 150 percent FPL, the cost sharing amount would increase to 20 percent. The commenter also recommended that cost sharing be capped at a reasonable amount.

Response: Cost sharing limits are specified in this rule as required by section 1916A of the Act. However, because a 20 percent cost sharing amount can be difficult or even impossible for Medicaid beneficiaries to pay given their limited incomes, in this revised final rule at § 447.62(b)(3), we clarify that States have the option to impose premiums and cost sharing that are below the maximum levels permitted under this subpart.

Public Schedule (§ 447.76)

In the February 22, 2008 proposed rule, we proposed at § 447.76(a) that State plans provide for schedules of premiums and cost sharing and specified the information contained on such schedules. In addition, at § 447.76(b), we proposed that the State make the public schedule available to beneficiaries at the time of enrollment and reenrollment, applicants, all participating providers, and the general public.

In the November 25, 2008 final rule, we added § 447.76(a)(7) to specify that the State must make available either a list of preferred drugs or a method to obtain such a list upon request.

Specific comments to this section submitted during the reopened comment periods and our responses to those additional comments are as follows:

Comment: One commenter requested that States give adequate notice to pharmacy providers, beneficiaries, and the public of changes to cost-sharing requirements when State plan amendments implementing the changes

are submitted to CMS, no later than 60 days prior to the effective date.

Response: We agree that providers need adequate time to adjust their procedures and protocols to incorporate changes, and that beneficiaries and their advocates need time to prepare for changes in cost sharing. Such notice is consistent with administration of the State plan in the best interests of beneficiaries. In this revised final rule, we added a new paragraph (c) to § 447.76 to require a State to provide the public with advance notice and reasonable opportunity to comment in a form and manner provided under applicable State law prior to submitting for CMS approval a Medicaid State plan amendment (SPA) to establish alternative premiums or cost sharing under section 1916A of the Act or to modify substantially an existing plan for alternative premiums or cost sharing. Also, the State must submit documentation with the SPA to demonstrate that this requirement was met. This requirement is similar to the requirements at § 447.205 about public notice prior to submitting a Medicaid SPA revising providers' payment rates for services and at § 457.65(b)–(d) about public notice prior to submitting a CHIP SPA eliminating or restricting eligibility or benefits or implementing or increasing cost sharing charges or the cumulative cost sharing maximum.

Section 447.76 also requires States to make a public schedule with cost sharing information available to beneficiaries, applicants, providers, and the general public. Therefore, the public schedule must be changed as necessary to remain current. In this revised final rule, we modified § 447.76 (b)(1), to clarify that beneficiaries must receive advance written notice when their premiums, cost sharing charges, or aggregate limits are revised.

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

In the February 22, 2008 proposed rule at § 447.78(a), we proposed that for individuals with family income above 100 percent of the FPL the aggregate amount of premiums and cost sharing imposed under sections 1916 and 1916A of the Act not exceed 5 percent of a family's income for a monthly or quarterly period, as specified in the State plan. We received no comments questioning this proposal, and received at least one comment supporting the broad reach of this language. Thus, we included this language in the November 25, 2008 final rule. While sections 1916A(b)(1)(B)(ii) and (2)(A) of the Act for families with income above 100 percent of the FPL only specifically

reference sections 1916A(c) and (e) of the Act in reference to the 5 percent aggregate limit, we read these provisions together with the provision at section 1916A(a)(2)(B) to establish a 5 percent aggregate limit regardless of which statutory option the State selects. To read these provisions in isolation would frustrate the statutory purpose and permit a State to effectively impose aggregate cost sharing far in excess of 5 percent of family income by using the two statutory cost sharing options cumulatively. Such a result would be an inadequate beneficiary protection, and would not achieve the statutory purpose of the aggregate limit. The clear statutory purpose is to limit family cost sharing obligations to 5 percent of family income and that purpose can be achieved only if the aggregate limit applies to all cost sharing imposed under the State plan for all family members, including cost sharing imposed under section 1916. Thus, we believe that Congress intended the three aggregate limit provisions to establish a single aggregate limit for cost sharing under either section 1916 or 1916A regardless of the underlying authority for the cost sharing. Applying all cost sharing under the State plan to the aggregate limit is also consistent with simplicity of administration and the best interests of beneficiaries as required by section 1902(a)(19) of the Act because it eliminates any need to distinguish between the statutory authority for any particular cost sharing.

At § 447.78(b) of the proposed rule, we proposed that for individuals with family income at or below 100 percent of the FPL the aggregate amount of cost sharing under sections 1916 and 1916A of the Act not exceed 5 percent of a family's income for the monthly or quarterly period, as required by section 1916A(a)(2)(B) of the Act, and consistent with the reading above. We also proposed at § 447.78(c) that family income should be determined in a manner 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.

In the November 25, 2008 final rule, we revised § 447.78(c) to include the phrase, "including the use of such disregards as the State may provide."

Specific comments to this section submitted during the reopened comment periods and our responses to those additional comments are as follows:

Comment: One commenter recommended that the total aggregate amount of cost sharing for individuals in a family be limited to 2 percent of the family's income.

Response: We are unable by rule-making to revise the total aggregate limit of 5 percent specified in statute at sections 1916A(b)(1)(B)(ii) and 1916A(b)(2)(A) of the Act. However, in this revised final rule, we clarify at § 447.62(b)(3) that States have the option to impose premiums and cost sharing below the maximum levels under this subpart. Also, we recognize that some families include children in Medicaid and CHIP, so we encourage States to consider implementing a 5 percent limit on families' aggregate premiums and cost sharing in both Medicaid and CHIP.

Comment: One commenter stated that families should be permitted to request a change in the aggregate limit on their cost sharing when the household's income changes.

Response: We had not previously considered this issue, and we agree with the commenter. In this revised final rule, we have modified § 447.78(c) to require that State plans include a process for individuals to request a reassessment of the family's aggregate limit if the family's income is reduced or if eligibility is being terminated due to nonpayment of a premium.

Enforceability of Alternative Premiums and Cost Sharing (§ 447.80)

In the February 22, 2008 proposed rule at § 447.80(a), we proposed to permit a State to condition Medicaid eligibility for individuals in a specified group or groups upon prepayment of premiums, to terminate the eligibility of an individual for failure to pay after 60 days or more, and to waive payment in any case where requiring the payment would create undue hardship. At § 447.80(b), we proposed that a State 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, before it can require payment of the cost sharing and treat

the non-emergency medical condition, must first provide the individual with the name and location of an available and accessible alternate non-emergency services provider, information that the alternate provider can provide the services with imposition of no or lesser cost sharing, and a referral to coordinate scheduling of treatment. 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.

In the November 25, 2008 final rule, we accepted the provisions of the proposed rule without substantive changes.

Specific comments to this section submitted during the reopened comment periods and our responses to those additional comments are as follows:

Comment: One commenter recommended that States not be given the option to deny treatment for Medicaid beneficiaries or terminate them from Medicaid eligibility if they are unable to pay a premium or copayment. Also, the commenter recommended that States be encouraged to use alternative payment schedules.

Response: Under section 1916A(d) of the Act, States have the flexibility to take certain specified actions in the event of nonpayment of premiums, and may allow providers to condition the delivery of services on payment of the alternative cost sharing. The statute expressly permits States and providers to use such enforcement flexibly, to respond to individual circumstances. For example, a State may waive premiums on a case-by-case basis due to hardship. Also, providers may reduce or waive cost sharing on a case-by-case basis.

Comment: One commenter asked who would want to decide if an emergency was "serious enough" so a copayment would not be charged.

Response: We clarify here that we interpret an emergency to include circumstances consistent with the "prudent layperson" standard set forth in section 1932(b)(2) of the Act and § 438.114(a). Under that standard, an emergency service is one needed to evaluate or stabilize an emergency medical condition, which is a condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of medical attention to result in jeopardy to health (including the health of an unborn child), serious impairment to bodily functions, or the serious dysfunction of any bodily organ

or part. This would, at a minimum, include the required medical screening under current regulations at § 489.24, including circumstances under which services are required to stabilize the patient.

Comment: One commenter recommended that copayments for non-emergency use of hospital emergency departments not be imposed if Medicaid beneficiaries are using the emergency room due to lack of access to primary care physicians or other alternative care.

Response: We agree that this is what the statute requires. The requirements at § 447.80(b)(2) are intended to assure that alternative copayments for non-emergency use of hospital emergency departments are not imposed if alternative non-emergency services providers are not available and accessible in a timely manner to treat the individual's medical condition.

Comment: Several commenters recommended that § 447.80(b) specify that giving providers the discretion to waive mandatory copayments on a case-by-case basis may not have the effect of discriminating against individuals who do not speak English or against individuals on the basis of race, color, national origin, or disability (title VI of the Civil Rights Act of 1964, Americans with Disabilities Act, 42 CFR 430.2(b), 45 CFR Part 80).

Response: Existing HHS regulations under these civil rights and other statutes, including section 504 of the Rehabilitation Act, already prohibit both States and entities that receive Medicaid funding from taking discriminatory actions. The HHS Office for Civil Rights (responsible for Departmental enforcement of most civil rights laws) and the Department of Justice (which also has responsibility for enforcement of certain civil rights laws, including the Americans with Disabilities Act), are available to investigate any questions or complaints as to illegal discrimination under these statutes and the implementing regulations.

Comment: A commenter agreed with the rule that providers should be able to decide when to reduce or waive cost sharing on a case-by-case basis. If a State significantly increases cost sharing, the pharmacy provider, rather than the State, must decide whether to condition rendering pharmacy services on the receipt of full payment of cost-sharing from the beneficiary. Otherwise, the providers will likely be the ones paying the higher charges, especially in States where pharmacy providers are quite often unable to collect the current nominal co-payments.

Response: We agree. This policy is consistent with the statute and the

revised final rule at § 447.82(a). If a State elects the option permitting providers to require a beneficiary to pay an allowable cost sharing charge as a condition for receiving an item or service, the provider has the discretion to reduce or waive the application of cost sharing on a case-by-case basis. In this revised final rule, we added a new paragraph (c) to § 447.82 requiring States to identify for providers, ideally through the use of automated systems, whether cost sharing for a specific item or service may be imposed on an individual beneficiary and whether the provider may require the beneficiary, as a condition for receiving the item or service, to pay the cost sharing charge.

Comment: A commenter advised that the rule should provide guidance for how hospitals are to implement cost sharing for non-emergency services rendered in a hospital emergency department without violating the Emergency Medical Treatment and Active Labor Act (EMTALA), which requires hospitals to screen patients who request an emergency examination and not delay treatment to stabilize a patient in order to inquire about the individual's method of payment or insurance status.

Response: We are revising § 447.80(c)(1) to state that nothing in paragraph (b)(2) relating to alternate cost sharing for non-emergency services in hospital emergency departments shall be construed to limit a hospital's obligations with respect to screening and stabilizing treatment of an emergency medical condition under EMTALA, which is codified at section 1867 of the Act relating to EMTALA, and is the basis for the regulation at § 489.24.

Restrictions on Payments to Providers (§ 447.82)

In the February 22, 2008 proposed rule at § 447.80(a), we proposed to require States to reduce the amount of the State's payments to providers by the amount of beneficiaries' cost sharing obligations, regardless of whether the provider successfully collects the cost sharing. We noted in the rule's preamble that 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.

In the November 25, 2008 final rule, we accepted the provisions of the proposed rule without change.

Specific comments to this section submitted during the reopened comment periods and our responses to those additional comments are as follows:

Comment: One commenter recommended that States not be required to reduce payments to providers by the required copayments if the provider waives or reduces the cost sharing amounts. Another commenter stated that the DRA cost sharing is tantamount to a hidden rate reduction for MCOs and other providers. Since cost sharing is deducted from providers' payments, MCOs must decide whether to absorb high administrative costs to track cost sharing or to forego the collection of the fees. Also, commenters requested that MCOs be required to pay providers in full when providers decide not to collect cost sharing from beneficiaries; otherwise, providers will leave the network.

Response: The requirement that States not reimburse providers for unpaid cost sharing is a longstanding Medicaid policy set forth at § 447.57, and is consistent with the overall policy set forth at § 447.15, that the Medicaid agency must limit participation in the Medicaid program to providers who accept, as payment in full, the amounts paid by the agency plus any deductible, coinsurance or copayment required by the State plan to be paid by the individual. There is no indication of any intent to change this longstanding policy in the DRA provisions that added section 1916A to the Act.

Consistent with such requirements, section 5006(a) of the Recovery Act added section 1916(j)(1)(B) of the Act to require that payment due to an Indian health care provider or a health care provider through referral under contract health services for directly furnishing an item or service to a Medicaid-eligible Indian not be reduced by the amount of any enrollment fee, premium, or similar charge, or any deductible, copayment, cost sharing, or similar charge that would otherwise be due. Each State through its regular administrative and political processes, in consultation with the Tribes as required by section 5006(e) of the Recovery Act, must decide how to implement this requirement and how to assure that providers are paid in full under such circumstances.

III. Provisions of the Revised Final Rule

In this revised final rule, we are adopting the provisions as set forth in the November 25, 2008 final rule, subject to the following changes.

A. Implementation of Section 5006(a) of the Recovery Act

The following provisions are open for public comment. The provisions implement and interpret section 5006(a) of the Recovery Act, which exempts Indians from premiums and cost sharing

under certain circumstances effective July 1, 2009. Also, the provisions respond to public comments received on these new statutory requirements during the March 27, 2009 extended comment period on the November 25, 2008 final rule.

Section 5006(a) of the Recovery Act amends sections 1916 and 1916A of the Act, to exempt Indian applicants and beneficiaries from Medicaid premium and cost sharing requirements under certain circumstances and to assure that Indian health care providers, and health care providers providing contract health services (CHS) under a referral from an Indian health care provider, will receive full payment. Premiums and cost sharing exemptions for Indians under CHIP are not affected. The provisions took effect on July 1, 2009.

Specifically, the Recovery Act:

- Exempts Indians from payments of enrollment fees, premiums, or similar charges if they either are eligible to receive or have received an item or service furnished by an Indian health care provider or through referral under CHS.

- Exempts Indians from payment of a deductible, coinsurance, copayment, or similar charge for any item or service covered by Medicaid if the Indian is furnished the item or service directly by an Indian health care provider or through referral under CHS.

- Prohibits any reduction of payment that is due under Medicaid to an Indian health care provider or a health care provider through referral under CHS for directly furnishing an item or service to an Indian. The State must pay these providers the full Medicaid payment rate for furnishing the item or service. Their payments may not be reduced by the amount of any enrollment fee, premium, deductible, copayment, or similar charge that otherwise would be due from the Indian.

Definitions

In administering the Recovery Act's cost sharing provisions related to Indians, the following definitions apply—

- *Indian health care provider* means a health care program operated by the Indian.

- *Health Service (IHS)* or by an Indian Tribe, Tribal Organization, or Urban Indian Organization (otherwise known as an I/T/U) as those terms are defined in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603).

- *Indian* means any individual defined at 25 U.S.C. 1603(c), 1603(f), or 1679(b), or who has been determined eligible as an Indian, pursuant to 42 CFR 136.12. This means the individual:

(1) Is a member of a Federally-recognized Indian tribe;

(2) resides in an urban center and meets one or more of the four criteria: (a) Is a member of a tribe, band, or other organized group of Indians, including those tribes, bands, or groups terminated since 1940 and those recognized now or in the future by the State in which they reside, or who is a descendant, in the first or second degree, of any such member; (b) is an Eskimo or Aleut or other Alaska Native; (c) is considered by the Secretary of the Interior to be an Indian for any purpose; or (d) is determined to be an Indian under regulations promulgated by the Secretary;

(3) is considered by the Secretary of the Interior to be an Indian for any purpose; or

(4) is considered by the Secretary of Health and Human Services to be an Indian for purposes of eligibility for Indian health care services, including as a California Indian, Eskimo, Aleut, or other Alaska Native.

The IHS administers the CHS Program for the provision of services to Indians when those services are not available at IHS or Tribal facilities. Any IHS-eligible Indian Medicaid beneficiary who receives a referral, including any authorization for payment, by an IHS or Tribal provider to an outside provider for contract health service is eligible for the exemption from cost sharing for that service. States will need to educate non-IHS providers about such documents, so that providers will know to waive cost sharing requirements for referrals through CHS for which payment may be made by Medicaid. States must inform providers, ideally through the use of automated systems, whether an individual is exempted from premiums or cost sharing. Reference materials about CHS may be accessed on the IHS Web page at: <http://www.ihs.gov/NonMedicalPrograms/chs/>.

State Medicaid programs must consult with the IHS, Tribes, Tribal Organizations, and Urban Indian Organizations within the State to determine what documents the Indian health care providers will use for exemption of Indians from enrollment fees, premiums, or other similar charges and from deductibles, coinsurance, copayments, or similar charges for referrals to providers through the CHS Program.

Cost Sharing: Basis and Purpose (§ 447.50)

We added a new paragraph (b) with definitions for “Indian” and “Indian health care provider.”

Requirements and Options (§ 447.51)

We added a new paragraph (a)(2) that exempts Indians from payments of enrollment fees, premiums, or similar charges if they are eligible to receive or have received an item or service furnished by an Indian health care provider or through referral under CHS.

Applicability; Specification; Multiple Charges (§ 447.53)

We added a new paragraph (b)(6) to exclude from cost sharing under Medicaid all items and services furnished to an Indian directly by an Indian health care provider or through referral under CHS.

Restrictions on Payments to Providers (§ 447.57)

We added a new paragraph (c) to specify that payment under Medicaid due to an Indian health care provider or a health care provider through referral under CHS for directly furnishing an item or service to an Indian may not be reduced by the amount of any enrollment fee, premium, or similar charge or any deductible, copayment, cost sharing, or similar charge that otherwise would be due. Note that there is no exemption for cost sharing, such as deductibles, coinsurance or copayments, on services rendered to eligible individuals at non-Indian health care providers where there was not referral or authorization through CHS as defined below.

Contract health service means any health service that is (1) delivered based on a referral by, or at the expense of, an Indian health program; and (2) provided by a public or private medical provider or hospital that is not a provider or hospital of the Indian health program.

General Alternative Premium Protections (§ 447.66)

We added a new paragraph (a)(7) to exclude Indians from payments of enrollment fees, premiums, or similar charges if they are eligible to receive or have received an item or service furnished by an Indian health care provider or through referral under contract health services.

In addition, we added a new paragraph (c) to specify that a State may apply additional limitations on imposition of premiums that may apply to an individual receiving Medicaid who is an Indian.

General Alternative Cost Sharing Protections (§ 447.70)

We added a new paragraph (a)(10) to exclude from cost sharing under Medicaid all items and services furnished to an Indian directly by an

Indian health care provider or through referral under CHS.

Restrictions on Payments to Providers (§ 447.82)

We added a new paragraph (b) to specify that payment under Medicaid due to an Indian health care provider or a health care provider through referral under CHS for furnishing an item or service directly to an Indian may not be reduced by the amount of any enrollment fee, premium, or similar charge, or any deductible, copayment, cost sharing, or similar charge that otherwise would be due.

B. Additional Changes to the Medicaid Regulations in Response to Public Comments Requirements and Options (§ 447.51)

We revised paragraphs (a) and (c) to clarify the requirements for consistency with section 1916 of the Act, to specify the categorically needy populations for which the State Medicaid agency may impose an enrollment fee, premium, or similar charge in accordance with section 1916(c), (d), (g), or (i) of the act.

Applicability; Specification; Multiple Charges (§ 447.53)

We revised the definition of “emergency services” in paragraph (b)(4) to cite the definition which includes the “prudent layperson” standard at section 1932(b)(2) of the Act and § 438.114(a).

Maximum Allowable and Nominal Charges (§ 447.54)

We revised paragraph (a)(1) and (a)(3)(ii) to clarify the requirements for consistency with section 1916 of the Act. Also, we revised the example in paragraph (a)(1) for a 6-month certification period rather than a 3-month period for consistency with States’ practices.

We also revised paragraph (a)(4), in response to public comments, to delete a higher maximum copayment of \$5.70 per visit for services provided by an MCO, when the State does not have a fee-for-service delivery system, for Medicaid expansion optional targeted low income children for whom enhanced Federal match is paid under section XXI of the Act. Since these are Medicaid-eligible children, they will be subject to the Medicaid limit for such coverage of \$3.40 per visit, rather than the limit imposed for separate CHIP programs under title XXI.

In addition, we revised paragraph (b) to correct a citation to § 431.57. Also, the paragraph was revised for consistency with sections 1916(a)(3) and 1916(b)(3) of the Act that the Secretary of Health & Human Services will only

approve a waiver of the requirement that cost sharing charges must be limited to a nominal amount if the State establishes to the Secretary's satisfaction that alternative sources of nonemergency, outpatient services are actually available and accessible to Medicaid beneficiaries in a timely manner.

Standard Co-Payment (§ 447.55)

We revised paragraph (b) to correct a citation to § 447.54(a) and (c).

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

We revised paragraph (a) to clarify the requirements for consistency with section 1916A of the Act.

We also revised paragraph (b) to take into account the amendment to section 1916(f) of the Act made by section 6041(b)(1) of the DRA.

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

We revised paragraphs (a), (c), and (d) to clarify the requirements for consistency with section 1916A of the Act.

We also revised paragraph (d), in response to public comments, to require that if a State imposes cost sharing that could result in aggregate costs to a family that exceed five percent of the family's income, the State must develop a tracking mechanism and not rely on the so-called "shoebox" method that puts the burden on families to track cost sharing. Specifically, a State must describe in its Medicaid State plan the methodology it will use to identify beneficiaries who are subject to premiums or cost sharing for specific items or services and track the premiums and cost sharing incurred, in order to inform beneficiaries and providers of beneficiaries' liability and notify beneficiaries and providers when individual beneficiaries have reached the five percent limit on family out-of-pocket expenses and are no longer subject to further cost sharing for the remainder of the family's current monthly or quarterly cap period. Such methods must assure that families' cost sharing will not exceed the statutory limit.

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

We revised paragraphs (b), (c), (d), (f)(1), and (f)(2) to clarify the requirements for consistency with section 1916A of the Act.

We revised paragraph (d) to specify that a State must describe in its Medicaid State plan the methodology it will use to identify beneficiaries who are subject to premiums or cost sharing for specific items or services and, if cost sharing could exceed five percent of family income, to track beneficiaries' incurred premiums and cost sharing through a tracking system developed by the State, in order to inform beneficiaries and providers of beneficiaries' liability and notify beneficiaries and providers when individual beneficiaries have reached the five percent limit on family out-of-pocket expenses to assure that costs do not exceed the five percent statutory limit.

Paragraph (f) is revised to clarify that the aggregate limit under § 447.78 on a family's premium and cost sharing applies to section 1916 and/or 1916A for all individuals in the family enrolled in Medicaid.

General Alternative Cost Sharing Protections (§ 447.70)

We renumbered and revised this section to make it consistent with section 1916A of the Act. In addition, we revised this section in response to public comments.

We revised the definition of "emergency services" in paragraph (a)(6) (previously (a)(1)(vi)) and referenced this term in paragraph (b) to cite the definition which includes the "prudent layperson" standard at section 1932(b)(2) of the Act and § 438.114(a).

We revised paragraph (a)(2) (previously (a)(1)(ii)) to specify at a minimum the services listed at § 457.520 as the preventive services excluded from alternative cost sharing for children younger than age 18, which reflect the well baby and well child care and immunizations described by the Bright Futures guidelines of the American Academy of Pediatrics.

We revised paragraph (a)(7) (previously (a)(1)(vii)) to specify that the family planning services and supplies exempted from cost sharing include contraceptives and other pharmaceuticals for which the State claims or could claim Federal match at the enhanced rate under section 1903(a)(5) of the Act for family planning services and supplies.

We revised paragraph (a)(9) (previously (a)(1)(ix)) to explain that disabled children receiving medical assistance by virtue of sections 1902(a)(10)(A)(ii)(XIX) and 1902(cc) of the Act who are exempted from alternative cost sharing are those covered in accordance with the

Medicaid eligibility option offered by the Family Opportunity Act.

We revised paragraph (a)(11) (previously (a)(1)(x)) and paragraph (c) (previously (b)) to specify that drugs not identified by the State's Medicaid program as non-preferred drugs within a class are subject to the same exclusions and limits for cost sharing as drugs identified by the State as preferred drugs within a class.

We revised paragraph (b) (previously (a)(2)) for consistency with section 1916A(e)(2)(B) of the Act to specify that cost sharing of no more than the nominal amounts defined in § 447.54 may be imposed on the exempt populations specified in paragraph (a) of this section for nonemergency services furnished in a hospital emergency department, under certain conditions.

Also, we revised paragraph (d) (previously (c)) to specify that drugs identified by a State's Medicaid program as non-preferred drugs within a class are subject to the same exclusions and limits for cost sharing as preferred drugs within a class if the individual's prescribing physician determines that the preferred drug for treatment of the same condition either would be less effective for the individual or would have adverse effects for the individual or both. We deleted as unnecessary the additional requirement that the State's criteria for prior authorization, if any, must be met.

Alternative Premium and Cost Sharing Exemptions and Protections for Individuals With Family Incomes at or Below 100 Percent of the FPL (§ 447.71)

We revised paragraphs (b)(1), (b)(3), and (c) and added a new paragraph (d) to clarify the requirements for consistency with sections 1916 and 1916A of the Act. Paragraph (d) specifies that a State may not impose on individuals with family income at or below 100 percent of the FPL the DRA's alternative premiums and cost sharing defined at section 1916A of the Act, but may impose cost sharing that does not exceed the nominal amounts specified at § 447.54.

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 (§ 447.72)

We revised the introduction to paragraph (b) and its subsection (2) and paragraph (c) to clarify the requirements for consistency with section 1916A of the Act.

We revised paragraph (b)(3), in response to public comments, to delete a higher maximum copayment of \$5.70

per visit for services provided by an MCO, when the State does not have a fee-for-service delivery system, for Medicaid expansion optional targeted low income children for whom enhanced Federal match is paid under section XXI of the Act. Since these are Medicaid-eligible children, they will be subject to the Medicaid limit for such coverage of \$3.40 per visit in FY 2009, rather than the limit imposed for separate CHIP programs under title XXI.

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

We revised paragraphs (a), (b), and (c) to clarify the requirements for consistency with section 1916A of the Act.

We also revised paragraph (b) to delete a higher maximum copayment of \$5.70 per visit for services provided by an MCO, when the State does not have a fee-for-service delivery system, for Medicaid expansion optional targeted low income children for whom enhanced Federal match is paid under section XXI of the Act. Since these are Medicaid-eligible children, they will be subject to the Medicaid limit for such coverage of \$3.40 per visit in FY 2009, rather than the limit imposed for separate CHIP programs under title XXI.

Public Schedule (§ 447.76)

We revised paragraph (b)(1) for a minor change by replacing the words “and the” with the word “or” before “aggregate”.

Also, in response to public comments, we added a new paragraph (c) to require a State to provide the public with advance notice and reasonable opportunity to comment in a form and manner provided under applicable State law prior to submitting for CMS approval a Medicaid State plan amendment (SPA) to establish alternative premiums or cost sharing under section 1916A of the Act or to modify substantially an existing plan for alternative premiums or cost sharing. Also, the State must submit documentation with the SPA to demonstrate that this requirement was met.

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

We revised paragraphs (a), (b), (c), and (c)(2) to clarify the requirements for consistency with section 1916A of the Act. In particular, we clarify that the total aggregate limit of 5 percent of a family's income applies for premiums and/or cost sharing imposed under section 1916 and/or 1916A of the Act

for all individuals in the family enrolled in Medicaid.

We also revised paragraph (c), in response to public comments, to require that States describe in their State plan for alternative premiums or cost sharing the process for individuals to request a reassessment of the family's aggregate limit if the family's income is reduced or if eligibility is being terminated due to nonpayment of a premium.

Enforceability of Alternative Premiums and Cost Sharing (§ 447.80)

We revised paragraphs (a)(3) and (b) and added a new paragraph (c) to clarify and specify the requirements for consistency with section 1916A of the Act related to alternative cost sharing for nonemergency services provided in hospital emergency departments. Also, we revised paragraph (b)(2) to reference the definition of “emergency services” at section 1932(b)(2) of the Act and § 438.114(a).

Restrictions on Payments to Providers (§ 447.82)

We revised this section to make the existing text a new paragraph (a).

We added a new paragraph (c) to require that a State describe in its Medicaid State plan how the State identifies for providers, ideally through the use of automated systems, whether cost sharing for a specific item or service may be imposed on an individual beneficiary and whether the provider may require the beneficiary, as a condition for receiving the item or service, to pay the cost sharing charge.

C. Changes to the CHIP Regulations

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

We revised paragraphs (a)(1)(i) and (a)(2) for minor changes in clarification.

IV. Response to Comments on Revised Final Rule

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on

the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

A proposed rule was published on February 22, 2008 with a public comment period. A final rule was issued on November 25, 2008. The November 25, 2008 final rule published in the **Federal Register** included a description of changes to the proposed rule based on the public comments and our responses to comments received during the public comment period. On January 27, 2009 and March 27, 2009, we published final rules to delay the effective date of the November 25, 2008 final rule and to reopen the public comment period. The March 27, 2009 final rule specifically indicated that analysis of comments received during the first reopened comment period indicated a need for revisions to the November 25, 2008 final rule, and also specifically requested public comments on changes needed to address section 5006(a) of the Recovery Act. On October 30, 2009, we published a proposed rule in the **Federal Register** to delay the effective date of the November 25, 2008 final rule until July 1, 2010.

In keeping with the Department's Tribal consultation policy and the new provisions in the Recovery Act, CMS collaborated and consulted with the Tribal Technical Advisory Group (TTAG) and the IHS to solicit advice on implementing these provisions. The Tribal Affairs Group and the Center for Medicaid, CHIP, and Survey and Certification within CMS jointly hosted two All Tribes Calls on June 5 and 12, 2009, to consult on implementation of section 5006 of the Recovery Act. Two face-to-face consultation meetings were held in Denver on July 8 and 10, 2009, to solicit advice and input on these provisions from federally-recognized Tribes, Indian health care providers, and Urban Indian Organizations. An All States Call was held on June 10, 2009, with the State Medicaid and CHIP programs to describe the CMS Tribal consultation process and the Recovery Act provisions and to solicit feedback and questions from States. We believe the requirement of a notice of proposed rulemaking has been effectively met through the issuances described in the

preceding paragraphs. However, to the extent that the requirement has not been met, we find good cause to waive a notice of proposed rulemaking because it is unnecessary when the purposes of the requirement have been met through the prior issuances, which clearly indicated the intent to revise the November 25, 2008 final rule and invited public comment to inform our revisions.

Specifically, the two 2009 final rules included a reopening of the public comment period, indicated that the November 25, 2008 final rule would be revised, and requested specific comments on the changes required by section 5006(a) of the Recovery Act. In doing so, these final rules effectively proposed revision of the November 25, 2008 final rule and invited public comment. These actions fully satisfied the requirements for notice of proposed rulemaking, and further process would be unnecessary.

With respect to the provisions of this revised final rule that concern section 5006(a) of the Recovery Act, we further find good cause to waive the notice of proposed rulemaking based on the strong public interest in protecting beneficiaries from premiums and cost sharing in accordance with law. Section 5006(a)(1) became effective on July 1, 2009, and prompt implementation is necessary to ensure that its protections are applied without delay. Delay in implementation would harm the Indian beneficiaries whom the statute was specifically intended to help.

Therefore, we find good cause to waive the notice of proposed rulemaking and to issue this final rule on an interim basis. We are providing a 30-day public comment period.

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 are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs Regarding

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

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

(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 charges imposed.

(c) The methodology used to determine family income for purposes of the limitations on premiums related to family income level that are described in § 447.78(c) of this chapter, including the period and periodicity of those determinations.

(d) The methodology used by the State to:

(1) Identify beneficiaries who are subject to premiums or to cost sharing for specific items or services; and

(2) If the State adopts cost sharing rules that could place families at risk of reaching the total aggregate limit for premiums and cost sharing under Medicaid, defined at § 447.78 as 5 percent of the family's income, track beneficiaries' incurred premiums and cost sharing through a mechanism developed by the State that does not rely on beneficiaries, in order to inform beneficiaries and providers of beneficiaries' liability and notify beneficiaries and providers when individual beneficiaries have reached the 5 percent limit on family out-of-pocket expenses and are no longer subject to further cost sharing for the remainder of the family's current monthly or quarterly cap period.

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

(f) 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 Alternative Copayments, Coinsurance, Deductibles, or Similar Cost Sharing Charges: State Plan Requirements

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

(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 in § 447.78(c) of this chapter, including the period and periodicity of those determinations.

(c) The schedule of the copayments, coinsurance, deductibles, or similar cost sharing charges imposed for each item or service for which a charge is imposed.

(d) The methodology used by the State to identify beneficiaries who are subject to premiums or cost sharing for specific items or services and, if the State adopts cost sharing rules that could place families at risk of reaching the total aggregate limit for premiums and cost sharing under Medicaid, defined at § 447.78 as 5 percent of the family's income, track beneficiaries' incurred premiums and cost sharing through a tracking system developed by the State, in order to inform beneficiaries and providers of beneficiaries' liability and notify beneficiaries and providers when the individual beneficiaries reached the 5 percent limit on family out-of-pocket expenses and are no longer subject to further cost sharing for the remainder of the family's current monthly or quarterly cap period.

(e) The process for informing beneficiaries, 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 of this chapter.

(f) The methodology used to ensure that:

(1) The aggregate amount of premiums and cost sharing imposed under section 1916 and section 1916A of the Act for all individuals in the family enrolled in Medicaid with family income above 100

percent of the Federal poverty level (FPL) does not exceed 5 percent of the family's income of the family involved.

(2) The aggregate amount of cost sharing under section 1916 and section 1916A of the Act for all individuals in the family enrolled in Medicaid with family income at or below 100 percent of the FPL does not exceed 5 percent of the family's income of the family involved.

(g) 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.

Section 447.76 Public Schedule

Section 447.76(a) requires States to 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 charges.
- (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 beneficiary 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.

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 and territories will be affected by this requirement for an annual burden of 18.67 hours.

Section 447.76(c) requires the State, prior to submitting to the Centers for Medicare & Medicaid Services for approval a Medicaid State plan amendment to establish alternative premiums or cost sharing under section 1916A of the Act or an amendment to modify substantially an existing plan for alternative premiums or cost sharing, to provide the public with advance notice of the amendment and allow reasonable opportunity to comment with respect to

such amendment in a form and manner provided under applicable State law. The State must submit documentation with the SPA to demonstrate that this requirement was met.

The burden associated with this requirement is the time and effort it would take for a State to provide advance notice to the public and prepare and submit documentation with the SPA. We estimate it would take 1 State approximately 3 hours to meet this requirement; therefore, the total annual burden associated with this requirement is 3 hours.

Section 447.80 Enforceability of Alternative 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 need emergency services before providing treatment and imposing alternative cost sharing on an individual in accordance with § 447.72(b)(2) and § 447.74(b) of this chapter for non-emergency services as defined in section 1916A(e)(4)(A) of the Act, must provide:

- (1) 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;
- (2) Information that the alternate provider can provide the services in a timely manner with the imposition of a lesser cost sharing amount or no cost sharing; and
- (3) A referral to coordinate scheduling of treatment by this provider.

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 to that provider. 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.

B. Comments on ICRs

We have submitted a copy of this final rule to OMB for its review of the information collection requirements described above. We will revise OMB number 0938-0993 to reflect any additional burden not currently approved.

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 revised final rule with comment period; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, 2244-FC, Fax: (202) 395-6974; or E-mail: OIRA_submission@omb.eop.gov.

VII. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VIII. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects of \$100 million or more in any 1 year. We estimate this final rule with comment period will not reach the economically significant threshold of \$100 million in benefits and costs and consequently is not a major rule under the Congressional Review Act.

The economic impact associated with this final rule relates to changes it proposes to the November 25, 2008, final rule. The main change estimated to have a budget impact is the Recovery Act's exemption of Indians from premiums and cost sharing under certain circumstances. The estimated budget impact of section 5006 of the Recovery Act has been included in the FY 2011 President's budget. 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. 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's (SBA) definition of a small business (having revenues of less than \$7 million to \$34.5 million in any 1 year.) Individuals and States are not included in the definition of a small entity. Therefore, the Secretary has determined that this final rule with comment period will not have a significant 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 metropolitan statistical area and has fewer than 100 beds. Therefore, the Secretary has determined that this final rule with comment period will 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) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2009, that threshold is approximately \$133 million. This final rule with comment period will not impose spending costs on State, local, or tribal governments in the aggregate, or by the private sector, of \$133 million in any one year.

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. This final rule with comment period will not have substantial direct requirement costs on State and local governments, preempt State law, or otherwise have Federalism implications.

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 447.50 is amended by adding a new paragraph (b) to read as follows:

§ 447.50 Cost sharing: Basis and purpose.

* * * * *

(b) *Definitions.* For the purposes of this subpart:

(1) *Indian* means any individual defined at 25 USC 1603(c), 1603(f), or 1679(b), or who has been determined eligible as an Indian, pursuant to § 136.12 of this part. This means the individual:

- (i) Is a member of a Federally-recognized Indian tribe;
- (ii) Resides in an urban center and meets one or more of the following four criteria:

(A) Is a member of a tribe, band, or other organized group of Indians, including those tribes, bands, or groups terminated since 1940 and those recognized now or in the future by the State in which they reside, or who is a descendant, in the first or second degree, of any such member;

(B) Is an Eskimo or Aleut or other Alaska Native;

(C) Is considered by the Secretary of the Interior to be an Indian for any purpose; or

(D) Is determined to be an Indian under regulations promulgated by the Secretary;

(iii) Is considered by the Secretary of the Interior to be an Indian for any purpose; or

(iv) Is considered by the Secretary of Health and Human Services to be an Indian for purposes of eligibility for

Indian health care services, including as a California Indian, Eskimo, Aleut, or other Alaska Native.

■ 3. Section 447.51 is amended by revising paragraph (a) and the introductory text of paragraph (c) to read as follows:

§ 447.51 Requirements and options.

(a) The plan must provide that the Medicaid agency does not impose any enrollment fee, premium, or similar charge for any services available under the plan upon:

(1) Categorically needy individuals, as defined in § 435.4 and § 436.3 of this subchapter, except for the following populations in accordance with sections 1916(c), (d), (g), and (i) of the Act:

(i) A pregnant woman or an infant under one year of age described in subparagraph (A) or (B) of section 1902(l)(1) of the Act, who is receiving medical assistance on the basis of section 1902(a)(10)(A)(ii)(IX) of the Act and whose family income equals or exceeds 150 percent of the Federal poverty level (FPL) applicable to a family of the size involved;

(ii) A qualified disabled and working individual described in section 1905(s) of the Act whose income exceeds 150 percent of the FPL;

(iii) An individual provided medical assistance only under section 1902(a)(10)(A)(ii)(XV) or section 1902(a)(10)(A)(ii)(XVI) of the Act and the Ticket to Work and Work Incentives Improvement Act of 1999 (TWWIIA); and

(iv) A disabled child provided medical assistance under section 1902(a)(10)(A)(ii)(XIX) of the Act in accordance with the Family Opportunity Act; and

(2) An Indian who either is eligible to receive or has received an item or service furnished by an Indian health care provider or through referral under contract health services.

* * * * *

(c) For each charge imposed under paragraph (a) or (b) of this section, the plan must specify—

* * * * *

■ 4. Section 447.53 is amended by revising paragraph (b)(4) and adding a new paragraph (b)(6) to read as follows:

§ 447.53 Applicability; specification; multiple charges.

* * * * *

(b) * * *

(4) *Emergency services.* Services as defined at section 1932(b)(2) of the Act and § 438.114(a).

* * * * *

(6) *Indians.* Items and services furnished to an Indian directly by an

Indian health care provider or through referral under contract health services.

* * * * *

§ 447.54 [Amended]

- 5. Section 447.54 is amended by—
 - A. Republishing the introductory text.
 - B. Revising paragraph (a)(1), paragraph (a)(3)(ii), and paragraph (a)(4).
 - C. Revising paragraph (b).
- The 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 6-month period, the maximum deductible which may be imposed on a family for that period of eligibility is \$13.80. In succeeding years, any deductible 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.

* * * * *

(3) * * * (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.

(4) For Federal FY 2009, any copayment that the State imposes for services provided by a managed care organization (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. When there is no fee-for-service delivery system, the copayment may not exceed \$3.40 per visit. In succeeding years, any copayment 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.

(b) *Waiver of the requirement that cost sharing amounts be nominal.* Upon approval from CMS, the requirement that cost sharing charges must be nominal may be waived, in accordance with sections 1916(a)(3) and 1916(b)(3) of the Act and § 431.57 of this chapter, for non-emergency services furnished in a hospital emergency department, if the State establishes to the satisfaction of the Secretary that alternative sources of nonemergency, outpatient services are actually available and accessible to Medicaid beneficiaries in a timely manner.

* * * * *

- 6. 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 (c) 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).

- 7. Section 447.57 is amended by adding a new paragraph (c) to read as follows:

§ 447.57 Restrictions on payments to providers.

* * * * *

(c) Payment under Medicaid due to an Indian health care provider or a health care provider through referral under contract health services for directly furnishing an item or service to an Indian may not be reduced by the amount of any enrollment fee, premium, or similar charge, or any deductible, copayment, cost sharing, or similar charge that otherwise would be due from the Indian.

- 8. Section 447.62 is revised to read as follows:

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

(a) Section 1916A of the Act sets forth options for a State through a Medicaid State plan amendment to impose 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 or cost sharing, § 447.64, § 447.66, § 447.68, § 447.70, § 447.71,

§ 447.72, § 447.74, § 447.76, § 447.78, § 447.80, and § 447.82 prescribe State plan requirements and options for alternative premiums and cost sharing for a group or groups of individuals (as specified by the State) for services or items (as specified by the State) and the standards and conditions under which States may impose them. The State may vary the premiums and cost sharing among groups of individuals or types of services or items, consistent with the limitations specified in this subpart and section 1916A(a)(1) of the Social Security Act. Otherwise, premiums and cost sharing must comply with the requirements described in § 447.50 through § 447.60.

(b) Waivers of the limitations described in this subpart on deductions, cost sharing, and similar charges may be granted only in accordance with the provisions of section 1916(f) of the Act.

§ 447.64 [Amended]

- 9. Section 447.64 is amended by revising paragraphs (a), (c), and (d) to read as follows:

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

* * * * *

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

* * * * *

(c) The methodology used to determine family income for purposes of the limitations on premiums related to family income level that are described in § 447.78(c) of this chapter, including the period and periodicity of those determinations.

(d) The methodology used by the State to:

(1) Identify beneficiaries who are subject to premiums or cost sharing for specific items or services; and

(2) If the State adopts cost sharing rules that could place families at risk of reaching the total aggregate limit for premiums and cost sharing under Medicaid, defined at § 447.78, track beneficiaries' incurred premiums and cost sharing through a mechanism developed by the State that does not rely on beneficiaries, in order to inform beneficiaries and providers of beneficiaries' liability and notify beneficiaries and providers when individual beneficiaries have incurred family out-of-pocket expenses up to that limit and are no longer subject to further cost sharing for the remainder of the family's current monthly or quarterly cap period.

* * * * *

- 10. Section 447.66 is amended by—

■ A. Adding a new paragraph (a)(7).

■ B. Adding a new paragraph (c).

The additions read as follows:

§ 447.66 General alternative premium protections.

(a) * * *

(7) An Indian who is eligible to receive or has received an item or service furnished by an Indian health care provider or through referral under contract health services.

* * * * *

(c) Nothing in this subsection shall be construed as restricting the application of any other limitations on the imposition of premiums that may apply to an individual receiving Medicaid who is an Indian.

■ 11. Section 447.68 is amended by revising paragraphs (b) through (d) and (f) to read as follows:

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

* * * * *

(b) The methodology used to determine family income, for purposes of the limitations on cost sharing related to family income level that are described in § 447.78(c) of this chapter, including the period and periodicity of those determinations.

(c) The schedule of the copayments, coinsurance, deductibles, or similar cost sharing charges imposed for each item or service for which a charge is imposed.

(d) The methodology used by the State to identify beneficiaries who are subject to premiums or cost sharing for specific items or services and, if families are at risk of reaching the total aggregate limit for premiums and cost sharing under Medicaid defined at § 447.78, track beneficiaries' incurred premiums and cost sharing through a mechanism developed by the State that does not rely on beneficiaries, in order to inform beneficiaries and providers of beneficiaries' liability and notify beneficiaries and providers when individual beneficiaries have incurred family out-of-pocket expenses up to that limit and are no longer subject to further cost sharing for the remainder of the family's current monthly or quarterly cap period.

* * * * *

(f) The methodology used to ensure that:

(1) The aggregate amount of premiums and cost sharing imposed under section 1916 and section 1916A of the Act for all individuals in the family enrolled in Medicaid with family income above 100 percent of the Federal poverty level

(FPL) does not exceed 5 percent of the family's income of the family involved.

(2) The aggregate amount of cost sharing imposed under section 1916 and section 1916A of the Act for all individuals in the family enrolled in Medicaid with family income at or below 100 percent of the FPL does not exceed 5 percent of the family's income of the family involved.

* * * * *

■ 12. Section 447.70 is revised to read as follows:

§ 447.70 General alternative cost sharing protections.

(a) 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 prescription drugs identified by a State's Medicaid program as non-preferred within a class of such drugs or for non-emergency use of the emergency room.

(1) 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, including services furnished to individuals with respect to whom child welfare services are being 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) Preventive services, at a minimum the services specified at § 457.520, provided to children under 18 years of age regardless of family income, which reflect the well baby and well child care and immunizations in the Bright Futures guidelines issued by the American Academy of Pediatrics.

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

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

(5) 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.

(6) Emergency services as defined at section 1932(b)(2) of the Act and § 438.114(a), 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 need emergency services consistent with the requirements of paragraph (b) of this section.

(7) Family planning services and supplies described in section 1905(a)(4)(C) of the Act, including contraceptives and other pharmaceuticals for which the State claims or could claim Federal match at the enhanced rate under section 1903(a)(5) of the Act for family planning services and supplies.

(8) 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).

(9) 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, in accordance with the Family Opportunity Act.

(10) Items and services furnished to an Indian directly by an Indian health care provider or through referral under contract health services.

(11) Preferred drugs within a class, or drugs not identified by the State's Medicaid program as a non-preferred drug within a class, for individuals for whom cost sharing may not otherwise be imposed as described in paragraphs (a)(1) through (10) of this section.

(b) For the exempt populations specified in paragraph (a) of this section, a State may impose nominal cost sharing as defined in § 447.54 of this chapter for services furnished in a hospital emergency department, other than those required under § 489.24, if the hospital has determined based on the medical screening required under § 489.24 that the individual does not need emergency services as defined at section 1932(b)(2) of the Act and § 438.114(a), the requirements of § 447.80(b)(1) are met, and the services are available in a timely manner without cost sharing through an outpatient department or another alternative non-emergency health care provider in the geographic area of the hospital emergency department involved.

(c) In the case of a drug that a State's Medicaid program either has identified as a preferred drug within a class or has not otherwise identified as a non-preferred drug within a class, cost sharing may not exceed the nominal levels permitted under section 1916 of the Act as specified in § 447.54 of this chapter. Cost sharing can be imposed

that exceeds the nominal levels permitted under section 1916 of the Act for drugs that are identified by a State's Medicaid program as non-preferred drugs within a class in accordance with section 1916A(c) of the Act.

(d) In the case of a drug that is identified by a State's Medicaid program as a non-preferred drug within a class, the cost sharing is limited to the amount imposed for a preferred drug if the individual's prescribing physician determines that the preferred drug for treatment of the same condition either would be less effective for the individual or would have adverse effects for the individual or both.

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

- 13. Section 447.71 is amended by—
- A. Revising paragraphs (b)(1), (b)(3), and (c).
- B. Adding a new paragraph (d).

The additions and revisions read as follows:

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

* * * * *

(b) * * *

(1) The State may impose cost sharing under authority provided under section 1916 of the Act and consistent with the levels described in such section and § 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 the services are available in a timely manner without cost sharing through an outpatient department or other alternative non-emergency services health care provider in the geographic area of the hospital emergency department involved.

(c) Aggregate cost sharing under sections 1916 and 1916A of the Act for all individuals in the family enrolled in Medicaid may not exceed the maximum permitted under § 447.78(b).

(d) The State may not impose alternative premiums and cost sharing in accordance with section 1916A of the Act on individuals whose family income is at or below 100 percent of the FPL, but may impose cost sharing that does not exceed the nominal amount as defined at § 447.54 and section 1916 of the Act.

- 14. Section 447.72 is amended by revising paragraphs (b) and (c) to read as follows:

§ 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.

* * * * *

(b) Cost sharing may be imposed under the State plan for individuals whose family income exceeds 100 percent, but does not exceed 150 percent, of the FPL if the cost sharing does 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(b)(2) 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 to a Medicaid beneficiary, including a child covered under a Medicaid expansion program for whom enhanced match is claimed under title XXI of the Act, may not exceed \$3.40 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 under sections 1916 and 1916A of the Act for all individuals in the family enrolled in Medicaid may not exceed the maximum permitted under § 447.78(a).

(c) Aggregate cost sharing under sections 1916 and 1916A of the Act for all individuals in the family enrolled in Medicaid may not exceed the maximum permitted under § 447.78(a).

- 15. Section 447.74 is revised to read as follows:

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

(a) States may impose premiums under the State plan consistent with the aggregate limits set forth in § 447.78(a) on individuals whose family income exceeds 150 percent of the FPL.

(b) Cost sharing may be imposed under the State plan on individuals whose family income exceeds 150 percent of the FPL if the cost sharing does 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 to a Medicaid beneficiary, including a child covered under a Medicaid expansion program for whom enhanced match is claimed under title XXI of the Act, may not exceed \$3.40 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 premiums and cost sharing under sections 1916 and 1916A of the Act for all individuals in the family enrolled in Medicaid may not exceed the maximum permitted under § 447.78(a).

- 16. Section 447.76 is amended by revising paragraph (b)(1) and adding a new paragraph (c) to read as follows:

§ 447.76 Public schedule.

* * * * *

(b) * * *

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

* * * * *

(c) Prior to submitting to the Centers for Medicare & Medicaid Services for approval a State plan amendment (SPA) to establish alternative premiums or cost sharing under section 1916A of the Act or an amendment to modify substantially an existing plan for alternative premiums or cost sharing, the State must provide the public with advance notice of the amendment and reasonable opportunity to comment with respect to such amendment in a form and manner provided under applicable State law, and must submit documentation with the SPA to demonstrate that this requirement was met.

- 17. Section 447.78 is revised to read as follows:

§ 447.78 Aggregate limits on alternative premiums and cost sharing.

(a) The total aggregate amount of premiums and cost sharing imposed under sections 1916 and 1916A of the Act for all individuals in a family enrolled in Medicaid 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 imposed under sections 1916 and 1916A of the Act for all individuals

in a family enrolled in Medicaid 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 by the State in the State plan.

(c) Family income shall be determined in a manner, for such period, and at such periodicity as specified by the State in the State plan, including the use of such disregards as the State may provide and the process for individuals to request a reassessment of the family's aggregate limit if the family's income is reduced or if eligibility is being terminated due to nonpayment of a premium.

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

(2) States may use a different methodology for determining the family's income to which the 5 percent aggregate limit is applied than is used for determining income eligibility.

■ 18. Section 447.80 is amended by—
 ■ A. Revising paragraph (a)(3), the introductory text of paragraph (b), and paragraph (b)(2).

■ B. Adding a new paragraph (c).

The additions and revisions read as follows:

§ 447.80 Enforceability of alternative premiums and cost sharing.

* * * * *

(a) * * *

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

(b) With respect to alternative cost sharing, a State may amend its Medicaid State plan to permit a provider, including a pharmacy or hospital, 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.

* * * * *

(2) A hospital that has determined after an appropriate medical screening pursuant to § 489.24 of this chapter, that an individual does not need emergency services as defined at section 1932(b)(2) of the Act and § 438.114(a), before providing treatment and imposing alternative cost sharing on an individual in accordance with § 447.72(b)(2) and § 447.74(b) of this chapter for non-emergency services as defined in section 1916A(e)(4)(A) of the Act, must provide:

(i) 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.

(ii) Information that the alternate provider can provide the services in a timely manner with the imposition of a lesser cost sharing amount or no cost sharing.

(iii) A referral to coordinate scheduling of treatment by this provider.

* * * * *

(c) Nothing in paragraph (b)(2) of this section shall be construed to:

(1) Limit a hospital's obligations with respect to screening and stabilizing treatment of an emergency medical condition under section 1867 of the Act; or

(2) Modify any obligations under either State or Federal standards relating to the application of a prudent-layperson standard with respect to payment or coverage of emergency medical services by any managed care organization.

§ 447.82 [Amended]

■ 19. Section 447.82 is revised to read as follows:

§ 447.82 Restrictions on payments to providers.

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

(b) Payment that is due under Medicaid to an Indian health care provider or a health care provider through referral under contract health services for directly furnishing an item or service to an Indian may not be reduced by the amount of any enrollment fee, premium, or similar charge, or any deductible, copayment, cost sharing, or similar charge that otherwise would be due.

(c) The plan must describe how the State identifies for providers, ideally through the use of the automated systems, whether cost sharing for a specific item or service may be imposed on an individual beneficiary and whether the provider may require the beneficiary, as a condition for receiving the item or service, to pay the cost sharing charge.

PART 457—ALLOTMENTS AND GRANTS TO STATES

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

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

■ 21. Section 457.555 is amended by revising paragraphs (a)(1)(i) and (a)(2) to 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) * * * *

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

State payment for the service	Maximum Copayment
\$15 or less	\$1.15
\$15.01 to \$40	\$2.30
\$40.01 to \$80	\$3.40
\$80.01 or more	\$5.70

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(2) For Federal FY 2009, any copayment that the State imposes for services provided by a managed care organization may not exceed \$5.70 per visit. In succeeding years, 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.

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

Dated: April 22, 2010.

Marilyn Tavenner,

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

Approved: May 18, 2010.

Kathleen Sebelius,

Secretary.

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