DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 431, 433, 435, 436, and 457

[HCFA–2006–F]

RIN 0938–AI28

State Child Health; Implementing Regulations for the State Children's Health Insurance Program

AGENCY: Health Care Financing Administration (HCFA) , HHS.

ACTION: Final rule.

SUMMARY: Section 4901 of the Balanced Budget Act of 1997 (BBA) amended the Social Security Act (the Act) by adding a new title XXI, the State Children's Health Insurance Program (SCHIP) . Title XXI provides funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner. To be eligible for funds under this program, States must submit a State plan, which must be approved by the Secretary.

This final rule implements provisions related to SCHIP including State plan requirements and plan administration, coverage and benefits, eligibility and enrollment, enrollee financial responsibility, strategic planning, substitution of coverage, program integrity, certain allowable waivers, and applicant and enrollee protections. This final rule also implements the provisions of sections 4911 and 4912 of the BBA, which amended title XIX of the Act to expand State options for coverage of children under the Medicaid program. In addition, this final rule makes technical corrections to subparts B, and F of part 457.

DATES: This final rule is effective April 11, 2001. *Compliance dates:* To the extent contract changes are necessary, however, States will not be found out of compliance until the next contract cycle. By contract cycle, we mean the earlier of the date of the original period of the existing contract, or the date of any modification or extension of the contract (whether or not contemplated within the scope of the contract) .

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I. Background

Section 490l of the BBA, Public Law 105–33, as amended by Public Law 105–100, added title XXI to the Act. Title XXI authorizes the SCHIP program to assist State efforts to initiate and expand the provision of child health assistance to uninsured, low-income children. Under title XXI, States may provide child health assistance primarily for obtaining health benefits coverage through (1) a separate child health program that meets the requirements specified under section 2103 of the Act; (2) expanding eligibility for benefits under the State's Medicaid plan under title XIX of the Act; or (3) a combination of the two approaches. To be eligible for funds under this program, States must submit a State child health plan (State plan), which must be approved by the Secretary.

The State Children's Health Insurance Program is jointly financed by the Federal and State governments and is administered by the States. Within broad Federal guidelines, each State determines the design of its program, eligibility groups, benefit packages, payment levels for coverage, and administrative and operating procedures. SCHIP provides a capped amount of funds to States on a matching basis for Federal fiscal years (FY) 1998 through 2007. At the Federal level, SCHIP is administered by the Department of Health and Human Services, through the Center for Medicaid and State Operations (CMSO) of the Health Care Financing Administration (HCFA). Federal payments under title XXI to States are based on State expenditures under approved plans effective on or after October 1, 1997.

This final rule implements the following sections of title XXI of the Act:

- Section 2101 of the Act, which sets forth the purpose of title XXI, the requirements of a State plan, State entitlement to title XXI funds, and the effective date of the program.
- Section 2102 of the Act, which sets forth the general contents of a State plan, including eligibility standards and methodologies, coordination, and outreach.
- Section 2103 of the Act, which contains coverage requirements for children's health insurance.
- The following parts of section 2105 of the Act: 2105(c)(2)(B), which relates to cost-effective community based health delivery systems; 2105(c)(3), which relates to waivers for purchase of family coverage; 2105(c)(5), which relates to offsets for cost-sharing receipts, and 2105(c)(7) which relates to limitations on payment for abortion.
- Section 2106 of the Act, which describes the process for submission and approval of State child health plans and plan amendments.
- Section 2107 of the Act, which sets forth requirements relating to strategic objectives, performance goals and program administration.

• Section 2108 of the Act, which requires States to submit annual reports and evaluations of the effectiveness of the State's title XXI plan.
• Section 2109 of the Act, which sets forth the relation of title XXI to other laws.
• Section 2110 of the Act, which sets forth title XXI definitions.

This final rule also implements the provisions of sections 4911 and 4912 of the BBA, that amended title XIX of the Act to provide expanded coverage to children under the Medicaid program. Specifically, section 4911 of the BBA set forth provisions for use of State child health assistance funds for enhanced Medicaid match for expanded eligibility under Medicaid to provide medical assistance to optional targeted low-income children. Section 4912 of the BBA added a new section 1920A to the Act creating a new option to provide presumptive eligibility for children. Both title XXI and title XIX statutory provisions are discussed in detail in section II. of this preamble.

This final rule also implements section 704 of the Balanced Budget Refinement Act of 1999 (BBRA, Public Law 106–113), enacted on November 29, 1999, which requires the Secretary to refer to the title XXI program as the ''State Children's Health Insurance Program'' or ''SCHIP'' in any publication or other official communication.

We note that on May 24, 2000, HCFA published in the **Federal Register** a final rule (HCFA 2114–F) concerning financial program allotments and payments to States under SCHIP at (65 FR 33616). In that rule, we implemented section 2104 and portions of section 2105 of the Act, which relate to allotments and payments to States under title XXI. For a detailed discussion of title XXI and related title XIX financial provisions, including the allotment process, the payment process, financial reporting requirements and the grant award process, refer to the May 24, 2000 final rule (65 FR 33616). Please note that, to eliminate duplication and provide clarity, this final rule also amends selected sections of the financial rule within Subpart B.

II. Provisions of the Proposed Rule and Discussion of Public Comments

A. Overview

1. Summary of Proposed Provisions and Significant Revisions in This Final Rule.

On November 8, 1999, we published a proposed rule that set forth the programmatic provisions of the State Children's Health Insurance Program (64 FR 60882). The provisions of the proposed regulation were largely based on previously released guidance, and therefore represented policies that had been in operation for some time. In the proposed rule, we identified a number of areas in which we elaborated on previous guidance or proposed new policies.

We received 109 timely comments on the proposed rule. Interested parties that commented included States, advocacy organizations, individuals, and provider organizations. The comments received varied widely and were often very detailed. We received a significant number of comments on the following areas: State plan issues, such as when an amendment to an existing plan is needed; information that should be provided or made available to potential applicants, applicants and enrollees; the exemption to cost sharing for American Indian/Alaska Native children; eligibility and ''screen and enroll'' requirements; Medicaid coordination issues; eligibility simplification options such as presumptive eligibility; the definition of a targeted low-income child; substitution of private coverage; data collection on race, ethnicity, gender and primary language; grievance and appeal procedures and other enrollee protections; and premium assistance for employer-sponsored coverage.

All public comments have been summarized and are discussed in detail in section II below. A brief summary of key issues discussed in the proposed rule as well as significant revisions made in this final rule follows:

• Subpart A—State Plan Requirements

The proposed regulation included several conditions under which States must submit amendments to approved SCHIP plans. For example, we proposed that a State must submit a plan amendment when the funding source of the State share changes, prior to such change taking effect. In addition, we proposed that amendments to impose cost sharing on beneficiaries, increase existing cost-sharing charges, or increase the cumulative cost-sharing maximum considered the same as amendments proposing a restriction in benefits. We noted that States would be required to follow rules regarding prior public notice and retroactive effective dates for these amendments.

The final regulation clarifies several issues surrounding the circumstances under which amendments must be submitted. It lists more clearly the program changes that must be included in the State plan by submitting an amendment. In addition, the final rule modifies the budget requirements to require a 1-year projected budget for those amendments that have a significant budgetary impact. Budgets are no longer required with every State plan amendment; however States must submit a 3-year projected budget with its annual report (discussed in subpart G). Finally, States must submit an amendment before making changes in the source of the non-Federal share of funding.

We have provided additional clarification with regard to the requirements for coordination between SCHIP and Medicaid, as well as coordination with other public programs. We have modified the regulation text to further emphasize the need for coordination with other public programs after screening for Medicaid eligibility during the SCHIP application process, as well as assisting in enrollment in SCHIP of children determined ineligible for Medicaid.

The section laying out provisions for enrollment assistance and information requirements has been modified to include the provision of linguistically appropriate materials to families of potential applicants, applicants and enrollees in SCHIP to assist them in making informed health care decisions about their health plans, professionals and facilities. We have also clarified that, in addition to information about the types of benefits and participating providers. In addition, States must inform applicants and enrollees about their rights and responsibilities regarding procedures for review of adverse decisions regarding eligibility or health services decisions and the circumstances under which they may be subject to enrollment caps and waiting lists.

• Subpart C—Eligibility, Screening, Applications and Enrollment

The proposed rule outlined provisions for eligibility and enrollment for separate child health programs and implementation of the ''screen and enroll'' requirement. It also included the title XXI restrictions on the participation of children of public agency employees who are eligible to participate in a State health benefits plan, children who are residing in institutions for mental disease (IMDs), and children who are inmates of public institutions.

The final rule further elaborates on issues surrounding eligibility, enrollment and ensuring that children eligible for Medicaid benefits are enrolled in Medicaid. We have modified the definition of ''targeted low-income child'' to parallel a modification to the definition of ''optional targeted low-

income child'' under the Medicaid regulations. This modification effectively excludes from title XXI ''maintenance of effort'' provisions certain section 1115 demonstrations that were in place on March 31, 1997, but that were so limited in scope that we do not consider them to be equivalent to Medicaid.

We clarified the standards for eligibility for separate child health programs, including: (1) Clearly permitting self-declaration of citizenship; (2) prohibiting durational residency requirements; (3) prohibiting lifetime caps or other time limits on eligibility; (4) permitting 12 months of continuous eligibility; and (5) permitting enrollment caps and waiting lists when approved as part of the State plan. In addition, we have specifically required States to implement standards for conducting eligibility determinations and a process that does not exceed 45 days (excluding days during which the application has been suspended).

The rule provides further clarification of the issues surrounding children of public employees, children in IMDs and children who are inmates of public institutions. For example, we clarified that the children of public employees are eligible only if the employer contribution under a State health benefits plan is no more than a nominal contribution of $10 per family, per month. We also modified the definition of ''State health benefits plan'' to exclude separately run county, city, or other public agency plans that receive no State contribution toward the cost of coverage and in which no State employees participate.

The final rule also further clarifies the requirements for treatment of children found to be potentially eligible for Medicaid after applying for coverage under a separate child health program. In order to ensure the effectiveness of the screening mechanisms, States are required to establish a system for monitoring the screen and enroll process. Finally, the rule lays out procedures for States that opt to provide presumptive eligibility for the separate child health program while the application and eligibility determination process is underway.

- Subpart D—Coverage and Benefits

The proposed rule provided for some flexibility for States in keeping the SCHIP benefit package current. A State using the benchmark benefit package option is not required to submit an amendment each time the benchmark package changes, as long as it continues to offer the same benefits covered under the approved State plan. However, States must submit an amendment to their State plan any time the benefits offered to enrollees change. If the change in benefits is intended to conform the separate State benefit package to the benchmark coverage, then the benefit package remains benchmark coverage. But if the change in benefits causes the State-offered benefits to differ from the benchmark coverage, then the benefits must be reclassified as benchmark equivalent or one of the other benefit package options.

The proposed rule included the requirement that States use the ''prudent layperson standard'' in defining coverage for emergency services under SCHIP. The proposed rule also required use of the American Committee on Immunization Practices (ACIP) schedule for age-appropriate immunizations.

The final rule retains all of the same provisions as included in the proposed rule. In addition, for purposes of clarity, we have moved a provision formerly found in Subpart G, Strategic Planning, Reporting, and Evaluation into this Subpart. The provision, entitled ''State assurance of access to care and procedures to assure quality and appropriateness of care'' includes the requirements for assuring access to covered services, including emergency services, well-baby, well-child and well-adolescent care, and age appropriate immunizations. This provision also requires States to assure appropriate and timely procedures to monitor and treat enrollees with chronic, complex, or serious medical conditions, including access to an adequate number of visits to specialists experienced in treating the specific medical condition. Finally, this provision requires States to assure decisions related to the provision of health services are completed within 14 days of the request for the service, in accordance with the medical needs of the child.

- Subpart E—Enrollee Financial Responsibilities

Title XXI permits States to impose cost sharing on enrollees in separate child health programs, but places a 5 percent cap on the amount of cost-sharing expenditures for families with incomes greater than 150 percent of the Federal Poverty Level (FPL). In an attempt to preserve State flexibility, we proposed to give States the option to use either gross or net family income when calculating this cost-sharing cap for families. In addition, we proposed to place a limit of 2.5 percent on cost sharing for families with incomes at or below 150 percent of the FPL, in order to ensure that those families with lower incomes will not be required to spend the same percentage of their income on cost sharing as those with higher incomes. Many commenters supported the need for this distinction, given the more limited amount of disposable income in such families. Under the proposed rule, States also had the option to apply medical costs for non-covered or non-eligible family members toward the cumulative maximum cap.

We proposed that States must have a process in place that will protect enrollees by ensuring an opportunity to pay past due cost-sharing amount before they can be disenrolled from the program for failure to pay cost sharing. We suggested that States should look for a pattern of nonpayment, and provide clear notice and opportunities for late payment before taking action to disenroll.

Finally, title XXI includes provisions to ensure enrollment and access to health care services for American Indian and Alaska Native (AI/AN) children. The proposed regulation incorporated our interpretation that in light of the unique Federal relationship with tribal governments, cost-sharing requirements for individuals who are members of a Federally recognized tribe are not consistent with this statutory requirement.

The final rule clarifies that States must provide to the family of each individual SCHIP enrollee, the cumulative cost-sharing maximum amount for that year. In addition, this subpart confirms that the State plan must clearly describe a State's cost-sharing policy in terms of which children will be subject to cost sharing, the consequences for enrollees who do not pay a charge, and the disenrollment protections provided to enrollees in the event that they do not pay the cost sharing. States must also describe the methodology to ensure that families do not exceed the cumulative cost-sharing maximum and assure that families will not be held liable for cost-sharing amounts, beyond the copayment amounts in the State plan, for emergency services provided outside of an enrollee's managed care network.

The final rule confirms the protections included in the proposed rule related to AI/AN children and clarifies that States may use self-declaration of tribal membership for identifying AI/AN children in order to facilitate implementation of the cost-sharing exemption.

The final rule continues to require that States may not impose more than one type of cost sharing on a service; and that States may only impose one copayment based on the total cost of

services furnished during one office visit.

Finally, States must provide enrollees with an opportunity to show that their family income has declined before being disenrolled for failure to pay cost sharing, because the child may have become eligible for a category with lower or no cost sharing if family income has declined. States must also provide enrollees with an opportunity for an impartial review to address disenrollment from the program for this reason (see discussion of new Subpart K, Applicant and Enrollee Protections).

• Subpart G—Strategic Planning, Reporting and Evaluation

The proposed regulation included provisions intended to ensure compliance with the statute and the elements of the State's approved title XXI plan. This subpart included the essential elements of strategic objectives and performance measures to assist the States and the Federal government in assessing the effectiveness of the SCHIP program in increasing the number of children with health insurance, and an assessment of the quality of and access to needed health care services.

The proposed rule also outlined the quarterly statistical reporting requirements and the required elements of States annual reports and the March 31, 2000 SCHIP evaluation.

The final rule confirms these requirements and further describes data elements to be reported by the States, including data on gender, race, ethnicity, and primary language. The gender, race and ethnicity data will be required in the State's quarterly statistical enrollment reports; and the annual reports will include a description of data regarding the primary language of SCHIP enrollees. In addition, the annual reports will include an updated budget for a 3-year period, including any changes in the source of the non-Federal share of State plan expenditures. The annual reports must also include description of the State's current income eligibility standards and methodologies.

Finally, the final rule notes the Secretary's intention to develop, with input from States, academic and intergovernmental organizations, a core set of national performance goals and measures. When developed, States will also be required to report on these measures in their annual reports.

• Subpart H—Substitution of Coverage

The proposed rule set forth requirements for ensuring that States have in place mechanisms aimed at preventing substitution of public coverage for private group coverage. With respect to coverage provided directly through SCHIP, the preamble included a description of HCFA's three-tiered policy to apply increased scrutiny to States' substitution prevention strategies at higher incomes. For coverage provided through premium assistance for employers' group health plans, the proposed rule set forth specific requirements for a six-month period of uninsurance and a minimum 60 percent employer premium contribution.

Due to a general lack of evidence of the existence of substitution below 200 percent of the FPL and the significant number of comments received on this subpart, we have revised the final rule to clarify our policy related to substitution. The preamble to the final rule clarifies that for coverage provided other than through premium assistance programs, we will no longer require a substitution prevention strategy for families with incomes below 250 percent of the FPL. Instead, States will be required to monitor the occurrence of substitution below 200 percent of the FPL. Between 200 and 250 percent of the FPL, we will work with States to develop procedures, in addition to monitoring, to prevent substitution that would be implemented in the event that an unacceptable level of substitution is identified. Above 250 percent of the FPL, States must have a substitution prevention mechanism in place, however we encourage States to use other strategies than waiting periods.

For States wishing to utilize premium assistance programs, we have revised the final rule to provide additional flexibility. While we have retained the 6-month waiting period without group health plan coverage, States have flexibility to include a number of exceptions for circumstances such as involuntary loss of coverage, economic hardship, and change to employment that does not offer dependent coverage. We have also removed the requirement for States to demonstrate an employer contribution of at least 60 percent when providing coverage through premium assistance programs. Rather, we have clarified that States must demonstrate cost-effectiveness of their proposals by identifying a minimum contribution level and providing supporting data to show that the level is representative of the employer-sponsored insurance market in their State.

Finally, the final rule provides that the Secretary has discretion to reduce or waive the minimum period without private group health plan coverage.

• Subpart I—Program Integrity

The provisions in this subpart are intended to preserve program integrity in the State Children's Health Insurance Program. We proposed that States must have fraud and abuse protections in place, but provided flexibility to States in developing program integrity protections for separate child health programs. States with separate child health programs may utilize systems already existing for Medicaid, but are not required to do so. In addition, we proposed that States have additional flexibility in setting procurement standards more broadly than are available under Medicaid. We proposed that States may choose to base payment rates on public and/or private rates for comparable services for comparable populations, and where appropriate, establish higher rates in order to ensure sufficient provider participation and access.

Finally, the proposed regulation included various enrollee protections consistent with the President's directive regarding the *Consumer Bill of Rights and Responsibilities,* including provisions regarding grievances and privacy protections. In response to public comment about the need for consistency of provisions throughout the final rule, we have moved the overview of the enrollee protections to the preamble of this final rule, but have removed it from the final regulation text, as it repeated the protections included throughout the proposed rule. The discussion of enrollee protections is now found in subpart K—Applicant and Enrollee Protections.

The final rule confirms the significance of maintaining program integrity in SCHIP and clarifies issues related to the certification of data that determines payment and the development of actuarially sound payment rates. It notes that States should base payment rates on public and/or private rates for comparable services for comparable populations, consistent with the principles of actuarial soundness. We have also moved the subsection formerly entitled, ''Grievances and appeals'' to the new Subpart K, where these requirements are retained and elaborated upon.

Finally, the rule confirms the importance of maintaining the integrity of professional advice to enrollees by requiring compliance with the provisions of the final Medicare+Choice rule that prohibit interference with health care professionals' advice to enrollees; require that professionals provide information about treatment options in an appropriate manner; limits

physician incentive plans; and provides requirements related to information disclosure related to physician incentive plans.

• Subpart J—Waivers

The proposed rule noted the requirements for obtaining a waiver to provide coverage through a community-based delivery system and discussed the circumstances under which a State may obtain a waiver in order to provide title XXI coverage to entire families. We proposed that in order to qualify for a family coverage waiver, the State must meet several requirements, including a requirement that the proposal be cost-effective.

In the final rule, we have clarified that the provisions of this subpart apply to separate child health programs. The provisions apply to Medicaid expansions only in cases where the State files claims for administrative costs under title XXI and seeks a waiver of limitations on such claims for coverage under a community-based health delivery system. We have clarified that HCFA will review requests for waivers under this subpart using the same time frames (the 90-day review clock) as those used for the review of State plan amendments under SCHIP. In addition, in response to comments received on this subpart, we have extended the approval period for the waivers to provide coverage through a community based delivery system from two years to three years in an attempt to better align with the period of availability for SCHIP allotments.

With regard to the family coverage waiver, the final rule clarifies that when applying the cost-effectiveness test, States must assess cost-effectiveness in its initial request for a waiver, and then annually. States may do the assessment either on a case-by-case basis or in the aggregate.

• Subpart K—Applicant and Enrollee Protections

The proposed rule emphasized the importance of enrollee protections by including many of the elements of the Consumer Bill of Rights and Responsibilities throughout the rule. In addition, an overview of these protections was presented in Subpart I—Program Integrity and Beneficiary Protections. We received several comments on our decision to implement the CBRR through this regulation. While we have retained the protections included in the proposed rule in the appropriate location as related to the issue, we have attempted to clarify the required protections by creating a new subpart dedicated to privacy and a process for review of certain eligibility and health services matters, Subpart K—Applicant and Enrollee Protections.

We have included more specific requirements than those that were included in Subpart I of the proposed rule and will require the State plan to include a description of the State's process for review and resolution of eligibility and enrollment matters such as denial or failure to make a timely determination of eligibility, and suspension or termination of enrollment, including disenrollment for failure to pay cost sharing. States must also provide enrollees with an opportunity for external review of health services matters, such as delay, denial, reduction, suspension or termination of health services, in whole or in part; and the failure to approve, furnish, or provide payment for health services in a timely manner. Exceptions to these requirements can be made in the event that the sole basis for such a decision is a change in the State plan or a change in Federal or State law that affects all or a group of applicants or enrollees without regard to their individual circumstances.

The final rule lays out requirements for the core elements of review of eligibility or health services matters, and requires that the reviews be impartial, conducted by a person or entity that has not been directly involved or responsible for the matter under review. The rule also establishes a 90-day time frame within which external reviews (or a combination of an internal and an external review) must be completed. States should take into consideration the medical needs of the patient when conducting the reviews and provide expedited time frames if an enrollee's physician determines that a longer time frame could seriously jeopardize the enrollees life, health or ability to attain or regain maximum function. If the enrollee has access to both internal and external review, each level of expedited review may take no more than 72 hours.

The final rule requires States to provide continuation of enrollment pending the completion of review of a suspension or termination of enrollment, including disenrollment for failure to pay cost sharing. States must also provide enrollees with timely written notice of any determinations subject to review including the reasons for the determination, an explanation of applicable rights to review, the time frames for review, and circumstances under which enrollment may continue pending a review.

Finally, the rule provides an exception for States that operate premium assistance programs under SCHIP. If the State utilizes a premium assistance program that does not meet the requirements for review under this Subpart, the State must give applicants and enrollees the option to enroll in the non-premium assistance program in the State. States must provide this option at initial enrollment and at each renewal of eligibility.

• Expanded Coverage of Children under Medicaid and Medicaid Coordination.

In this section we set forth our changes to the Medicaid regulations that allow for expanded coverage of children under title XIX. Although these regulations are related to title XXI and SCHIP, they are changes to the Medicaid program and all existing Medicaid regulations also apply. We set forth requirements related to presumptive eligibility for children, the enhanced FMAP (Federal medical assistance percentage) rate for children, and the new group of optional targeted low-income children established by the statute. The presumptive eligibility provisions have been clarified in this final rule to lay out specific notification requirements and establish procedures for making presumptive eligibility determinations and expands the definition of ''qualified entity'' in accordance with the Benefits Improvement and Protection Act of 2000 (BIPA). Finally, the rule establishes consistent coordination requirements between Medicaid and SCHIP.

2. General Comments

In this section, we have summarized and responded to general public comments on the SCHIP programmatic regulation. These comments relate to the program or the proposed rule as a whole and not to any particular provision of the proposed rule. All other public comments are addressed below in the context of the relevant subpart.

Comment: We received a great number of comments discussing the issue of providing SCHIP coverage through premium assistance programs. Many commenters noted the difficulty that States would have in requiring employer plans to meet the proposed requirements. Many commenters argued that the proposed rule imposed too many requirements on SCHIP coverage obtained through employer-sponsored insurance and that the proposed provisions would stifle State innovation in utilizing such insurance.

Response: At the time of publication of the proposed rule, the experience with premium assistance programs in SCHIP had been limited to only a few States. Therefore, the proposed

regulation did not include a great deal of specificity regarding the regulation's applicability to premium assistance models. We have attempted to provide States with flexibility, while ensuring that States meet their statutory obligation to all SCHIP enrollees regardless of the insurance product being provided. Further, it would not be consistent with the SCHIP statute to exempt certain enrollees from the protections established by law, simply because of the delivery model. However, we also recognize the value and the increased potential for reaching children associated with interaction with the employer-based insurance market. Thus, while we will ensure compliance with the protections set forth in this final rule, we look forward to working closely with States to help in the development and approval of proposals that utilize premium assistance programs. As noted in the overview section, we have provided some additional flexibility in subpart H, Substitution, with respect to premium assistance programs that we hope will facilitate increased use of premium assistance programs in SCHIP. We have also provided some flexibility with regard to certain enrollee protections in subpart K.

Comment: One commenter noted that there is an inequity in funding that disadvantages States that expanded eligibility prior to March 31, 1997. Another commenter indicted that it is difficult for States that had expanded Medicaid to high levels prior to March 31, 1997 to access SCHIP funds and suggested that States be allowed to use SCHIP funds to subsidize employer-sponsored insurance.

Response: We recognize the inequities that have been caused by the ''maintenance of effort'' provision in the SCHIP statute, which holds States to the current eligibility levels in effect on March 31, 1997, and we applaud States that were progressive in expanding their Medicaid programs through section 1115 demonstrations and through the flexibility provided under section 1902(r)(2) and section 1931 of the statute. However, the maintenance of effort provision in the SCHIP statute was put in place specifically to ensure that States did not roll back the eligibility and benefits standards that were in place prior to the existence of SCHIP, and to encourage further expansion in implementing States' SCHIP programs.

Comment: Several commenters asserted that the proposed regulations were overly prescriptive, limit State flexibility, and raise program administrative costs. Several commenters specifically complained that the proposed regulations appeared to push States toward Medicaid or Medicaid-like programs. Some commenters asserted that the overall approach directly contradicted Executive Order 13132 on Federalism. Some argued that the regulations should be limited to areas Congress specifically required the Secretary to address in regulations, the administrative review process for State plans, or to clarification of essential terms. While some commenters recognized the need for federal guidance, they supported the inclusion of such guidance in the preamble and other guidance documents rather than in the regulation text.

Response: In developing the proposed and final regulations, we have taken great care to try to balance the need to ensure that SCHIP will provide the full intended benefits to uninsured, low-income children with the goal of retaining as much State flexibility as possible. HCFA has tried to administer the program and develop policies in a manner that gives States a full opportunity to develop programs that met local needs, whether through a Medicaid expansion or a separate child health program.

To make it possible for States to develop and implement their programs, from the time of enactment of the SCHIP program, HCFA has worked with States to disseminate as much information as possible, as quickly as possible. In the first three months of the program's existence, we released over 100 answers to frequently asked questions and issued several policy guidance letters. We continue to take into consideration the changing needs of States. The programs that States developed vary in scope, delivery system and many other respects. The diversity and innovation that has been displayed is an indication that State flexibility does indeed exist.

In addition, we consulted with State and local officials in the course of the design and review stages of State proposals, and many of the policies found in the proposed and this final rule are a direct result of these discussions and negotiations with the States. To the extent consistent with the objectives of the statute, to obtain substantial health care coverage for uninsured low-income children in an effective and efficient manner, we have endeavored to preserve State options in implementing their programs.

We developed these final regulations with the goal of providing a balanced view of both Medicaid expansions and separate child health programs. We made careful determinations as to whether each subpart should be applicable to separate child health programs *and* Medicaid expansions, or only to separate programs. In doing this, we have attempted to maximize flexibility and avoid the need for duplication of effort, while at the same time recognizing the basic differences between the two approaches.

We believe our considerations, and the consultative process we followed during the State plan review process, fully comported with the requirements of Executive Order 13132, and the final regulations contain the framework necessary for States to achieve the statutory requirements and objectives set forth by Congress.

Comment: Several commenters were concerned that the proposed regulations would narrow available State options, with particular mention of barriers to private sector models, and impose additional burdensome requirements on States. Some commenters were concerned that the proposed regulations would require administrative costs that would be a difficult financial burden for a small separate child health program.

Response: We recognize the commenters' concern and have tried to keep potential administrative burden in mind in developing these regulations. Some administrative investment, however, is necessary to ensure proper delivery of health care coverage to uninsured low-income children, and to provide enrollees with protections to ensure that such coverage is furnished in an effective and efficient manner that is coordinated with other sources of health benefits coverage for children.

3. Table of Contents for Part 457

We set forth the new provisions for the State Children's Health Insurance Program in regulations at 42 CFR part 457, subchapter D. We note that the following table of contents is for all of part 457 and lists some subparts which have been reserved for provisions set forth in the May 24, 2000 final financial regulation (65 FR 33616).

Subchapter D—State Children's Health Insurance Program (SCHIP)

PART 457—ALLOTMENTS AND GRANTS TO STATES

Subpart A—Introduction; State Plans for Child Health Insurance Programs and Outreach Strategies

Sec.

B. Subpart A—Introduction; State Plans for Child Health Insurance Programs and Outreach Strategies

1. Program Description (§ 457.1)

In proposed § 457.1, we set forth a description of the State Children's Health Insurance Program. Title XXI of the Social Security Act, enacted in 1997 by the BBA, authorizes Federal grants to States for provision of child health assistance to uninsured, low-income children. The program is jointly financed by the Federal and State governments and administered by the States. Within broad Federal rules, each State decides eligible groups, types and ranges of services, payment levels for benefit coverage, and administrative and operating procedures. We received no comments on this section and have retained the proposed language in this final rule.

2. Basis and Scope of Subchapter D (§ 457.2)

Proposed § 457.2 set forth the basis and scope of subchapter D. This subchapter implements title XXI of the Act, which authorizes Federal grants to States for the provision of child health assistance to uninsured, low-income children.

The regulations in subchapter D set forth State plan requirements, standards, procedures, and conditions for obtaining Federal financial participation (FFP) to enable States to provide health benefit coverage to targeted low-income children, as defined in § 457.310. We received no comments on this section and have retained the proposed language in this final rule.

3. Definitions and Use of Terms (§ 457.10)

This subpart includes the definitions relevant specifically to the State Children's Health Insurance Program under title XXI. In this subpart, we defined key terms that are specified in the statute or frequently used in this regulation. We note that those terms that are specific to certain subparts of this

regulation are defined at the opening of each subpart, however, all the terms are listed here. Because of the unique Federal-State relationship that is the basis for this program and because of our commitment to State flexibility, States have the discretion to define many terms.

We proposed the following definitions:

• *American Indian/Alaska Native (AI/AN)* means (1) a member of a Federally recognized Indian tribe, band, or group or a descendant in the first or second degree, of any such member; (2) an Eskimo or Aleut or other Alaska Native enrolled by the Secretary of the Interior pursuant to the Alaska Native Claims Settlement Act 43 U.S.C. 1601 *et seq;* (3) a person who is considered by the Secretary of the Interior to be an Indian for any purpose; (4) a person who is determined to be an Indian under regulations promulgated by the Secretary.

• *Child* means an individual under the age of 19.

• *Child health assistance* has the meaning assigned in § 457.402.

• *State Children's Health Insurance Program (SCHIP)* means a program established and administered by a State, but jointly funded with the Federal government to provide child health assistance to uninsured, low-income children through a separate child health program, a Medicaid expansion program, or a combination of both.

• *Combination program* means a program under which a State provides child health assistance through both a Medicaid expansion program and a separate child health program.

• *Contractor* has the meaning assigned in § 457.902.

• *Cost-effective* has the meaning assigned in § 457.1015.

• *Creditable health coverage* has the meaning given the term ''creditable coverage'' at 45 CFR 146.113. Under this definition, the term means the coverage of an individual under any of the following:

—A group health plan (as defined in 45 CFR 144.103).
—Health insurance coverage (as defined in 45 CFR 144.103).
—Part A or part B of title XVIII of the Act (Medicare).
—Title XIX of the Act, other than coverage consisting solely of benefits under section 1928 (the program for distribution of pediatric vaccines).
—Chapter 55 of title 10, United States Code (medical and dental care for members and certain former members of the uniformed services, and for their dependents).
—A medical care program of the Indian Health Service or of a tribal organization.
—A State health benefits risk pool (as defined in 45 CFR 146.113).
—A health plan offered under chapter 89 of title 5, United States Code (Federal Employees Health Benefits Program).
—A public health plan. (For purposes of this section, a public health plan means any plan established or maintained by a State, county, or other political subdivisions of a State that provides health insurance coverage to individuals who are enrolled in the plan.)
—A health benefit plan under section 5(e) of the Peace Corps Act (22 U.S.C. 2504(e)).

The term ''creditable health coverage'' does not include coverage consisting solely of coverage of excepted benefits including limited excepted benefits and non-coordinated benefits. (See 45 CFR 146.145)

• *Emergency medical condition* has the meaning assigned at § 457.402.

• *Emergency* services has the meaning assigned in § 457.402.

• *Employment with a public agency* has the meaning assigned in § 457.301.

• *Family income* means income as determined by the State for a family as defined by the State.

• *Federal fiscal year* starts on the first day of October each year and ends on the last day of September.

• *Fee-for-service entity* has the meaning assigned in § 457.902.

• *Grievance* has the meaning assigned in § 457.902.

• *Group health insurance coverage* means health insurance coverage offered in connection with a group health plan as defined at 45 CFR 144.103.

• *Group health plan* means an employee welfare benefit plan, to the extent that the plan provides medical care as defined in section 2791(a)(2) of the PHS Act (including items and services paid for as medical care) to employees or their dependents directly (as defined under the terms of the plan), or through insurance, reimbursement, or otherwise, as defined at 45 CFR 144.103.

• *Health benefits coverage* has the meaning assigned in § 457.402.

• *Health maintenance organization (HMO) plan* has the meaning assigned in § 457.420.

• *Joint application* has the meaning assigned in § 457.301.

• *Legal obligation* has the meaning assigned in § 457.560.

• *Low-income child* means a child whose family income is at or below 200 percent of the poverty line for the size family involved.

• *Managed care entity (MCE)* has the meaning assigned in § 457.902.

• *Medicaid applicable income level* means, with respect to a child, the effective income level (expressed as a percentage of the poverty line) that has been specified under the State plan under title XIX (including for these purposes, a section 1115 waiver authorized by the Secretary or under the authority of section 1902(r)(2)), as of March 31, 1997, for the child to be eligible for medical assistance under either section 1902(l)(2) or 1905(n)(2) of the Act.

• *Medicaid expansion program* means a program where a State receives Federal funding at the enhanced matching rate available for expanding eligibility to targeted low-income children.

• *Post-stabilization services* has the meaning assigned in § 457.402.

• *Poverty line/Federal poverty level* means the poverty guidelines updated annually in the **Federal Register** by the U.S. Department of Health and Human Services under authority of 42 U.S.C. 9902(2).

• *Preexisting condition exclusion* has the meaning assigned at 45 CFR 144.103, which provides that the term means a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the first day of coverage, whether or not any medical advice, diagnosis, care or treatment was recommended or received before that day. A preexisting condition exclusion includes any exclusion applicable to an individual as a result of information that is obtained relating to an individual's health status before the individual's first day of coverage, such as a condition identified as a result of a pre-enrollment questionnaire or physical examination given to the individual, or review of medical records relating to the pre-enrollment period.

• *Premium assistance for employer-sponsored group health plans* means State payment of part or all of premiums for group health plan or group health insurance coverage of an eligible child or children.

• *Public agency* has the meaning assigned in § 457.301.

• *Separate child health program* means a program under which a State receives Federal funding from its title XXI allotment under an approved plan that obtains child health assistance through obtaining coverage that meets the requirements of section 2103 of the Act.

• *State* means all States, the District of Columbia, Puerto Rico, the U.S.

Virgin Islands, Guam, American Samoa and the Northern Mariana Islands.

• *State health benefits plan* has the meaning assigned in § 457.301.

• *State plan* means the approved or pending title XXI State child health plan.

• *State program integrity unit* has the meaning assigned in § 457.902.

• *Targeted low-income child* has the meaning assigned in § 457.310.

• *Uncovered child* means a child who does not have creditable health coverage.

• *Well-baby and well-child care services* means regular or preventive diagnostic and treatment services necessary to ensure the health of babies and children as defined by the State. For purposes of cost sharing, the term has the meaning assigned at § 457.520.

We note that comments concerning definitions that are specific to certain subparts are discussed at the opening of those subparts. We received the following comments on the terms defined in this section:

Comment: We received a comment suggesting that we use the terms ''SCHIP'', ''Medicaid expansion program'' and ''separate child health program'' consistently throughout the regulation. The commenter noted that we repeatedly use the term ''SCHIP'' when it appears the term ''separate child health program'' is meant.

Response: We agree with the commenter and have revised the rule for clarity and consistency. Throughout this regulation, we use the terms ''Medicaid expansion program'' and ''separate child health program'' to refer to the different types of programs that States may establish under title XXI. These terms are defined at § 457.10. We use the term ''SCHIP'', also defined at § 457.10, to refer to the State's title XXI program regardless of whether it is a Medicaid expansion program or a separate child health program.

Also for purposes of clarity and consistency, we have added definitions of the terms ''applicant'', ''enrollee'', ''health care services'', and ''uninsured or uncovered child'' to the definitions section of the final rule. We felt that it was important to make clear both the distinctions and the similarities between these two groups of children for purposes of SCHIP (either individually or through action by family or other interested parties).

''Applicant'' means a child who has filed an application (or who has had an application filed on his/her behalf) for health benefits coverage through SCHIP. A child is an applicant until the child receives coverage through SCHIP. An ''enrollee'' is a child who receives health benefits coverage through SCHIP. ''Health care services'' means any of the services, devices, supplies, therapies, or other items listed in § 457.402(a). ''Uncovered child or uninsured child'' means a child who does not have creditable health coverage.

We have added a few definitions related to presumptive eligibility under Subpart C, including ''qualified entity'', ''presumptive income standard'' and ''period of presumptive eligibility''. The Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) expanded the list of entities specifically eligible to make presumptive eligibility determinations and extended the provision related to presumptive eligibility for children under Medicaid to separate child health programs.

Finally, we have added the definition of ''health services initiatives'' to the overall definitions section because it is used throughout the regulation. This term was previously discussed only in Subpart J, in relation to the waiver authority to provide services through community-based delivery systems.

Comment: One commenter indicated that the definition of AI/AN should include a reference to the standards used by the Secretary to define an AI/AN. The commenter agreed with our use of section 4(c) of the Indian Health Care Improvement Act, 25 U.S.C. 1603(c) to define AI/AN. The commenter believes our proposed definition will assist States in meeting requirements regarding the AI/AN population.

Another commenter indicated that our use of the definition of AI/AN set forth in the Indian Health Care Improvement Act is appropriate for purposes of the premium and cost sharing exclusion. However, the commenter notes that the proposed definition of AI/AN set forth at § 457.10 is narrowed by the cost-sharing provisions at § 457.535, which specify that only American Indians and Alaska Natives who are members of a Federally recognized tribe are excluded from cost-sharing charges. The commenter believes that the definition of AI/AN at § 457.535 is more restrictive than that set forth in the Indian Health Care Improvement Act and has no basis in title XXI. The commenter believes that the definition at § 457.535 is also inconsistent with the proposed consultation provisions of § 457.125(a), which expressly requests that States consult with ''Federally recognized tribes and other Indian tribes and organizations in the State * * *'' The commenter asserted that there is little point in consulting with non-Federally recognized tribes about enrollment in SCHIP if the children of those tribes are not excluded from premiums and cost sharing.

Response: We have modified the definition of AI/AN, after discussion with IHS, to make the definition as consistent as possible with both the Indian Health Care Improvement Act (IHCIA) and the Indian Self Determination Act. The definition no longer includes descendants, in the first or second degree, of members of federally recognized tribes, and we have removed the reference in paragraph (4) to regulations to be promulgated by the Secretary. We believe that this definition is substantially equivalent to, and no more restrictive than, the definition in the IHCIA, but is consistent with the flexibility available under the Indian Self Determination Act. We have used this definition because it gives full weight to federally recognized government-to-government relationship between the federal government and tribal governments. We do not intend, however, to restrict the States' ability to engage in a wider scope of consultation in developing their programs.

Comment: One commenter indicated that the definition of ''child'' is inconsistent with their State's statute which considers children up to age 19 for child support purposes. Another commenter supports HCFA's definition of family income as it gives States the flexibility to define income and family.

Response: The definition of ''child'' was taken from section 2110(c) of the Act. With regard to the definition of family income, we appreciate the support and want to give States as much flexibility as possible when defining this aspect of their SCHIP programs.

Comment: We received a comment on the definition of premium assistance for employer-sponsored group health plans. The commenter states that according to the definition of this term at § 457.10, a State can pay all or part of the premium. The commenter notes that this definition appears to conflict with proposed § 457.810(b)(2)(i) and (ii) which require that an employer contribute 60 percent of the cost of the premium, or a lower amount if the State can show that the average contribution in the State is lower than 60 percent, as a protection against substitution of coverage.

Response: The commenter is correct. In order for the purchase of employer-sponsored coverage to be cost-effective in accordance with § 457.810(b)(2), it was our intent to say that the State can pay for all or part of the enrollee's share of the premium for group health plan coverage of an eligible child or children. It is unlikely that a State's payment of

all of the premium would meet the cost-effectiveness test. Accordingly, we have revised the definition of premium assistance for employer-sponsored group health plans to indicate that a State can pay for all or part of the enrollee's share of the premium.

It should also be noted that, in this final rule we have made some significant changes in the list of terms defined, in order to clarify terminology for health benefits coverage provided through a group health plan or group health coverage. We defined the term ''premium assistance for employer-sponsored group health plans.'' We also used the term ''employer-sponsored group health plan'' and ''employer-sponsored group health plan coverage'' throughout the proposed rule.

In hopes of simplifying discussions of our policy, we have elected to create a new term that is intended to be inclusive of all types of group health coverage. We no longer use the term ''employer-sponsored'' prior to references to group health plan or group health insurance coverage in this final rule. We believe that the use of the term ''employer-sponsored insurance'' or ''employer-sponsored group health plan'' could unintentionally narrow the scope of permitted premium assistance programs and wanted to avoid that result. Under HIPAA, the term ''group health plan'' has a very specific legal meaning and refers to a broad array of coverage arrangements; it does not solely refer to health plans offered by a single employer. Therefore, we did not want to cause confusion around the possible scope of programs permitted under Title XXI by using the term ''employer-sponsored'' in connection with provisions relating to premium assistance programs and rather, refer to all of these types of programs accordingly.

Comment: One commenter suggested that HCFA include in the final rule the definition of ''health services initiatives'' set forth in the August 6, 1998 letter to State Health Officials. In the letter, the term is defined as ''activities that protect the public health, protect the health of individuals or improve or promote a State's capacity to deliver public health services and/or strengthens resources needed to meet public health goals.''

Response: We agree with the commenter. We have added the definition of ''health services initiatives'' as set forth in the August 6, 1998 letter.

Comment: Commenters asserted that the definition of well-baby and well-child care for purposes of cost sharing (set forth at § 457.520) be used in three other sections of the regulation: Definitions and use of terms § 457.10; Child health assistance and other definitions § 457.402; and Health benefits coverage options § 457.410(b)(2). One commenter urged that our recognition in § 457.520 that preventive oral health care is part of well-baby and well-child care be extended to the definition of this term at §§ 457.10, 457.402, 457.410(b)(2). The commenter believes that the definition of well-baby and well-child care which includes preventive oral health care should not be treated simply as a category of services left to State discretion for definitional purposes. The commenter noted that the Medicaid program provides for a comprehensive set of services and screenings for oral health care services through EPSDT services. The commenter believes that a clearly defined set of well-baby and well-child care benefits is essential to ensuring a baseline of care in separate child health programs.

Response: EPSDT services are required to be provided to eligible Medicaid beneficiaries under the age of 21 and are defined at section 1905(r) of the Act. Title XXI does not contain the same type of definition for well-baby and well-child care provided under a separate child health program. Therefore, States have the flexibility to design health benefits packages that best fit their needs and resources. In addition, for States that have elected benchmark plans as their health benefits option, these plans may already include standards for furnishing well-baby and well-child care; and it would be inconsistent with the flexibility provided by the statute in this area, as well as cause confusion among plans and providers if we implemented another definition.

Although most separate child health plans do include some type of dental coverage, it is by no means common. Therefore, it is not appropriate to require these services as part of well-baby well-child care. If dental coverage is provided, however, it should be included as part of well-baby well-child care for purposes of cost sharing. Specifically, dental care can be viewed as the oral health equivalent of immunizations in that it can prevent most cavities and subsequent tooth loss, both of which are highly correlated to poverty and lack of access to dental care. Second, we found that the prevailing practice among State employee plans and large HMOs is to pay 100 percent for any routine preventive and diagnostic dental benefits offered for children. Therefore, consistent with section 2103(e)(2) of the Act ''no cost-sharing on benefits for preventive services'' cost sharing may not be applied to these services, if a State chooses to offer them under the State plan.

Comment: Commenters suggested including the word ''adolescent'' in the definition of well-baby and well-child care services. The commenters believe that we should focus on the unique health needs of adolescents, which make up approximately 39 percent of SCHIP eligible youth because their health needs differ from those of younger children. The commenters also urged HCFA to list specifically in the regulation medical sources that have guidelines for regular or preventive diagnostic and treatment services for infants, children and adolescents. These sources should include the American Academy of Pediatrics' ''Guidelines for Health Supervision of Infants, Children and Adolescents,'' the American Medical Association's ''Guidelines for Adolescent Preventive Services,'' and the American College of Obstetricians and Gynecologists' ''Primary and Preventive Health Care for Female Adolescents.''

Response: We have not adopted this suggestion. The definition of child for purposes of SCHIP at § 457.10 and section 2110(c)(1) of the Act indicates that a ''child'' is an ''individual under the age of 19.'' Adolescents under age 19 are clearly included in this age group and therefore we have not included this term in referring to well-baby and well-child care. We encourage States to adopt one of the guidelines mentioned by the commenter, but we have not required adherence to a particular definition.

The commenters urged HCFA to list specifically in the regulation medical sources that have guidelines for regular or preventive diagnostic and treatment services for infants, children and adolescents. The examples of medical sources that are listed in the preamble are meant to serve as recommendations not requirements. The American Medical Association's ''Guidelines for Adolescent Preventive Services,'' is an acceptable medical standard of practice for adolescents and States may use this standard if they choose.

Comment: We received numerous comments on proposed § 457.402(b) and (c), which set forth the definitions of emergency medical condition and emergency services, respectively. Many commenters supported the use of the prudent layperson standard in defining emergency services. Several commenters encouraged HCFA to retain this language because some State Medicaid programs and managed care organizations are not in compliance

with the prudent layperson standard and have denied payment for emergency services because prior authorization was absent. The commenters recommended that HCFA closely monitor the States' programs and managed care organizations on this issue.

Response: We note the support for this provision. With respect to the definition of emergency services under a separate child health plan, States will need to review their contracts with managed care organizations and may need to revise their contracts in order to comply with this requirement. HCFA will monitor States for compliance with this requirement as described in § 457.40 of the final regulation.

Comment: One commenter stated that the required emergency care provisions may disqualify many employer plans. The commenter agreed that such policies can enhance access to emergency care. However, the commenter noted that States using premium assistance programs to subsidize employer-sponsored coverage lack control over emergency coverage. Unlike health plans with direct contracts to provide Medicaid or SCHIP services, requirements for employer-sponsored plans are set by State legislative mandate or dictated by the insurance market. If employer-sponsored plans do not adopt the prudent layperson standard or abandon pre-authorization for emergency care, their coverage may not qualify for SCHIP premium assistance, despite other elements that facilitate emergency care. The emergency care provisions could therefore pose a major barrier to using premium assistance programs for SCHIP purposes.

The commenter recommended that HCFA recognize that the emergency care requirements of the proposed regulations may exclude many valuable employer plans from SCHIP premium assistance programs. To facilitate the use of premium assistance and to reflect the flexibility provided by title XXI, the commenter suggests that HCFA should consider State approaches to ensuring access to emergency care on a case-by-case basis.

Response: We appreciate the recognition that the prudent layperson standard enhances access to emergency care. While we understand the commenter's concerns about the difficulty posed by these requirements if States seek to provide premium assistance for available group health plan coverage, we cannot permit States to deny emergency care to children covered through group health plans. While we encourage States to provide premium assistance for group health plan coverage, it is important that all SCHIP enrollees receive necessary emergency care. States will need to carefully review group health plans to determine whether the required emergency services provisions required by this regulation are in place. If they are not, the State must disqualify those plans from participation in the program or ensure that these requirements are met by providing coverage for emergency services through a wrap-around coverage package to supplement the group health plan coverage.

Comment: One commenter noted that the definition of emergency services should include the availability of necessary resources to evaluate and treat illness and injury.

Response: We have revised the definition of emergency services to clarify the scope of such services. Because the terms ''emergency medical condition'' and ''emergency services'' are used throughout this final regulation, we have moved the definitions for these terms to § 457.10. Section 457.10 defines ''emergency services,'' in part, as services that are ''needed to evaluate or stabilize an emergency medical condition.'' ''Emergency medical condition'' is defined as a medical condition manifesting itself by acute symptoms of sufficient severity such that the absence of immediate medical attention could result in: serious jeopardy to the health of the individual or, in the case of a pregnant woman, the health of a woman or her unborn child; serious impairment of bodily function; or serious dysfunction of any bodily organ or part. Section 457.495 requires that States describe in their State plan the methods they use to assure the quality and appropriateness of care and access to services covered under the plan. Specifically, States must assure access to emergency services. We are not including requirements for State monitoring of such services in the definition because we address such monitoring separately at § 457.495. Compliance with that section includes an assurance that enrollees have access to required emergency services.

Comment: One commenter referenced comments on the proposed Medicaid managed care rules that concerned consistency with Emergency Medical Treatment and Active Labor Act (EMTALA) requirements. The commenter suggested HCFA should coordinate its efforts to enforce relevant requirements for coverage of emergency services with EMTALA enforcement, and should work with OIG, State Medicaid agencies, health plans, and children's health programs to protect Medicare, Medicaid, and SCHIP enrollees.

Response: The comments submitted on the Medicaid managed care regulation are beyond the scope of the proposed rule. Responses to comments received on the Medicaid managed care proposed rule will be addressed in the final publication of that regulation.

With respect to the issue of consistent Federal rules, we are mindful of other definitions of emergency services and have attempted to reconcile our approach with other approaches to the extent permitted by the statute. As for coordination of enforcement efforts, HCFA will monitor the operation of State plans as described in § 457.40 of this final regulation and work with States and other Federal agencies to the extent possible in enforcing the requirements relating to coverage of emergency services.

Comment: One commenter mentioned the need to provide for appropriate payment to hospitals for services provided within the scope of the hospital's obligations under EMTALA. Hospitals feel that if the government requires certain medical screening and other stabilizing treatment, the government should also address how hospitals will be paid for these services. They also noted that obtaining payment for services covered under the prudent layperson standard will help to address the financial burden borne by hospitals.

Response: We refer the commenter to § 457.940 for information on payment rates under separate child health plans. We encourage States to ensure that provider payments are adequate to promote an adequate level of provider access and provider participation and the appropriate provision of services.

Comment: One commenter noted that freestanding urgent care facilities must have the capability to identify children with emergency conditions, stabilize them, and provide timely access to further necessary care. The commenter also stated that urgent care facilities must have appropriate pediatric equipment and staff trained and experienced to provide critical support until patients are transferred for definitive care. In addition, the commenter noted that it is necessary for urgent care facilities to have prearranged access to comprehensive emergency services through transfer and transport agreements to which both facilities adhere. Available and appropriate modes of transport should be identified in advance.

The commenter also noted that after-hours urgent care clinics used as a resource for pediatric urgent care, should solicit help from the pediatric

professional community. Moreover, in this commenter's view, pediatricians who are prepared to assist in the stabilization and management of critically ill and injured children should be accessible. Pediatricians responsible for managing the health care of children may occasionally need to use the resource of urgent care facilities after hours. When such clinics are recommended to patients, pediatricians should be certain that the urgent care center is prepared to stabilize and manage critically ill and injured children.

Response: As noted earlier, under § 457.495 of this final regulation, States must assure appropriateness of care and access to emergency services. A State has flexibility to determine the providers who furnish services, including emergency services. However, a State using free-standing or urgent care facilities as providers under its SCHIP plan for the delivery of emergency services, must meet the requirements of § 457.495 in doing so.

As far as the suggestion that available and appropriate modes of transport be identified in advance, we encourage States and urgent care providers to have arrangements to ensure that transportation is available to appropriate facilities; however the terms of such arrangements are left to States' discretion.

Comment: One commenter is pleased with the guaranteed access to emergency services without prior authorization; however, the commenter was concerned about what happens in a State that provides for no mental health coverage in its State plan.

Response: Under a separate child health program, States are given flexibility, within the confines of the health benefits coverage options outlined in § 457.410, to design their benefit packages. There is no requirement for a State to provide mental health services under its State plan unless the health benefits coverage option selected by the State includes those services. However, we encourage States to provide coverage for mental health services. In addition, we note that emergency mental health services that meet the prudent layperson definition of ''emergency medical condition'' must be available regardless of whether mental health services are covered under the separate child health program.

Comment: Three commenters indicated that children who were covered by section 1115 demonstration projects with a limited benefit package should not be considered to have been recipients of Medicaid. The commenters urged HCFA to provide clarification on the treatment of children eligible for Medicaid under a section 1115 demonstration project that limited eligibility or provided a limited range of services and the availability of enhanced matching for such children.

Response: We agree with the general principle expressed by the commenters that it would not further the purpose of title XXI to exclude from children who were eligible only under a section 1115 demonstration project that was significantly limited in scope and, therefore, was not generally comparable with traditional Medicaid coverage.

In regard to the definition of ''targeted low income child'' at section 2110(b)(1)(C) of the Act, children are excluded from coverage in a separate child health program only when they are found eligible for Medicaid. These comments are relevant, however, the interpretation of the general condition set forth at section 2105(d)(1) of the Act which was implemented by the regulatory provision at 42 CFR 457.622(b)(5), contained in the financial rule published May 24, 2000 (65 FR 33616). That provision merely codified section 2105(d)(1) into regulations without interpretation. In addition, the factors discussed by the commenters affect how we look at ''Medicaid applicable income level'' which is part of the financial need standard that a targeted low-income child must meet.

We have added an additional paragraph to § 457.310 that clarifies that policies of the State's title XIX plan do not include statewide section 1115 demonstration projects that covered an expanded group of eligible children but that either (i) did not provide inpatient hospital coverage, or (ii) did not impose a general time limit on coverage but did limit eligibility by both allowing only children who were previously enrolled in Medicaid to qualify and imposing premiums as a condition of participation in the demonstration.

We have excluded these types of demonstrations because they were particularly narrow in scope and not of the type intended to be encompassed by the reference to ''Medicaid applicable income level'' in section 2110(b)(4) of the Act. This provision ensures that separate child health programs serve low-income children whose income exceeds preexisting Medicaid income levels. However, we do not believe the provision was intended to preclude States from claiming enhanced matching funds for expanded coverage to children whose income is below the demonstration project eligibility thresholds in place as of March 31,1997, if those programs did not offer comprehensive coverage or limited eligibility to individuals who were previously enrolled in Medicaid. Our experience with SCHIP and our increased understanding of how this provision is affecting States' ability to expand coverage have led us to agree with the commenters that an overly broad interpretation of the provision is contrary to the primary purpose of the statute. We have clarified this provision in the final rule accordingly. As a result, children previously eligible for these types of demonstration projects may be included in a separate child health program as a ''targeted low-income child.''

4. Basis, Scope, and Applicability of Subpart A (§ 457.30).

As proposed, this subpart interprets sections 2101(a) and (b), and 2102(a), and 2106, and 2107(c), (d) and (e) of title XXI of the Social Security Act and sets forth the related State plan requirements for a SCHIP program. It includes the requirements related to administration of the State program, the general requirement for a State plan and the process for Federal review of a State plan or plan amendment. This subpart applies to all States that seek to provide child health assistance through SCHIP.

We received no comments on this section and have therefore retained the regulation text language as proposed, except for technical changes.

5. State Program Administration (§ 457.40)

Consistent with section 2106(d)(1) of the Act, at § 457.40(a) we proposed that it is the State's responsibility to implement and conduct its program in accordance with the approved State plan and plan amendments, the requirements of title XXI and title XIX (as appropriate), and the regulations in chapter IV.

To ensure that the State is operating its program accordingly, we indicated that HCFA would review the operation of the program through on-site review or monitoring of State programs. At § 457.40(a), we also proposed that HCFA would monitor the operation of the approved State plan and plan amendments to ensure compliance with title XXI, title XIX (as appropriate) and the regulations in chapter IV. In the preamble to the proposed rule we discussed in detail the general goals for the monitoring provisions as well as expected outcomes of monitoring. We noted that the review process and the implications of noncompliance are specifically addressed in § 457.200, which was set forth in the May 24, 2000

final financial regulation, HCFA–2114–F. (65 FR 33616)

To ensure involvement in and commitment to the program at the highest level of State government, we proposed in § 457.40(b) to require that the State plan and plan amendments be signed by the Governor or by an individual who has been delegated such authority by the Governor. This individual could be the Secretary of Health, the SCHIP Administrator, the Medicaid Director or any other individual who has been delegated authority by the Governor to submit the State plan or plan amendment. In order to facilitate communication between the appropriate State and HCFA staff, we proposed in § 457.40(c) to require that the State plan or plan amendment identify the State officials who are responsible for program administration and financial oversight.

We noted in the preamble that when the passage of State enabling legislation is required to implement a State plan, a State can submit its State plan application before the passage of the legislation. States must indicate in their application if such legislation is necessary and when it will be in place. At § 457.40(d), we proposed that the State plan must include an assurance that the State will not claim expenditures for child health assistance prior to the time that the State has legislative authority to operate the State plan or plan amendment as approved by HCFA.

Comment: One commenter recommended that § 457.40(a) be amended to clarify that States must operate State plans and plan amendments not only in accordance with titles XIX and XXI, but also in accordance with Federal civil rights laws, including title VI of the Civil Rights Act of 1964 and the Americans With Disabilities Act. Accordingly, the commenter recommended that HCFA also monitor the operation of the State plans and plan amendments for compliance with these laws.

Response: It is true that States must operate State plans and plan amendments in accordance with Federal civil rights laws, and we require in § 457.130 that a State provide an assurance in its State plan that it will comply with all applicable civil rights requirements. In addition, § 457.40(a) requires that States implement their programs in accordance with the regulations of this chapter, which include § 457.130. Therefore, we do not believe that it is necessary to amend § 457.40(a) to reference civil rights provisions. Moreover, while HCFA will monitor compliance with § 457.130, the Office for Civil Rights is the primary authority within the Department for monitoring programs and enforcing federal civil rights laws.

Comment: A few commenters suggested that States should be able to designate the program officials by title only, rather than by name, so that the State plan does not need to be amended when there is a staffing change. Another commenter suggested that a Governor or person designated by the Governor inform HCFA in writing of the names of the persons who are responsible for program administration and financial oversight. Another commenter requested that HCFA add a requirement that States identify in the State plan or in a subsequent State plan amendment the State officials who are responsible for providing data on children's enrollment in SCHIP and Medicaid.

Response: We agree with the commenters that it is unnecessary to require State plan amendments when there is a staffing change. Our goal of facilitating communication between the appropriate State staff and HCFA staff would be accomplished by the identification of program officials by position title. As proposed, the regulation text did not indicate that this practice would suffice, and the preamble had indicated that the names of the officials would be required. Therefore, we are revising § 457.40(c) to require that the State must identify, in the State plan or State plan amendment, the position title of the State officials who are responsible for program administration and financial oversight. While we agree with the importance of obtaining enrollment data on a timely basis, we do not believe that the State plan or plan amendments must include a list of program officials who are responsible for specific topics addressed in the State plan, including the official responsible for providing enrollment data. An interested party may contact the individual identified as the official responsible for program administration for specific information on the State program.

Comment: One commenter supported the provision of the proposed rule that prohibits the implementation of a State plan amendment until the amendment had been authorized through enabling legislation by the State legislature if such authorization is required. In this commenter's opinion, ''this represents an important recognition of the ongoing role of the State legislature with the design and operation of SCHIP.''

Response: We appreciate the support of the commenter.

Comment: A few commenters expressed their support for the proposal stated in the preamble to conduct formal State reviews after the first anniversary of each State plan to ensure compliance with the requirements of titles XXI and XIX. More specifically, one commenter commended HCFA for including HRSA officials in the State review.

Response: We appreciate the support of the commenters.

Comment: One commenter found it disappointing that the focus of monitoring of State programs, as set out in the preamble, appeared to be punitive in nature. In the view of this commenter, it appeared that the Department was anticipating the failure of the States to comply and that it therefore must be ready to take corrective and enforcement actions. The commenter suggested that, at the very least, ''identifying the need for corrective action, enforcement and improvement within the State title XXI programs'' should be the last of the four listed expected outcomes of the monitoring.

Response: We did not intend to be punitive, nor do we anticipate the failure of the States to comply with statutory or regulatory requirements or the specifications of the approved State plan. During the monitoring visits that have taken place thus far, the Department has focused on identifying best practices and needs for technical assistance rather than on compliance. In keeping with the commenters' views, we have rearranged the list of expected outcomes of monitoring as follows: (1) Recognizing and sharing best practices that may lead to increased enrollment; (2) identifying States' needs for technical assistance; (3) informing HCFA as we prepare for the Secretary's report to Congress; and (4) identifying the need, if any, for corrective action, enforcement and improvement within State title XXI programs.

Comment: One commenter recognized that ongoing review of State programs is an evolving process, but suggested that HCFA identify either in this regulation or in a separate policy document ''the core set of key policy areas'' that it intends to monitor and to establish a protocol for doing so. The commenter specifically recommended adopting as key policy areas the methods to address the needs of racial and ethnic minority children and the needs of children with disabilities.

Response: The HCFA Central Office and Regional Offices develop procedural guidelines to use in the ongoing operation of the monitoring visits and review process. In the flexible Federal review process that we have established, we will monitor to ensure consistent implementation of the core

set of key policy areas specifically described in the title XXI statute. These areas include enrollment and retention procedures; outreach; coordination with other programs; quality, appropriateness and access to care; and other areas related to compliance with the statute, regulations and approved State plan. Because the review process may change over time and may vary from region to region, depending upon specific State needs and circumstances, we do not believe it is appropriate to further specify these procedures in regulation. We agree with the commenter's concern regarding the needs of racial and ethnic minority children, as well as children with special needs, and we plan to incorporate these issues into our monitoring as appropriate. Furthermore, in recognition of the importance of assessing how SCHIP is addressing the needs of racial and ethnic minority children, we have added reporting requirements to subpart G, at § 457.740(a)(2)(ii) for data on race, ethnicity and primary language as well as gender. We hope that these data, together with ongoing monitoring, will enable States, HCFA, and other interested parties to assess these important policy areas.

Comment: Many commenters indicated that it is essential for HCFA to add a requirement that State and local community based organizations and ''stakeholders'' be involved in HCFA's annual reviews of State SCHIP operations. One commenter explained that it is a practical reality that State officials are at times constrained in their ability to identify problems in their programs candidly; therefore, the inclusion of a diverse group of stakeholders would considerably strengthen HCFA's understanding of State operations and would improve accountability of State programs to their constituents. One commenter recommended including language to recognize the critical role that consumers, advocates, providers, and others play in the design, implementation, and monitoring of SCHIP programs. One of these commenters suggested a public hearing as part of the review. Several commenters expressed a desire that, in providing public input, HCFA provide these organizations and stakeholders with draft and final reports generated through the review process.

Response: We recognize the importance of public involvement in the monitoring process. As part of our ongoing monitoring of programs, including site visits, we have met with advocates, providers and other interested parties, and we have incorporated such contacts into our monitoring protocol. In many cases, as part of the SCHIP site visits, the Regional Office staff have met with advocates and providers to gain additional input on the State's programs. We plan to regularize such conduct, but do not plan to hold public hearings in the course of monitoring of State programs. Moreover, HCFA encourages stakeholders to contact their Regional Office at any time to inform them of issues, suggestions and concerns. The statute specifically requires public input in the development and implementation of SCHIP. Section 2107(c) of the Act, which requires public involvement, and the requirement at § 457.120, reflect the recognition of the importance of involvement of interested parties in the initial design and ongoing implementation of SCHIP. While we will value public input in the monitoring process, to avoid confusion that may be caused by inaccuracies in a draft monitoring report, we do not plan to release draft reports. We will provide final reports to interested parties upon request and encourage such parties to inform us of their comments on these reports.

Comment: One commenter encouraged HCFA to consult with key State level agencies, including Title V Maternal and Child Health and Children with Special Health Care Needs (MCH/CSHCN) programs, in conducting the reviews. In the views of this group, agencies that run State title V MCH/CSHCN programs are involved in SCHIP outreach and enrollment and are vital resources for understanding how SCHIP is working and, particularly, how it fits with other child and family services. One State specifically stated that the Child Support Enforcement (CSE) program should be included in the monitoring because CSE needs to be made aware of children in the child support enforcement caseload that are covered by this type of insurance.

Response: We will monitor for compliance with all regulatory requirements, including the requirement that States coordinate with other sources of health benefits coverage. This may include consulting with other State agencies or programs in conducting reviews as appropriate based on the unique circumstances in the State. We also encourage States to include these partners in the review process. We agree that the Child Support Enforcement agency is an important partner in coordination efforts in the SCHIP program, and issued guidance to this effect in a Fact Sheet on SCHIP and CSE released in January 1999. While we will not require their participation in the monitoring process, our Regional Offices have and will continue to work with State SCHIP agencies to help them identify key partners, including CSE agencies. Further discussion of our requirements for coordination with other programs is found in our responses to comments on § 457.80.

Comment: One commenter recommended that State legislators be included in HCFA site visits that occur as part of the review process.

Response: Because the legislative relationship with SCHIP is different in each State, States may have a widely varying degree of State legislator involvement in the ongoing implementation of their SCHIP programs. State legislators have a key role in the development and oversight of SCHIP programs; however, we do not believe it is appropriate for HCFA to require the inclusion of State legislators in every site visit, as that would intrude into the relationship between State executive and legislative branches. We are, however, willing and interested in meeting with State legislators who have an interest in SCHIP and appreciate their involvement and the special role they play in making SCHIP a success in their home State.

6. State Plan (§ 457.50)

We proposed that the State plan is a comprehensive written statement submitted by the State to HCFA for approval. The State plan describes the purpose, nature, and scope of its SCHIP and gives an assurance that the program will be administered in conformity with the specific requirements of title XXI, title XIX (as appropriate), and the regulations in this chapter. The State plan contains all information necessary for HCFA to determine whether the plan can be approved to serve as a basis for Federal financial participation (FFP) in the State program. We stated in the preamble that an approved State plan is comprised of the initial plan submission, responses to requests for additional information, any other written correspondence from the State and subsequent approved State plan amendments.

Comment: Several commenters strongly recommended consolidating the State plan into one up-to-date document rather than allowing the ''plan'' to be a conglomeration of the ''initial plan submission, responses to request for additional information and subsequent approved State plan amendments.'' Without such consolidation, the commenter indicated that the job of understanding the details of the program is extremely difficult for

policy makers, advocates, and researchers.

Response: We agree that, as some States receive approval for multiple State plan amendments, it will become more difficult to understand the details of the State programs. At this point, an approved State plan is comprised of the initial plan submission, responses to requests for additional information, any other written correspondence from the State related to provisions in the State plan or amendment and subsequent approved State plan amendments. However, in the future, we will request that all States submit consolidated State plans. At such time, we will issue guidance on the format and time frames for submission of a consolidated State plan.

Comment: A commenter asked that, in order to ensure that it will be possible to track States SCHIP policy choices over time, HCFA should commit to keep a copy of each States up-to-date, approved State plan in effect at the beginning of each fiscal year for future reference. Thus, the commenter observed, even if a State plan is subsequently amended, HCFA will have a record of the policies in place for any given State at the beginning of each fiscal year. By keeping an annual ''snapshot'' of States' SCHIP plans, the commenter noted that HCFA will make it possible for Federal, State, and local policy makers, as well as researchers, to evaluate the impact over time of States' SCHIP implementation choices.

Response: We will continue to keep a record of all State plans, including historic provisions with the effective date of each State plan amendment, so that we will have record of, and be able to make available to others, the policies that were in effect at any given time throughout the operation of a State's program.

Comment: One commenter stated that the plan should be ''easily accessible.'' One commenter suggested that the preamble language state that the approved State plan, including any attachments, will be made available to the public on the web.

Response: We will continue to make an effort, as resources permit, to make the approved State plan and any approved State plan amendments available to the public on the web site or through links to State sites. To facilitate the posting of this material, we encourage States to submit proposed plan amendments and responses to requests for additional information in an electronic format.

7. Amendments (§ 457.60)

Section 2106(b)(1) of the Act permits a State to amend its approved State plan in whole or in part at any time through the submittal of a plan amendment. We proposed in § 457.60(a) that the State plan must be amended whenever necessary to reflect changes in Federal law, regulations, policy interpretations or court decisions; changes in State law, organization, policy or operation of the program; or changes in the source of the State share of funding. In the preamble to the proposed rule, we discussed in detail our view that only changes that are substantial and noticeable would require amendments. Specifically, we stated that changes in program elements that would not ordinarily be required to be included in the State plan at all would not require an amendment. We proposed in § 457.60(b) that when the State plan amendment makes any modification to the approved budget, a State must include an amended budget that describes the State's planned expenditures for a three year period.

Comment: A few commenters suggested that HCFA provide SCHIP programs with ''preprints'' such as those provided in the Medicaid program to inform the State of changes in Federal law and regulations.

Response: We agree with commenters that providing preprints would assist States in complying with changes in Federal laws, regulations and policies. In Medicaid, a ''preprint'' is similar to the State plan template we have provided in SCHIP, where the State agrees to administer the Medicaid program in accordance with federal law and policy. The Medicaid State plan preprint sets forth the scope of the Medicaid program, including groups covered, services provided, and reimbursement rates for providers. In SCHIP, we have provided States with a State plan template, which also serves as the template for amendments to the State plan, and lays out in a series of questions and check boxes a guideline for States to follow in explaining the components of their program. We will be revising this template to reflect the provisions of this final regulation.

Comment: Many commenters asked that States be given a reasonable amount of time to implement new Federal requirements. One State specifically recommended that each State's contracting cycle time be used as the appropriate implementation time frame for new requirements. Another commenter urged the Department to take into consideration the many factors outside of Governors' control, such as contract cycles and legislative sessions, in determining when States must achieve final compliance.

Another commenter strongly urged that HCFA add a new subsection to § 457.60 that establishes a procedure by which States can submit State plan amendments that bring their State plans into compliance with the requirements of title XXI as set forth in the final version of the regulation. This commenter suggested that HCFA give States no more than six months after the issuance of the final regulations to submit State plan amendments that bring them into compliance.

Response: Most of the rules set forth in these final regulations are not new; in most cases, these rules reflect the pre-regulatory guidance issued since SCHIP was enacted into law. However, we note the commenters' concern that States need a reasonable amount of time to implement new Federal rules that have been promulgated in response to the comments received. We have considered that compliance with these final rules may require State legislation or changes to contracts. We will require that States come into conformity with new requirements within 90 days of publication of this rule, or if contract changes are necessary, the beginning of the next contract cycle. By contract cycle, we mean the earlier of the date of the end of the original period of the existing contract, or the date of any modification or extension of the contract (whether or not contemplated within the scope of the contract). If a new regulatory provision requires a new or amended description of procedures in the State plan, the State must implement the procedures within the above time frame, but the State plan amendment does not necessarily need to be submitted within the 90-day period as provided in § 457.65(a)(2). For example, if this final regulation were published on January 1, 2001, then States would have to comply with all new requirements by March 31, 2001 (unless the implementation of the new regulatory provision requires a contract change.) If a State needs to amend the State plan to include a new or revised description, then the State still must implement the new requirement by March 31, 2001, and must submit the State plan amendment by the end of that State fiscal year, or, if later, the end of the 90-day period.

Comment: A commenter requested that we require State plan amendments to describe the steps the State has taken to ensure that any organizations with which it contracts using title XXI funds are in full compliance. In some cases, the commenter noted, it is possible that a State will be unable to comply with

aspects of the final rule until it completes a contract cycle or convenes a legislative session. In such cases, the commenter recommended that a State could be given the opportunity to negotiate an alternative time frame with HCFA for implementation of selected aspects of the final rule.

Response: We do not agree with the suggestion that we require States to describe in their State plans how they have assured compliance of its contractors with title XXI. The State has the responsibility under section 2106(d)(1) of the Act for ensuring that the State, including its contractors, fulfills the obligations of title XXI. If we find through monitoring that services are being provided in a manner that is substantially noncompliant with applicable Federal law, regulations and the approved State plan, then we may take compliance actions in accordance with subpart B of part 457 (promulgated at 65 FR 33616, May 24, 2000).

Comment: One State indicated that modifications to its State plan to reflect changes in Federal law would be ''counterproductive'' because substantial changes to the ongoing program to come into compliance with new regulations could lead to coverage delays for some children. This same State also recommended that any new regulations or policy interpretations that would restrict or substantially alter a State's SCHIP should apply only prospectively, that States should not have to amend their approved State plans retroactively, and that ''agreements that were previously approved should not be changed unless HCFA could prove that a beneficiary would be substantially harmed in the absence of such a change.'' If HCFA requires States to make changes retroactively, this State recommended that HCFA should provide additional funds to help States finance the costs of the changes and that these funds should not be deducted from the States' title XXI allotments.

Response: We are requiring that States comply with this final rule on a prospective basis. States will not need to comply with new requirements retroactively. As previously set forth, this regulation will take effect 90 days after the publication date, although, if contract changes are necessary to comply with a particular requirement States will not be considered out of compliance if they do not comply with that requirement until the beginning of the next contract cycle, as described above. Pre-existing Federal requirements that have been incorporated into this regulation are already effective. States that are not complying with these pre-existing requirements could be subject to an enforcement action.

Comment: Several commenters asserted that proposed § 457.60(a)(2) requiring a State plan amendment to reflect ''[c]hanges in State law, organization, policy or operation of the program'' was too expansive and exceedingly burdensome. One commenter suggested that operational changes that do not affect eligibility or benefits not be treated as changes that require State plan amendments. Another commenter recommended that we require a State plan amendment only for a change that eliminates, restricts, or otherwise modifies eligibility, even if the change impacts only a small number of enrollees.

Some commenters recommended that the State plan amendments should be required for any changes in the following areas: (1) Eligibility, including crowd-out policies; (2) benefits, including type, scope, and duration; (3) cost sharing; (4) data reporting; (5) screen and enroll procedures under §§ 457.350 and 457.360; (6) procedures for rationing access to enrollment; (7) disenrollment for failure to pay cost sharing or for cause; and (8) substantial changes in outreach and enrollment policies.

Response: We agree that the proposed requirement set forth at proposed § 457.60(a)(2), (now § 457.60(b)), was administratively burdensome. Our intention was better reflected in the preamble to the proposed rule, although this, too (particularly our use of the phrase ''substantial and noticeable'') merited further clarification. We had specifically requested comments on this issue in the preamble to the proposed regulation.

In light of these comments, we have revised § 457.60 to be more precise about when amendments must be submitted. We have revised proposed § 457.60(a)(1), now § 457.60(a), to generally require a State to amend its State plan whenever necessary to reflect changes in Federal law, regulations, policy interpretation, or court decisions, that affect provisions in the approved State plan. This element of the final rule assures that a State keeps its State plan up-to-date; this is particularly important to assure ongoing public involvement in program implementation. We have revised proposed § 457.60(a)(2), now § 457.60(b), to require a State to amend its State plan whenever necessary to reflect changes in State law, organization, policy or operation of the program that affect key program elements. Thus, amendments are required when there are changes in eligibility, including but not limited to enrollment caps and disenrollment policies; procedures to prevent substitution of private coverage, including exemptions or exceptions to required periods of uninsurance; the type of health benefits coverage offered; addition or deletion of benefits offered under the plan; basic delivery system approach; cost sharing; screen and enroll procedures, and other Medicaid coordination procedures; and other comparable required program elements. We may issue guidance to further interpret ''other comparable required program elements'' as the program evolves and experience demonstrates that there are other changes that should require an amendment.

We do not agree that required State plan amendments should be limited only to those that eliminate or restrict eligibility or benefits. We also have not required a State plan amendment for changes in data reporting, as suggested by the commenters, because for approval of a State plan, a State is only required to provide an assurance that it will provide data as required by HCFA and that data may change over time. Finally, we have not required a State plan amendment for substantial changes in outreach strategies, as suggested by the commenters, because we believe that a State needs to have flexibility to adapt its outreach strategies as frequently as it finds necessary to best reach potentially eligible children without having to submit a State plan amendment in order to do so.

Comment: Several commenters praised HCFA for noting in the preamble its intent only to require an amendment for substantial and noticeable program changes and hoped this flexibility would be reflected in the final rule.

Several commenters noted that ''substantial and noticeable'' changes can be interpreted in a variety of ways, depending upon whom the change affects. One commenter noted that a change that affects the eligibility of 300 families across the State, 25 families in one community, or a particular group such as immigrant families, will be substantial and noticeable to the affected families, but likely to be inconsequential and unnoticed by the rest of the State or the community. Another commenter recommend that the ''substantial change'' language be added to the regulation text, as opposed to only being mentioned in the preamble, given that courts and other agencies cannot rely on language contained only in the preamble.

Response: We appreciate the commenters' support for our general

intent to require amendments only for significant and noticeable program changes. As discussed above, we agree that the discussion of this issue in the preamble to the proposed rule was not clear and did not provide sufficient guidance to States. Further, we agree that the policy should be included in the regulation text to ensure proper implementation. Therefore, we have revised § 457.60(a) (now § 457.60(b)) to clarify when a State plan amendment will be required, by identifying the categories of changes that, by their nature, have a significant effect. State plan amendments will be required for all program changes that fall into these categories.

Comment: One commenter believes that HCFA should not require either State plan amendments or public input for small program changes.

Response: As noted in previous responses, we have revised proposed § 457.60(a)(2), now § 457.60(b), to specify those changes that require a State plan amendment; the rules assure the plan will be revised to reflect significant program changes. We require States to provide assurances that it permits ongoing public involvement once the program has been implemented, and we require certification of public notice for State plan amendments relating to eligibility and benefit restrictions pursuant to § 2106(a)(3)(B) of the Act (see § 457.65(b)(1).) We are not, however, requiring that a State routinely certify that it has obtained public input prior to submitting a plan amendment to HCFA. We encourage States to obtain meaningful public input prior to submission of a State plan amendment and believe that public involvement prior to the implementation of a program change would constitute an important part of the ongoing public involvement. Further discussion of requirements for public involvement are found in response to comments on § 457.120.

Comment: One commenter suggested that proposed § 457.60(a)(3) (now § 457.60(c)) and § 457.65(d)(2) (the section containing more detail on State plan amendments regarding changes in certain sources of funding) be combined for organizational purposes. Another commenter recommended that HCFA delete the requirement that a State submit a State plan amendment when the source of the State share of the SCHIP funding changes because the source of State funding is ''irrelevant.'' Another commenter recommended that HCFA should consider another mechanism for ensuring that States do not use prohibited revenue sources such as impermissible provider taxes or donations. One commenter noted that this requirement will deter States from modifying their plans in order to better provide health services to children in need.

One commenter asserted that a certification by the State should be sufficient to assure that the State is not using impermissible taxes. Another commenter suggested that federal concerns would be better addressed by an effort to educate States as to the statutory limitations on such taxes.

Response: We agree that combining proposed § 457.60(a)(3) and § 457.65(d)(2) makes organizational sense because both relate to changes in the source of a State share of funding. Therefore, we have deleted proposed § 457.65(d)(2) and revised proposed § 457.60(a)(3), now § 457.60(c), to include the substance of § 457.65(d)(2). Section § 457.60(c) now requires a State to amend its State plan whenever necessary to reflect changes in the source of the State share of funding, except for changes in the type of non-health care related revenues used to generate general revenue.

However, we disagree with the commenter's recommendation to delete proposed § 457.60(a)(3), now § 457.60(c). The source of State funding is relevant because Section 2107(d) of the Act requires a State plan to include a description of the budget for the plan and include details on the sources of the non-Federal share of plan expenditures, as necessary. In addition, section 2107(e)(1)(C) of the Act provides that section 1903(w) of the Act (relating to limitations on provider taxes and donations) applies to States in the same manner under title XXI as it applies under title XIX. Because section 1903(w) of the Act prohibits States from collecting impermissible provider taxes and donations, and because the title XXI statute requires States to identify, in detail, sources of the States' share of expenditures, it is appropriate to evaluate the permissibility of the non-Federal funding sources involving health care-related taxes and/or donations prior to approval of a State plan and whenever the State changes its source of State funds. The method of evaluating the permissibility of State funding sources involving health care-related taxes and/or donations, as set forth at proposed § 457.60(a)(3), now § 457.60(c), is the most efficient mechanism to ensure protection to beneficiaries, Federal taxpayers, and States. However, it should be noted that if a State makes a programmatic change as a result of a change in the amount of the source of the State share, then it is required to submit a State plan amendment in accordance with § 457.60(b).

We believe it is our obligation to ensure the implementation of the congressional intent that States not use impermissible sources of funding for child health programs, as impermissible State funding would place a State's entire program at risk. Furthermore, it appears that Congress sought to avoid the process used in Medicaid of assessing penalties that may accumulate over a long period of time and the disruption in program operation that such penalties can create. By requiring a State to submit a State plan amendment for review, we have an opportunity to prevent the States' use of impermissible funding and any consequential disruption of the program. In the long run, the process better protects States' and the federal government's interest in assuring continuity and ongoing coverage of children.

Comment: A few commenters expressed their concern that the requirement at proposed § 457.60(b) for amended three-year budgets when States modify approved budgets creates a significant burden for both the States and HCFA. A State expressed the opinion that this requirement is particularly burdensome if applied to insignificant modifications to the approved budget.

Two commenters suggested that a three-year budget is difficult because ''State budget processes and legislatures do not always coincide with program decisions.'' Another commenter similarly noted that a three-year budget is longer than a State agency can reasonably determine at the time program decisions are made because the State portion of the budget is determined annually by the State legislature. An additional commenter stated that the requirement at proposed § 457.60(b) works against the budgetary processes currently in place at the State level, and that budgets are developed for two years into the future at most.

Several commenters argued that three year budget estimates will not be accurate, citing reasons such as the uncertainty caused by tremendous enrollment growth, changing populations, variations in State revenues, and unstable medical expenditures. Two States commented that three year budget estimates would not provide the level of information necessary to assure financial ability to support the program change, and would be of limited use because they would not reflect either actual expenditures or actual enrollment. These States thus

asserted that the stated rationale in the preamble, that such a projection would be useful to show if States plan to spend their money in the succeeding two years, will not apply.

One State asserted that there is no reason to look to Medicaid waiver processes for a model for SCHIP budget requirements, since the waiver process requires a demonstration of budget neutrality that is not necessary in SCHIP. This State argued that the model should be the title XIX State plan amendment process.

Some States suggested alternatives for the proposed requirement for three-year budgets with State plan amendments, such as an assurance of available funding; a three year budget with the annual report but not each State plan amendment; or a one-year budget rather than a three-year budget. Several commenters suggested that an amended three year budget should be required only when a State plan amendment would make a significant modification to the previously approved budget, such as a major change in the benefit package, eligibility rules, or cost-sharing.

Response: We agree with the commenters' concerns that the requirement for a three-year budget with a State plan amendment at proposed 457.60(b) creates an unnecessary burden for the States. Section 2107(d) requires that the State's description of the budget for its State plan be updated periodically as necessary. Because we otherwise require that the budget be updated periodically through the annual reports and through quarterly financial reporting, we have revised the requirement at proposed § 457.60(b), now § 457.60(d), to require that only a one-year budget be submitted with a plan amendment that has a significant impact on the approved budget. An amendment would have impact on the approved budget if it changes program elements related to eligibility, as required by § 457.60(b)(1) or cost sharing, as required by § 457.60(b)(6). We have also revised § 457.750 to reflect this change.

Section 457.140, will continue to require that the State submit a three-year budget with their annual report that describes the State's planned expenditures. Because States have up to three years to spend each annual allotment, a three-year budget is useful to show if States project that they will use their unused allotments in the succeeding two fiscal years. We realize that a State must base the required information on projections and that the budget projections submitted to HCFA are not approved by a State's legislature. We also recognize that projections of expenditures for a three-year period may vary from actual expenditures for a variety of reasons. Because SCHIP is a new program, States did not have experience at the beginning of the implementation of their programs to accurately predict enrollment of children or costs associated with providing services. However, we expect that as States gain experience in operation of their programs and as the State program rules stabilize over time, the three-year projections will become more accurate. A three-year budget helps the State plan program expenditures and helps HCFA to analyze spending and develop a responsive reallocation formula within the parameters of the statute.

The preamble for § 457.140 included a discussion of the budget projections required in other programs. We would like to clarify that this discussion was not intended to serve as a rationale for the requirement for a three-year projection of expenditures in the SCHIP program. This discussion was intended to demonstrate that we took the budgetary requirements of other programs into consideration as we determined our budget requirements for SCHIP.

8. Duration of State Plans and Plan Amendments (§ 457.65)

In § 457.65, we proposed that the State may choose any effective date for its State plan or plan amendment that is not earlier than October 1, 1997.

We noted in the preamble that a State may implement a State plan prior to approval of the plan but that any State that implements an unapproved State plan risks the possibility that the plan will not be approved as implemented. If a State implements a State plan prior to approval and it is approved, we also indicated in the preamble our interpretation that the State can receive Federal matching funds on a retroactive basis for expenses incurred (other than expenses incurred earlier than October 1, 1997) for the programs if the State operated in compliance with the approved State plan and all applicable statutory and regulatory requirements. In the event that the State plan is not approved, the Federal government would not match the State's prior expenditures for implementation of the State plan.

In the preamble to the proposed rule, we noted the risks involved in implementing a change in the State program without receiving prior approval of that change through a State plan amendment. If a State makes a change and the State plan amendment reflecting the change is later disapproved, the State may either risk its Federal matching or face a compliance action. The State cannot receive Federal matching for expenditures on a program change that is disapproved through the State plan amendment process if these expenditures can be segregated from expenditures on the approved State plan. The State would be subject to the compliance remedies described in section 2106(d) of the Act, as implemented in the final financial regulation (65 FR 33616), May 24, 2000, if the expenditures on such a program cannot be segregated from expenditures on the approved State plan. A compliance action is appropriate because the continued operation of the unapproved program change constitutes a failure to conduct the State program in accordance with the approved State plan.

Section 2106(b)(3)(C) of the Act provides that any State plan amendment that does not eliminate or restrict eligibility or benefits can remain in effect only until the end of the State fiscal year in which it becomes effective (or, if later, the end of the 90-day period in which it becomes effective) unless the State plan amendment is submitted to HCFA before the end of the period. We proposed to implement this provision at § 457.65(a)(2). Thus, if a State program change is implemented and the corresponding amendments are not submitted within the required time frame, the State risks being found out of compliance with its State plan and therefore, risks loss of Federal financial participation in expenditures beyond the scope of the approved State plan or other financial sanctions, as discussed in the final financial regulation (65 FR 33616), May 24, 2000.

Section 2106(d)(2) of the Act requires that the Secretary provide a State with a reasonable opportunity for correction before taking financial sanctions against the State on the basis of an enforcement action. Thus, we proposed to clarify certain provisions set forth in HCFA 2114–F (65 FR 33616, May 24, 2000). Specifically, paragraph (d)(2) of § 457.204, ''Withholding of payment for failure to comply with Federal requirements,'' discussed the opportunity for correction prior to a financial sanction for failure to comply with a Federal requirement. As proposed, § 457.204(d)(2) provided that if enforcement actions are proposed, the State must submit evidence of corrective action related to the findings of noncompliance to the Administrator within 30 days from the date of the preliminary notification. In the SCHIP

programmatic regulation, we proposed to revise § 457.204(d)(2) to address in more detail the possible scope of corrective action that could be required. We proposed that corrective action is action to ensure that the plan is and will be administered consistent with applicable law and regulations, to ameliorate past deficiencies in plan administration, and to ensure equitable treatment of beneficiaries.

In accordance with section 2106(b)(3)(B)(ii) of the Act, at § 457.65(b), we proposed that an amendment that eliminates or restricts eligibility or benefits under the plan may not be effective for longer than a 60-day period unless the amendment is submitted to HCFA before the end of that 60-day period. We further proposed, in accordance with section 2106(b)(3)(B)(i), that amendments that eliminate or restrict eligibility or benefits under the plan may not take effect unless the State certifies that it has provided prior public notice of the proposed change in a form and manner provided under applicable State law. The notice must be published prior to the requested effective date of change.

At § 457.65(c) we proposed that a State plan or plan amendment that implements cost-sharing charges, increases the existing cost-sharing charges or increases the cumulative cost-sharing maximum permitted under proposed § 457.560 is considered an amendment that restrict benefits and must meet the requirements of § 457.65(b).

At § 457.65(d), we proposed that a State plan amendment that requests approval of changes in the source of the State share of funding must be submitted prior to such change taking effect. With regard to source of funding, we stated that if a State has indicated that general revenues are the source of funding, then we would require a plan amendment for changes in the State's tax structure that reflect or include a change to general revenues based on health care related revenues used to finance the State's share of title XXI expenditures. We would not require a plan amendment to reflect changes in the type of non-health care related revenues used to generate general revenue.

In accordance with section 2106(e) of the Act, at § 457.65(e), we proposed that an approved State plan continues in effect unless the State modifies its plan by obtaining approval of an amendment to the State plan or until the Secretary finds substantial non-compliance of the plan with the requirements of the statute and regulations. An example of substantial non-compliance would be the imposition of cost-sharing charges that exceed Federal limits.

Comment: A few commenters expressed concern about the time frames for submission of State plan amendments. A commenter suggested that HCFA follow guidelines similar to Medicaid guidelines that allow a State to submit a plan amendment that is statutorily allowable in the quarter after the State's implementation of the change. Another commenter proposed that the time frames for submitting an amendment be the same regardless of whether the State plan amendment limits or restricts eligibility or benefits. In the view of this commenter, States are likely to make errors if the time frames are different.

Response: Section 2106(b)(3) of the Act provides specific time frames for submission of State plan amendments. A State plan amendment that does not eliminate or restrict eligibility or benefits can remain in effect until the end of the State fiscal year in which it becomes effective (or, if later, the end of the 90-day period in which it becomes effective) unless the State plan amendment is submitted to HCFA before the end of that State fiscal year or the 90-day period. This time frame is more liberal than the time frame under the Medicaid guidelines, which only permit a title XIX amendment to be effective from the first day of the quarter in which the amendment is submitted. Furthermore, under the statute, an amendment that eliminates or restricts eligibility or benefits under the plan may not be effective for longer than a 60-day period unless the amendment is submitted to HCFA before the end of that 60-day period. While we note the potential for confusion caused by two different time frames, section 2106(b)(3) of the Act explicitly provides for different time frames for different types of amendments and does not provide authority for a different process. States are encouraged to discuss planned amendments with HCFA to assure they are submitted in a timely manner.

Comment: One commenter appreciated HCFA's support for State flexibility in how to provide public notice of State plan amendments. Other commenters applauded HCFA's decision to treat State plan amendments that increase cost sharing as amendments that restrict ''eligibility or benefits.''

Response: We note the commenters' support.

Comment: One commenter requested that HCFA clarify whether it intends to require public notice when a family will experience an increase in its premium share because the subsidy rate is being applied to a premium that resulted from an insurance carrier rate increase. In this commenter's view, public notice is unnecessary in this situation because the State is not initiating the private sector rate increases. The State could continue to assure that the family's total cost sharing remains within Federal limits.

Response: A change in cost sharing that increases the amount of premium share owed by the enrollee, must be reflected in a State plan amendment that meets the requirements set forth in § 457.65(c). However, an increase in premium share that does not affect the enrollee's cost-sharing charges or that does not bring the cost sharing charges above the level reflected in the State plan would not be subject to the public notice requirements of § 457.65(b). We recognize that § 457.65(b) could be difficult to administer in States that provide premium assistance for coverage provided through group health plans, depending how a State chooses to design its premium assistance program. However, such an increase may impact the enrollee's access to services and participation in SCHIP and, consistent with the statutory requirements for amendments eliminating or restricting benefits at 2106(b)(3)(B), the public must be given notice prior to the increase. The statute does not provide an exception for coverage provided through group health plans.

However, a State has flexibility to design a system that will meet the prior public notice requirement. For example, a State may choose to require that the family be charged a fixed dollar amount, rather than a percentage of total premium, to hold constant the amount of premium share that the family is charged. Alternatively, a State may generally keep its charges for premium assistance programs below the level of cost sharing approved under the State plan to allow room for some cost-sharing increases that would not bring the charges above the level reflected in the plan. A State also may choose to establish a mechanism to be notified of increases prior to those increases taking effect so that it may provide prior public notice as required by § 457.65(b).

Comment: A commenter asked that HCFA clarify that ''cost sharing'' in this context is defined in the same way as it is in § 457.560 for purposes of imposing cumulative maximums.

Response: So that the term ''cost sharing'' has the same meaning throughout the final rule, we have added a provision in § 457.10 to define it to include premium charges, enrollment fees, deductibles, coinsurance, copayments, or other

similar fees that the enrollee has the responsibility for paying. However, we note that for purposes of the actuarial analysis required at § 457.431(b)(7), cost sharing includes only copayments, coinsurance and deductibles as described in the Notice of Proposed Rulemaking.

Comment: One commenter asked HCFA to clarify that amendments that lengthen or institute eligibility waiting periods of uninsurance or narrow exceptions to such waiting periods constitute amendments that affect ''eligibility or benefits.''

Response: To clarify that instituting or changing eligibility waiting periods without health insurance, narrowing exceptions to such periods, or changing open enrollment periods in a way that would further restrict enrollment in the program are considered to be State plan amendments that restrict eligibility, we have added a new paragraph (d) to § 457.65. This new provision specifies that a State plan amendment that implements eligibility waiting periods without health insurance; increases the length of existing eligibility waiting periods without health insurance; or institutes or expands the use of waiting lists, enrollment caps or closed enrollment periods is considered an amendment that restricts eligibility and must meet the public notice requirements set forth in this section. Eligibility waiting periods without health insurance and limited open enrollment periods are restrictions in eligibility because these enrollment procedures directly limit an enrollee's access to the program. We further clarified in § 457.305 that in the State plan, the State must include a description of the State's policies governing enrollment and disenrollment, including enrollment caps, process(es) for instituting waiting lists, deciding which children will be given priority for enrollment, and informing individuals of their status on a waiting list, if applicable to that State.

Comment: Many commenters expressed concern about whether the provision at § 457.65(b)(1) requiring States only to certify that they have provided public notice of such plan amendments ''in a form and manner provided under applicable State law'' provides meaningful public input into proposed State plan amendments. These commenters questioned whether ''notice'' provides the opportunity to comment on and discuss a proposal, and point out that the form of notice could prove largely meaningless, depending on a State's particular laws. Several commenters recommend that the final rule require States to certify that they have provided prior public notice and a meaningful opportunity for the public to submit comments on any proposed State plan amendments that affect eligibility or benefits. States have found such input to be helpful to identify ways in which the program can be improved and maintain strong support for the program. An additional commenter believed that State plan amendments to make changes in benefits require public notice and comment.

Response: We encourage States to obtain meaningful public input prior to submission of a State plan amendment that eliminates or restricts eligibility or benefits. Furthermore, we require, in § 457.120, that States involve the public once the program has been implemented. However, section 2106(b)(3)(B) of the Act specifically permits a State to certify that it has provided public notice of the change in a form and manner provided under applicable State law, and we believe the requirements under § 457.65 are consistent with the flexibility provided by this statutory provision.

Comment: One commenter requested that we clarify § 457.65(b)(1) to confirm that States must certify that they have complied with applicable State administrative procedure law or similar requirements mandating public notice and comment with respect to the promulgation of rules or regulations of general applicability. This commenter also requested modification of the provision to clarify that the State must certify that it has complied with all applicable State legal requirements for notice *and* a meaningful opportunity for public comment. Although State processes vary, this commenter indicated that there is generally a requirement that notice be issued for a specified period of time, followed by a period for public comment. This same commenter believes that § 457.65(b)(2), which requires that public notice be published before the effective date of the change, should be eliminated because it could be interpreted to allow State plan amendments that restrict or eliminate eligibility or benefits to become effective as long as the public notice was published before the requested date of the change, regardless of whether or not the State had provided meaningful opportunity for public comment or whether the applicable time frames had been met.

Response: As noted in the previous response, § 457.65(b)(1) implements section 2106(b)(3)(B) of the Act, which specifically permits a State to certify that it has provided prior public notice of the change in a form and manner provided under applicable State law. While we encourage States to consider public input, title XXI addresses only public notice as a condition for the effective date of certain State plan amendments. Our regulation is not intended to restrict notice and comment opportunities available under State law. We note that States must also comply with the requirements of § 457.120 regarding public involvement.

Comment: One commenter suggested that proposed and submitted State plan amendments be posted on the HCFA and State web sites. The commenter noted appreciation for the effort that HCFA has made to date to post information about the filing of State plan amendments on its web site and encourages the agency to modify the preamble to clarify that State plan amendments (along with State plans) will continue to be made available to the public through the HCFA web site. According to this commenter, the preamble should indicate that HCFA will post the actual plan amendments that are pending whenever possible and that, should this not be possible, the agency will list the name and phone number of a State official who can provide a copy of the pending State plan amendment.

Response: We will continue to make an effort, as resources permit, to make the approved State plan and any approved State plan amendments available to the public on the web site. However, we do not post pending State plan amendments on the web site because amendments are often altered during the approval process, and this may cause confusion to the public, although we will consider identifying on the HCFA web site whether a State has a pending plan amendment under review. The position title of the State official responsible for program administration may be found in the approved State plan. Also posted on the HCFA web site is a list of HCFA contacts for each State's SCHIP program.

Comment: Over a dozen commenters opposed the proposed provision at § 457.65(d) to require prior approval of a plan amendment regarding a States' share of program funds and requested that this requirement be withdrawn. According to these commenters, section 2106 of the Act contemplates a process under which States can specify the effective date of their plans or amendments and, if a plan is approved, a State can receive matching funds on a retroactive basis. In these commenters' view, the statute sets forth straightforward limits on a State's flexibility to specify effective dates, but those limits do not contemplate prior

approval of an amendment. The commenters asserted that the statutory scheme provides adequate remedies for the Secretary if the plan or plan amendment is subsequently disapproved.

Response: We believe the commenters' concerns may be based in a misunderstanding of the process. The requirement at proposed § 457.65(d) does not prevent States from implementing a new source of funding prior to receiving State plan or plan amendment approval. It requires that an amendment be submitted before the change can be implemented, but the amendment does not need to be approved in order for a State to receive matching funds for expenditures relating to the change. A State can submit its amendment on January 1, begin using the new source of funding on February 1, and receive matching funds retroactive to February 1 if the amendment is approved on or after that date.

The requirement at § 457.65(e) ensures that the time period during which a State may operate a program using impermissible funds is limited to the time during which the amendment is under review. HCFA can only approve a State plan amendment to the extent that the source of funding is considered permissible. Thus, while a State may implement a new source of funds prior to receiving State plan approval, the Federal matching funds are at risk until a determination of permissibility has been made. To the extent that source is determined to be impermissible, the State plan amendment would be disapproved and the State would realize the penalty against its SCHIP expenditures in accordance with the statutory penalty provisions. We expect that the required process will protect States from proceeding too far using impermissible State funds, and from thereby placing these programs and enrollee coverage at risk. Furthermore, a State is not required to submit a State plan amendment for changes in the source of general revenues used to fund SCHIP, as long as those changes are not affected by health care-related taxes or donations. For further rationale on our policy requiring amendments on changes in the source of State funding, please see earlier comments on § 457.60.

Comment: Several commenters asserted that the proposed § 457.65(d) intruded on State budgeting and financial prerogatives, was contrary to practices in other federal-state matching programs, and could not have been intended by Congress. One commenter did not understand why the Federal government wants prior approval of increases in State commitments under title XXI when Congress has provided States with firm allotments for at least five years. Several commenters noted that it may not be possible for the State to submit a State plan amendment to HCFA before the effective date of any change in the source of the State share of funding becomes effective because of the legislative budgeting cycle, which sometimes includes supplemental funding for incurred expenditures or legislation with a retroactive effective date to take advantage of previously unavailable funds.

Response: It is important to note that § 457.65(d) does not require prior approval of new State funding sources. We recognize that § 457.65(d) may reduce State flexibility, we must also consider the statutory penalties for the use of impermissible provider taxes and donations as specified in section 2107(e) and the public interest in assuring that States do not find themselves in a situation where they have been operating with impermissible funding sources for an extended period of time. Congress specifically imposed penalties for the use of impermissible funds and the process established by these rules protect States and SCHIP programs from the risk of a significant penalty that could make it difficult for the State to continue to operate its program for children. In light of the effective statutory prohibition on the use of these funding mechanisms, we do not believe we are unduly intruding on the States budget process through this requirement, as we are not questioning State legislative appropriations that are not derived from health care-related taxes or donations. A State is not required to submit a State plan amendment for changes in the sources of general revenue used to fund SCHIP, when those changes are not affected by health care-related taxes and donations. By reviewing the State source of funding, we have the opportunity to prevent the kind of disruption to ongoing program operations that could occur if a State was found to have used an impermissible source of funding for an extended period of time.

Comment: One State expressed its view that the proposed requirement of prior approval for SCHIP funding changes is not feasible given the State's commitment to developing a public/private partnership with private donors. The State indicated that it waited almost a year for approval from HCFA to be able to accept a contribution from a private foundation. This State asserted that this requirement would hinder the State's ability to accept contributions from private sources.

Response: States are not required to obtain approval of the State plan amendment prior to a change taking effect. Thus, we do not believe that the process will hinder States' ability to accept contributions from private sources. States are required by § 457.65(e) to submit a State plan amendment prior to a change in State source of funding taking effect. While any delay in approving the amendment would not affect a State's ability to rely on such funds, at its own risk pending review, we agree that HCFA should act in an expeditious manner to review these amendments. The statutory requirements governing contributions received by States are very restrictive and we have the responsibility to ensure that contributions received by States from private sources comply with these statutory requirements. Federal regulations require that we evaluate contributions received by States on a case-by-case basis. States must submit necessary documentation to us in accordance with the Federal regulations so that we may evaluate the permissibility of a contribution. That documentation is related to the nature of the contributor's business and financial characteristics, including the source of its annual revenues. We will make our best effort to determine the permissibility of a contribution promptly once a State has provided the information that we need to make a determination.

Comment: One commenter requested clarification of the exemption at § 457.65(d)(2) to the general requirement for the submission of State plan amendments relating to changes in the source of State funding for ''non-health care related revenues.'' The commenter stated that clarification is necessary to ensure that, for example, income tax receipts from medical professionals are not considered ''health care related revenues.''

Response: Taxes of general applicability are not considered ''health care-related'' for purposes of section 1903(w) of the Social Security Act, and the term has the same meaning under § 457.60(a)(3). (As noted earlier, § 457.65(d)(2) has been combined with 457.60(a)(3) for better organization of the regulation.) However, section 1903(w)(3)(A) of the Act and the Federal regulations implementing it at 42 CFR 433.55 specify that a tax will be considered to be health care-related if at least 85 percent of the burden of the tax falls on health care providers. These provisions further state that a tax is considered to be health care-related if

the tax is not limited to health care items or services, but the tax treatment of individuals or entities providing or paying for those health care items or services is different than the treatment provided to other individuals or entities.

Comment: One commenter suggested adding a new provision to proposed § 457.65(e), now § 457.65(f), to clarify that a State could discontinue its program by withdrawing its State plan.

Response: As set forth in § 457.170, a State may request withdrawal of an approved State plan by submitting a State plan amendment to HCFA as required by § 457.60. We note in § 457.170 that because withdrawal of a State plan is a restriction of eligibility, a State plan amendment to request withdrawal of an approved State plan must be submitted in accordance with requirements set forth in § 457.65(b), including those related to the provision of prior public notice. We have not added a new provision to proposed § 457.65 because we do not find it necessary to repeat this State option elsewhere in the regulation text.

9. Program Options (§ 457.70)

Under section 2101(a) of the Act, a State may obtain health benefits coverage for uninsured, low-income children in one of three ways: (1) a State may provide coverage by expanding its Medicaid program; (2) a State may develop a plan providing coverage that meets the requirements of section 2103 of the Act; or (3) a State may provide coverage through a combination of a Medicaid expansion program and a separate child health program. We set forth the program options at proposed § 457.70(a).

At § 457.70(b), we proposed that a State plan must include a description of the State's chosen program option.

At § 457.70(c)(1), we proposed that the following subparts apply to States that elect Medicaid expansions:

- Subpart A.
- Subpart B (if the State claims administrative costs under title XXI).
- Subpart C (with respect to the definition of a targeted low-income child only).
- Subpart F (with respect to determination of the allotment for purposes of the enhanced matching rate, determination of the enhanced matching rate, and payment of any claims for administrative costs under title XXI of the Act only).
- Subpart G.
- Subpart H (if the State elects the eligibility group for optional targeted low-income children and elects to operate a premium assistance program).
- Subpart J (if the State claims administrative costs under title XXI and seeks a waiver of limitations on such claims based on a community based health delivery system).

We proposed that subparts D, E, and I of part 457 do not apply to Medicaid expansion programs because Medicaid rules govern benefits, cost sharing, program integrity and other provisions included in those subparts. We note that the provisions of subparts B and F were set forth in the May 24, 2000 final rule (HCFA 2114–F, 65 FR 33616).

In addition, at proposed § 457.70(c)(2), we specified that States choosing a Medicaid expansion program must submit an approvable amendment to the State's Medicaid State plan, as appropriate.

At § 457.70(d), we proposed that a State that chooses to implement a separate child health program must comply with all the requirements in part 457.

At 457.70(e), we proposed that a State that elects to obtain health benefits coverage through both a separate child health program and a Medicaid expansion program must meet the requirements of (c) and (d) of this section.

Comment: While the statute specifies that States have the option of implementing their SCHIP programs as Medicaid expansions, State-only programs, or a combination of the two, a commenter contended that the regulations favor States that have elected to use title XXI to expand their Medicaid programs by imposing greater administrative burdens on separate child health programs.

Response: We do not agree that the regulations favor States that choose the Medicaid expansion option. Certain provisions in part 457 do not apply to Medicaid expansion programs because Medicaid rules govern those aspects of program operations. Furthermore, we do not believe that we have imposed greater administrative burdens on States that choose to implement separate child health programs. The regulations set forth in part 457 are consistent with the State options provided by title XXI and are important to ensure the efficient and effective administration of SCHIP. We have worked to ensure flexibility for States that wish to create separate child health programs within the parameters of the statute.

Comment: One commenter noted that § 457.70(c)(1)(vi) should be deleted because Subpart H only applies to separate child health programs. Another commenter said that the language of Section 457.70 should be clarified so that readers do not assume incorrectly that States that choose to develop separate programs must adhere to all Medicaid rules.

Response: We agree with the commenter that Subpart H does not apply to Medicaid expansion programs and have thus deleted § 457.70(c)(1)(vi) of the proposed regulation and renumbered the subsequent provision accordingly. Subparts C, D, E, H, I, and K of part 457 do not apply to Medicaid expansion programs because Medicaid rules govern the areas addressed by those subparts. A State that chooses to implement a separate child health program must comply with all the requirements in part 457 and is not required to comply with the requirements in title XIX, other than those specifically noted in § 457.135. We believe that § 457.70 clearly sets forth the applicable requirements for the respective program types. It should also be noted that because we no longer reference Subpart C in § 457.229, we have also deleted proposed § 457.70(c)(i)(iii).

10. Current State Child Health Insurance Coverage and Coordination (§ 457.80)

In accordance with sections 2102(a)(1) and (2) and 2102(c)(2) of the Act, we proposed to require that the State plan describe the State's current approach to child health coverage and its plans for coordination of the program with other public and private health insurance programs in the State. In proposed paragraphs (a) through (c), we specified that the State must provide a description of the following:

- The extent to which, and manner in which, children in the State, including targeted low-income children and other classes of children, by income level and other relevant factors, currently have creditable health coverage (as defined by § 457.10) and, if sufficient information is available, whether the creditable health coverage they have is under public health insurance programs or health insurance programs that involve public-private partnerships.
- Current State efforts to provide or obtain creditable health coverage for uncovered children, including the steps the State is taking to identify and enroll all uncovered children who are eligible to participate in public health insurance programs and health insurance programs that involve public-private partnerships.
- Procedures the State uses to accomplish coordination of the program under title XXI with other public and private health insurance programs, including procedures designed to increase the number of children with

creditable health coverage, and to ensure that only eligible targeted low-income children are covered under title XXI.

Comment: One commenter noted that HCFA should not require States to gather data on other creditable health coverage available in the State as proposed in § 457.80(a). While useful, this information is not critical to the successful implementation of a SCHIP and its collection may actually divert resources from SCHIP.

Response: Section 2102(a)(1) of the Act requires that the State plan include a description of the extent to which, and manner in which, children in the State, including targeted low-income children and other classes of children, by income level and other relevant factors, currently have creditable health coverage. Section 457.80(a) implements this statutory requirement. States do not necessarily have to generate new data to meet this requirement, but can rely on other data sources that may be available. Knowledge of the availability of creditable health coverage will help a State determine how best to design and to implement its SCHIP program and outreach strategies.

Comment: Several commenters requested that HCFA add to the categories of children for which it requests coverage information in § 457.80(a). Two commenters request that HCFA add ''migrant and immigrant status'' to the sentence in the preamble highlighting the categories that States might find useful in describing current availability of health insurance. In these commenters' view, migrant and immigrant children are especially susceptible to being without health insurance, and the Immigration and Naturalization Service recently clarified in its ''public charge'' guidance, issued in a Notice of Proposed Rulemaking (64 FR 28675, May 26, 1999) and an accompanying Memorandum published the same day (64 FR 28689), that receipt of health benefits will not harm one's chances for legal immigration. Another commenter recommended that the required factors include ''suburban'' in addition to the age group, race and ethnicity, and rural/urban categories already listed in the preamble because suburban areas across the county have a growing number of low-income and uninsured families.

Another commenter suggested that HCFA require that the State plan include a description of the extent of coverage by race, ethnicity, and primary language spoken. According to this commenter, it is now well-established that minority children are more likely than non-minority children to lack health insurance. In this commenter's view, collection of the data also gives HHS the tools needed to monitor and enforce title VI of the Civil Rights Act of 1964.

One commenter recommended that ''other relevant factors'' be clarified and several other commenters believed the list should include primary language, because children with limited English proficiency are at high risk of being uninsured.

Response: We encourage States to include a description of as many relevant categories of children in the State plan as possible, to the extent that data are available. We agree that more detailed data classifying children is useful to learn more about the health care coverage status of the children in the State, but recognize that States may have limited data sources and that some categories have more relevance than others, depending on the State. Because of the potential limited availability of this information at the outset of a program, we are retaining the flexibility in § 457.80(a) for a State to describe in the State plan the classes of children for which it has data available. We note, however, that we have added a provision in Subpart G, Strategic Planning, that requires States to report data on the gender, race and ethnicity of enrollees in their quarterly enrollment reports. In addition, States will be required to report information on the primary language of SCHIP enrollees in their annual reports.

We are not adopting the commenter's recommendation to require information for specific categories of children in the regulation. This provision requires that a State describe coverage provided to children at the beginning of implementation of its program. We recognize that States may have limited resources available at that time and request that they provide information sufficient to illustrate that the State has analyzed the extent of uninsurance among children in the State using available data sources.

Comment: One commenter interpreted § 457.80(b) to require a State to take steps to get uninsured children enrolled in public and private health insurance programs. In this commenter's view, families should have a choice of where to get coverage and States should therefore be allowed to inform families of coverage options and, upon request, assist in helping families with choices made.

Response: Section 457.80(b) requires that a State plan include a description of the current State efforts to provide or obtain creditable health coverage for uncovered children. This provision does not require that a State take particular steps to identify and enroll children in public and private health insurance programs, but rather to describe its efforts. However, States are required by §§ 457.350 and 457.360 to screen for Medicaid eligibility and to have procedures to ensure that children found through the screening process to be eligible for Medicaid apply for and are enrolled in Medicaid.

Comment: One commenter described its view that HCFA is creating unnecessary obstacles in these regulations to creating public-private partnerships. This commenter believes that one reason States have problems getting providers to participate in their programs is that many providers do not want to respond to the various idiosyncrasies of government programs such as the ''unnecessary'' paperwork and the ''awkward'' procedures that no other payor or insurance company requires. The commenter believes that these problems help stigmatize government programs and can cause well-intentioned providers to opt out of participation in SCHIP or other government programs. According to this commenter, providers that remain may develop negative attitudes about the program that transfer into negative attitudes about the participants, who may leave the program. To solve this problem, many States (including this commenter) have tried to address these and other stigma issues by creating separate child health programs that are more similar to private sector models and more familiar to providers and enrollees.

Response: The provisions set forth in this regulation are necessary to implement title XXI and are not intended to create obstacles to public-private partnerships. Title XXI and this final regulation provide States with significant flexibility in designing separate child health programs and we do not believe that federal rules are preventing States from employing procedures that address negative perceptions about public programs that may exist among providers. As noted in § 457.940, States have flexibility to set payment rates for providers and should do so in a manner that will attract a sufficient number and scope of providers that will adequately serve the SCHIP population. We believe this final rule confirms HCFA's commitment to working with States to establish and maintain programs that are not unduly burdensome to administer and accomplish the goal of providing needed health benefits coverage to children and families.

Comment: The preamble to § 457.80(b) explains that HCFA proposes to require States to provide an overview of current efforts made by the State to obtain coverage for children through other programs, such as WIC and the Maternal and Child Health Block Grant Program. Several commenters stated that although these programs offer health care or health-related services, they are not considered to be health insurance coverage programs, and requiring a description of coordination with these other programs in the State exceeds the scope of the SCHIP statute. Another State commented that describing the outreach and coordination efforts of all the other existing health programs would be extremely burdensome and should not be required.

One commenter supported the requirement of coordination between SCHIP and other publicly funded programs that provide coverage to uninsured children but expressed concern with an overly broad and burdensome requirement that puts States in the potential position of acting as unlicensed insurance agents or brokers to link consumers with private creditable coverage. One State expressed that HCFA should more clearly define what is meant by ''coordination with other public and private health insurance programs.'' In defining this term, HCFA should keep in mind that, especially in large States, staying involved in all parts of the private insurance market is a challenging task.

One commenter recommended that the Child Support Enforcement (CSE) program be included in the coordination provision at § 457.80(c) because CSE needs to be made aware of children in the CSE caseload who are covered by SCHIP. Another commenter noted that SCHIP enrollees may benefit from the services offered by a State child support program, and that families need to understand options related to obtaining or enforcing child support and medical support orders.

Response: We are responding to the comments requesting clarification of the required State plan provisions on coordination with other public and private health coverage programs by revising our proposed regulatory language to better reflect our intent and purposes. As described in the preamble, § 457.80(c) is meant to reflect the coordination requirements of Sections 2101(a), 2102(a)(3), and 2102(c)(2) of the Act. Section 2101(a) requires that in using title XXI funds to expand coverage to uninsured populations, this effort be ''coordinated with other sources of health benefits coverage for children.'' Section 2012(a)(3) of the Act requires that a State plan describe how the plan is designed to be coordinated with such efforts to increase coverage under creditable health coverage. As provided by section 2102(c)(2) of the Act, the plan must also describe the coordination of the administration of the State program under this title with other public and private health insurance programs.

In accordance with these requirements, we have revised § 457.80(c) to clarify that the State plan must include a description of the procedures the State uses to coordinate SCHIP with public and private health insurance and ''other sources of health benefits coverage'' for children. ''Other sources of health benefits coverage'' would include WIC and Maternal and Child Health Programs. Section 2108(b)(1)(D) of the Act supports this clarification. This section requires an assessment of State efforts to coordinate SCHIP with ''other public and private programs providing health care and health care financing including ''Medicaid and maternal and child health services.''

As noted in the preamble to the proposed rule, additional examples of sources of health benefits coverage could include community and migrant health centers, Federally Qualified Health Centers, Child Support Enforcement Programs, and special State programs for child health care. These can all be important sources of health benefits coverage for children. This list of examples is not intended to be an exhaustive list of those programs that a State should coordinate with its SCHIP program and describe in its State plan. We are not providing a specific list because we recognize that States are different and that it is important to respect the variety of programs and coverage plans that operate in each State. The State should describe its relationships with other State agencies, low-income community organizations, and large insurance providers in the State that provide health insurance or health benefits to children. For example, if a State has a high risk insurance pool program, it should describe the coordination between this program and SCHIP; however, not all States have such insurance pools and the nature of these pools will vary among States.

Each State has a unique relationship with Federally Qualified Health Centers (FQHCs) and we believe that the flexibility of the State to structure these relationships should be maintained. Therefore, we have not required specific enrollment coordination procedures with FQHCs. However, we recognize the importance of enrolling SCHIP and Medicaid eligible children at sites where they typically receive care, such as FQHCs. Due to this relationship, FQHCs are vital partners in outreach and enrollment for this population. We encourage States to utilize these facilities in their outreach efforts.

These coordination provisions should not be interpreted to mean that we are requiring any particular effort on the part of the State to enroll children in private coverage.

Comment: One commenter indicated that it is extremely important for the regulations to specify what steps States must take in order to satisfy the requirement that separate child health programs be coordinated with existing Medicaid programs (including, for example, coordination of outreach and education efforts, screen and enroll requirements, transitioning from coverage under one program to the other, etc.). This commenter also recommended that the regulations require States to provide training to eligibility determination workers in both programs (as well as other workers) to ensure that appropriate transitions are made.

Several commenters believed that § 457.80(c) of the regulation (and not just the preamble to that section) should require States to describe the specific steps they will take to ensure that children who are found ineligible for Medicaid (at initial application or at redetermination) are provided with the opportunity to be enrolled in SCHIP. Another commenter pointed out that neither title XXI nor the proposed regulations take into consideration the movement of children between title XXI and title XIX programs as their eligibility status changes, nor have the Medicaid regulations been updated to reflect this possibility. A couple of these commenters suggested that perhaps the Medicaid regulations should be amended to address this issue. Another commenter believed that States should be required to describe how they will monitor these processes.

Several commenters indicated that the regulations should address the coordination of enrollment procedures for Medicaid and SCHIP at Federally Qualified Health Centers (FQHCs).

Response: We have taken the first commenters' suggestion into consideration and have revised the regulation at § 457.80(c) to refer to the requirements in §§ 457.350 and 457.360. States that implement separate child health programs are required to meet the requirements of §§ 457.350 and 457.360. States that implement separate child health programs and States that implement Medicaid expansion

programs must both describe the procedures for coordination required by § 457.80(c); however, the ''screen and enroll'' requirements of §§ 457.350 and 457.360 are not relevant or applicable to States that implement Medicaid expansions.

We agree that some more specificity with respect to the specific steps States must take to coordinate with Medicaid programs would be helpful in providing more clarity for States. At the same time, we believe that States need to retain the flexibility in coordinating SCHIP and Medicaid particularly in light of the specific administrative structures of the States' programs.

We agree with the commenters that the regulation should be revised to require States to describe in the State plan procedures to ensure that children who are found ineligible for Medicaid are provided the opportunity to be enrolled in SCHIP. We have revised § 457.80(c) to require that the State plan include a description of procedures designed to assist in enrolling in SCHIP those children who have been determined ineligible for Medicaid. This should occur both at the time of application and at the time of redetermination. The Medicaid regulations do not need to be amended because title XXI and these implementing regulations require coordination between SCHIP and Medicaid. We believe that State efforts to coordinate SCHIP with other public programs should include efforts to ensure that these processes are effective and have modified the Medicaid regulations at § 431.636 accordingly. In addition, we expect States to have mechanisms to evaluate the effectiveness of coordination between the two programs, as noted in § 457.350(f)(2)(i)(C).

11. Outreach (§ 457.90)

In § 457.90, we proposed to require a State to include in its State plan a description of the outreach process used to inform families of the availability of health coverage programs and to assist families in enrolling their children into a health coverage program pursuant to section 2102(c) of the Act. At proposed § 457.90(b), we set forth examples of outreach strategies including education and awareness campaigns and enrollment simplification. We discussed these outreach strategies in detail in the preamble to the proposed rule.

Comment: Many commenters expressed support for the requirement of outreach procedures and the examples provided. One commenter strongly supported the requirement that would require States to identify outreach procedures used to inform and assist families of children likely to be eligible for child health assistance under SCHIP or under other public/private health coverage programs. Another commenter supported the requirement of outreach strategies including education and awareness campaigns and enrollment simplification. Yet another commenter supported a streamlined application and enrollment process as a practical means of enhancing participation by qualified children, thereby increasing demand for needed medical and dental services.

Response: We note the commenters' support.

Comment: One commenter appreciated the efforts of HHS to maintain flexibility for the States in the outreach area as each State has established and continues to refine state-specific outreach efforts to identify SCHIP and Medicaid eligible children in their communities.

Response: We note the commenter's support.

Comment: One commenter suggested that we provide more examples of effective outreach. The commenter noted that States are being very creative in how they are conducting outreach and the two examples listed do not even ''touch the tip of the iceberg''.

Response: There are many examples across the nation of successfully implemented, locally developed outreach campaigns. Because there are so many effective approaches for outreach, it is impracticable to list them in this regulation. Our intention was not to provide an exhaustive list of effective outreach methods in the preamble, but to highlight examples of a few major types of outreach strategies. HCFA, along with HRSA and other public agencies and private organizations, will continue to facilitate the sharing of ''best practices'' through information sharing sessions, technical assistance and guidance separate from this document.

Comment: One commenter expressed that outreach is critical to the success of SCHIP. This commenter noted that the State of Colorado has done a good job of disseminating information to the public that is easily understood.

Response: We agree with the commenter that outreach is critical to the success of SCHIP and it is for this reason that we included the requirements in § 457.90.

Comment: One commenter suggested that the discussion of outreach in the preamble to the proposed rule should have referred to ''migrant and immigrant populations'' instead of just ''migrant populations'' because of the importance of outreach for immigrants.

Response: States may choose to target outreach activities to special audiences known to have large numbers of uninsured children, such as migrant and immigrant populations, as well as other groups.

Comment: One commenter suggested that the discussion in the preamble to the proposed rule of the role of ''clinics'' should have included ''Community Health Centers, Rural Health Centers, and other community-based clinics that provide a large proportion of care to uninsured patients'' in the list of providers that States should consider for distributing SCHIP information.

Response: The list of providers through which States could distribute program information was not intended to be exhaustive. We encourage States to distribute information through any provider that has the potential for reaching uninsured children, including community health centers, rural health centers, and other community-based clinics.

Comment: One commenter recommended that HCFA encourage States to involve community-based organizations in application assistance activities and describe the available sources of Federal funds for these activities. The commenter noted that there are numerous examples of staff at community based organizations being trained to conduct initial processing of applications for both Medicaid and separate SCHIP programs. Another commenter suggested we add to the examples of organizations listed as potential partners with the State those community-based organizations with expertise in doing outreach to, and providing services to, specific ethnic communities. This commenter also recommended that § 457.90(b) be amended to add examples of using community-based organizations. Another commenter noted that community-based organizations, including migrant and community health centers, are important outreach sites for reaching members of the Hispanic community. According to this commenter, Hispanic community-based organizations could coordinate with community centers, churches, Head Start, GED, Job Corps and WIC offices, and locations such as grocery stores, pharmacies, and other commercial centers as well.

Another commenter noted that many of the enrollment simplification methods, including outstationing of enrollment workers, are key to reaching more families, including families of children with special needs. States need

to be versatile in utilizing community-based organizations to help spread the word of the program to reach enrollment goals, according to this commenter. This commenter indicated that mechanisms for explaining the importance of health coverage helps families recognize the benefits of health insurance for their children.

Response: We encourage States that implement separate child health programs to involve community-based organizations in application assistance activities. States that implement Medicaid expansions must follow all Medicaid rules relating to eligibility determinations, but are encouraged to use community-based organizations to help reach and assist low-income uninsured children to become enrolled. States can receive Federal matching funds for outreach activities; for States that establish separate child health programs, outreach matching funds are subject to the 10% limit on administrative expenditures.

State experience shows that one of the most effective methods for reaching ethnic groups is through community-based organizations. Not only are the employees of these organizations familiar with the language and culture of the groups they serve, they are trusted members of the community. We strongly encourage the use of community-based organizations with expertise in serving specific ethnic communities as part of an effective outreach campaign.

We agree that outstationing enrollment workers is an important method of reaching uninsured children and enrolling eligible children into SCHIP and Medicaid. Education and awareness campaigns and enrollment simplification procedures have proven to be highly effective strategies for successful outreach. Because there are so many effective methods of outreach, such as using community-based organizations and outstationing enrollment workers, we have not provided an exhaustive list in the regulation.

Comment: One commenter urged that dentists also be listed as participants in education and awareness campaigns, as well as State and local dental and pediatric dental societies.

Response: We encourage States to disseminate information through all providers that serve uninsured children.

Comment: One commenter suggested that HCFA discuss using the CDC's Immunization Registries to assist States in identifying families with uninsured children. In planning to transition away from the use of immunization clinics towards integrating immunizations as part of well-child care, we will have to pay more attention to potential financial barriers which could be appropriately addressed by linking immunization outreach to SCHIP/Medicaid outreach efforts.

Response: Several data sets are available to assist States in the identification of families of uninsured children, including the CDC's Immunization Registries. States should strive to link health coverage program outreach with other forms of health-related outreach in the State, such as immunization outreach.

Comment: One commenter believed States should use public benefit programs that serve low-income families with children to inform families about the availability of health coverage. The discussion regarding the use of existing ''data sets'' to identify uninsured children who are potentially eligible for coverage under Medicaid or SCHIP identifies the school lunch program participant lists as one of the sources. The commenter noted that the school lunch program only identifies low-income children, not specifically uninsured low-income children.

Response: We encourage the use of public benefit programs that serve low-income families to identify children who may be eligible for SCHIP or Medicaid, subject to applicable confidentiality rules. We appreciate the commenter's note that school lunch programs do not identify uninsured low-income children. We support the use of school lunch program participant lists, and other sources that assist in the identification of low-income families and inform them of potentially eligible children of the availability of SCHIP or Medicaid. Of course, in using these source of information, States must comply with applicable laws and should ensure confidentiality.

Comment: A few commenters believed that outreach strategies should be targeted specifically to adolescents and to their families. One commenter recommended the inclusion of the term ''age'' in giving examples of ways to reach diverse populations, and a distinction should be made between young children and adolescents. Other commenters believed that initiatives should include specific elements designed to reach underserved adolescent population such as runaway and homeless youth, youth in foster care or leaving state custody, immigrant youth, pregnant and parenting adolescents, and others. The commenters urged HCFA to encourage States to work with consumer groups and adolescent-oriented service providers to develop adolescent-specific outreach strategies and materials. One commenter believed the list of suggested outreach sites should also include as broad a range of adolescent-specific sites as permitted by Federal law. Adolescent medicine and service providers such as school-based health centers, family planning and STD clinics, Job Corps Centers, community colleges, summer job programs, and teen recreation centers should be added to the list of members of the provider community who can distribute program information.

Response: Adolescents under the age of 19 are included in the term ''child'', which is defined in § 457.10 as an individual under the age of 19. States may implement outreach initiatives that are specifically designed to reach different targeted subpopulations, such as adolescent, runaway and homeless youth, youth in foster care or leaving state custody, immigrant youth, and pregnant and parenting children. We encourage States to disseminate information through providers, such as those listed by the commenter, that serve targeted subpopulations.

Comment: One commenter supported HCFA's decision to emphasize the particular importance of using the provider community to target education and awareness campaigns to families of newborns in the preamble to the proposed regulation. This commenter urged HCFA to include language that also stresses the importance of targeting pregnant women with education and outreach campaigns to facilitate prompt enrollment of newborns and their siblings.

Response: We encourage States to target special audiences, such as pregnant women and families of newborns, in their development of comprehensive education and awareness campaigns. Pregnant women and families of newborns will benefit from educational programs designed to inform them of the advantages of enrolling eligible newborns and other children in the family in health insurance, including obtaining well-baby care, well-child care and immunizations.

Comment: One commenter suggested that HCFA encourage States to provide materials and or eligibility workers to child care programs to identify and assist families of uninsured children served by the programs, as well as uninsured children of the programs' employees. These should include regulated and unregulated family-based child care providers as well as center-based facilities.

Response: We encourage States to disseminate information through child care programs and, when practicable, to

outstation eligibility workers at child care provider sites.

Comment: One commenter supported the inclusion in the proposed regulation text of language regarding education and awareness campaigns including targeted mailings and enrollment simplification. This commenter strongly urged HCFA to strengthen this section by requiring that States report to HCFA steps they have taken to simplify enrollment.

Response: We note the commenter's support of the proposed regulation language regarding education and awareness campaigns. We clarified in § 457.305 that States must describe in their State plan, policies governing enrollment and disenrollment, including enrollment caps, process(es) for instituting waiting lists, deciding which children will be given priority for enrollment, and informing individuals of their status on a waiting list. However, we are not requiring States to report on their mechanisms for simplifying enrollment beyond the requirement under § 457.90 to include a description of outreach procedures in their State plan. We also anticipate that States may include information regarding enrollment simplification in their annual report's description of successes and barriers in State plans design and implementation and approaches under consideration to overcome these barriers. We will continue to work with the States in a collaborative way to provide technical assistance and share information on successful enrollment mechanisms to encourage States to simplify enrollment.

Comment: One commenter recommended that HCFA emphasize the use of a simplified application system. This commenter noted that a simplified system makes it easier for a State to coordinate its Medicaid and separate SCHIP programs and is an essential ingredient for successful outreach.

Response: A major key to successfully reaching and enrolling uninsured children in SCHIP and Medicaid is a simple application process. We wish to emphasize that a simplified application process is vital to successful outreach and have included a reference to simplified or joint application forms in § 457.90(b)(2) as examples of outreach strategies States could employ.

Comment: One commenter recommended that HCFA place a limit on the number of pages of the individual State applications. The commenter noted that HCFA should also require that States provide joint Medicaid and SCHIP applications to reduce the paperwork on the part of the applicant as well as the eligibility workers, and to ensure that applicants are registered for the appropriate program.

Response: We disagree with the commenters' recommendations to limit the length of the applications and to require joint applications. As noted in the previous response, we strongly encourage a simplified application process and the majority of States with separate child health programs have developed joint applications. However, rather than prescribing specific outreach and application methods for all States, we are partnering with States to encourage the most effective approaches in each State.

Comment: A few commenters strongly encouraged States to conduct coordinated outreach campaigns that help families understand their children's potential eligibility for regular Medicaid or SCHIP-funded coverage. They urged that HCFA make clear that comprehensive statewide education campaigns are needed to inform the public about the availability of both SCHIP and Medicaid, and how to enroll eligible children in both programs. In addition, the commenters recommend reversing the order of the first and second paragraphs of the response. Similarly, they suggested that the list of ''enrollment simplification'' strategies should emphasize that these steps can be taken in Medicaid, as well as in separate SCHIP programs.

Response: We share the commenters' interest in, and commitment to, enrolling uninsured children in both Medicaid and SCHIP. We agree that a comprehensive, Statewide education campaign is needed to inform the public about the importance of the availability of both SCHIP and Medicaid. Virtually all of the steps that States have taken to implement simplified application procedures in separate child health programs can be taken in Medicaid, such as simplifying the application form, streamlining verification requirements, and eliminating any assets test. However, different rules apply in Medicaid with respect to who must make the final eligibility determination. While enrollment simplification in Medicaid is very important, it is not appropriate to address this particular issue in further detail in this final SCHIP rule.

As required by section 2102(c) and implemented in § 457.90, a State must inform families of children likely to be eligible for child health assistance under the plan or under other public or private health coverage programs of the availability of the programs, and must assist them in enrolling their children in such programs. Medicaid is one of these other public health coverage programs. Furthermore, section § 457.80(c) requires that the State plan describe the State procedures to coordinate SCHIP with other public health insurance programs. Again, Medicaid is considered a public health insurance program.

We also note that the way in which States design their outreach initiatives has potential fiscal implications. Medicaid provides a federal match for States' expenditures associated with outreach to Medicaid-eligible children. SCHIP funds may be used to pay for outreach to SCHIP-eligible children (subject to the 10% limit on administrative expenditures). Because all children who apply for SCHIP must be screened for Medicaid eligibility (as required by § 457.350), outreach targeted to children likely to be found eligible for SCHIP likely also will reach children eligible for Medicaid.

Comment: Several commenters suggested that bilingual outreach workers, linguistically appropriate materials, and culturally appropriate strategies must be provided when needed. One commenter noted that HCFA should elaborate on Title VI's mandate for linguistic access to services and give examples of how States and contracted entities can comply with this mandate. One commenter recommended that HCFA specify that States must provide access to linguistically and culturally appropriate health care services. In this commenter's view, States should be required to provide all written materials and application assistance in all applicable languages. States should also assure that linguistically and culturally appropriate outreach efforts are undertaken to all eligible populations. Another commenter recommended that HCFA require that applications be made available in the prevailing language in the community and that translation services be provided.

Response: As we seek to enroll all eligible children into coverage, States and HCFA should be sensitive to the cultural and linguistic differences of diverse populations. The diversity of the uninsured population requires outreach activities that are sensitive to the various cultural groups, their perceptions, needs and desires. For example, States could use outreach workers who live in the communities targeted for outreach, speak the language and know its cultural beliefs and practices. As noted in § 457.130, States must comply with all applicable civil rights requirements, including those related to language access. Within DHHS, the Office for Civil Rights (OCR) is responsible for assuring that DHHS-

funded programs comply with these laws. States are encouraged to contact OCR for additional guidance and technical assistance about how to comply with these laws.

Comment: Another commenter believed that outreach efforts should utilize Hispanic community-based organizations to ensure culturally and linguistically competent approaches to outreach. This commenter believed that specific outreach and education material be developed for the Hispanic community. Eligibility workers stationed in communities with a large Hispanic population should be able to speak the language spoken by potential applicants. The use of television (Spanish language) and other media sources should be used to target the Hispanic community. Another commenter suggested that HCFA amend § 457.90(b) to add examples of using ethnic media for education and awareness campaigns.

Response: Again, we encourage outreach activities that rely on workers who live in the communities being targeted for outreach, speak the relevant languages and know their cultural beliefs and practices. While we will not amend the text of § 457.90(b) to add examples of using ethnic media for education and awareness campaigns, we recognize that this can be an effective means of reaching ethnic communities. States are encouraged to implement outreach initiatives that are specifically designed to reach different targeted subpopulations such as the Hispanic community and other ethnic groups.

Comment: One commenter urged HCFA to amend § 457.90(a) to require State plans to include a description of outreach strategies to reach children and families with special needs including limited English proficiency populations, and families whose children have disabilities. This commenter also urged HCFA to include in § 457.90(b) examples of outreach strategies targeted to special populations.

Response: As noted in previous responses, States must implement outreach strategies that comply with all civil rights requirements. A State is required to describe its outreach strategies in the State plan, but we do not believe that States should be required to describe their strategies to target all special audiences, in part because State outreach activities are often changing in response to information about what does and does not work. The examples presented in the regulation are not meant to be exhaustive. As noted in a response above, it is impracticable to list in regulation all examples of effective outreach strategies.

Comment: One commenter suggested the final regulation include encouragement of State partnerships with HRSA grantees. This commenter believed that HRSA's access points in the field can and should be accountable for assisting States in making SCHIP outreach a success.

Response: We encourage States to partner with HRSA grantees to identify potentially eligible children, inform families of the availability of SCHIP and other public health coverage programs and provide application assistance.

Comment: Several commenters recommended that HCFA require States to describe in their SCHIP plans the efforts that they have made to consult with ''stakeholders'' regarding the outreach strategies that are likely to prove most effective. Suggested stakeholders include enrollees, providers, local officials, appropriate state agencies, WIC clinics, early childhood programs, schools, consumer groups, and homeless assistance programs. Another commenter recommended the use of stronger language than that used in the preamble to ensure public and potential enrollee participation in the creation of outreach materials and strategies. The commenter suggested replacing the word ''should'' with ''must'' in the following sentence: ''To be effective, messages and promotional materials must be developed with the assistance of people toward whom the message is directed.'' Another commenter recommended that HCFA require States to describe how they will identify populations of uninsured children and how they will enlist the assistance of members of these populations in developing procedures specifically designed to reach these populations and enroll them.

Response: States are required in § 457.120 to describe the methods the State uses to involve the public in both the design and implementation of the program and to ensure ongoing public involvement once the State plan has been implemented. We encourage States to consult with a wide variety of interested parties, including those listed by the commenters, in the development of outreach materials and strategies and recognize that such consultation, in many cases, is a mechanism for identifying the most effective outreach strategies. However, we have not revised the regulation text to specify that States describe in the State plan their efforts at consultation in regard to developing effective outreach strategies beyond the general requirements for public input already addressed in § 457.120. While States should develop materials with the assistance of people toward whom the message is directed, we do not believe that requiring States to consult with specific interested parties would ensure meaningful public involvement and provide States with continued flexibility regarding how best to involve targeted audiences in the development of outreach materials. A further discussion of public involvement is found in § 457.120.

Comment: Several commenters believed that the proposed requirements for State outreach programs were excessive because SCHIP is not an entitlement program, there is an express cap on administrative expenditures, and some States may elect not to fund SCHIP programs at a level to justify extensive outreach.

Another commenter asserted that the proposed regulation is overly prescriptive regarding the organizations that should be involved in outreach, the materials that should be produced, and the cultural variations that should be represented.

Response: We disagree that the requirements set forth in the proposed rule were too prescriptive. Section 2102(c) of the Act requires that a State plan include a description of its procedures to inform families of the availability of health coverage programs and to assist families in enrolling their children into a health coverage program. Therefore, families must be provided certain information to ensure that they are aware of available child health assistance. In addition, because of the importance of providing information that can be easily understood by the family, we have further specified information requirements in § 457.110 of this final rule. These basic rules for assuring that families are informed of the availability of coverage do not impose onerous burdens on States and in fact, are consistent with the activities States have already undertaken.

A key goal of this program is to ensure that families are informed about available coverage and are encouraged to participate. No single approach to reaching potentially eligible children is provided in the statute and thus, we are not requiring in § 457.90 that a State implement specific outreach activities. We also acknowledge that Federal funding for SCHIP is capped according to amounts specified by title XXI and States may design outreach programs with these caps in mind. States have the option to decide which methodologies and procedures it will use to inform families of potentially eligible children about the availability of SCHIP.

Comment: One commenter recommended that States be required to evaluate outreach efforts to determine which methods have been most effective (that is, collecting data from enrollment sites and polling enrollees about how they heard of the program.) This commenter also recommended that States should gather information from families who requested applications but did not complete them in order to determine their reasons for not submitting a completed application. States should use this information to choose the most effective and efficient outreach strategies.

Response: To conduct a successful outreach campaign, States should assess which outreach methods are most effective at enrolling eligible children into SCHIP. We will work with the States in a collaborative way to provide technical assistance and share successful strategies. However, we are not requiring a State to conduct a formal evaluation. In § 457.750, we do require States to report on strategic objectives in the annual reports. These objectives often address effectiveness of outreach.

Comment: Two commenters expressed concern about States involving the provider community in the program. One commenter suggested that the final rule encourage the participation of health care professionals through simplification of the provider enrollment process. Several commenters recommended that States be required to conduct outreach to the provider community about SCHIP and to provide information and training about the administrative/business procedures of the programs. This commenter noted that pediatricians and other providers must be informed about the new insurance programs as well as about Medicaid. One commenter noted that HCFA should require States to make administrative rules and procedures for SCHIP as simple and as similar to Medicaid as possible; coordinating these programs eases the administrative burden on physicians.

Response: We encourage States to partner with the provider community as part of their efforts to deliver health care services to Medicaid and SCHIP enrollees. Given that the provider level is the point at which enrollees access health care services, active provider participation and an understanding of the program is essential to the program's success. We strongly encourage States to work with provider groups in the State on an ongoing basis to facilitate provider participation in the program. If simplifying the provider application process is identified as needed in a State to increase access for SCHIP enrollees, then we would expect that a State would make every effort to address the issue.

A State and its providers should build a relationship based on the mutual goal of providing access to quality health care services. We encourage States to provide information about the administrative and business practices of SCHIP and Medicaid to providers' offices. We are promoting dual enrollment of providers.

Comment: One commenter noted that outreach should include providing information about the mental health and substance abuse, benefits in SCHIP plans, if provided.

Response: Neither the proposed not the final rules require States, as part of the outreach provision to provide information on benefits, including information on mental health and substance abuse benefits, to the general public. However, § 457.110(b)(1) requires that information on the types of benefits, and amount duration and scope of benefits available under the program must be made available to applicants and enrollees in a timely manner. This would include information of mental health and substance abuse benefits, if they are available under the State's approved benefit package.

Comment: One commenter recommended that HCFA require copies of client communication materials so that HCFA can evaluate the accuracy, effectiveness and perhaps establish a ''best practices'' culture for States in their partnership with HCFA in meeting their joint missions.

Response: We disagree with the commenter's recommendation that HCFA require copies of client communication materials, although we typically review such materials in our monitoring visits, we agree that direct communication material should be clear and consistent with the State plan rules and plan to work to provide technical assistance and facilitate the sharing of ''best practices.''

Comment: Several commenters urged HCFA to further discuss opportunities States have to outstation eligibility workers to help families enroll in separate child health programs. Several commenters suggested that HCFA include a full discussion of the advantages of using outstationed eligibility workers to enroll children in both Medicaid and SCHIP.

One commenter recommended that HCFA highlight that States are required under federal law to outstation workers at federally qualified health centers (FQHCs) and Disproportionate Share Hospitals (DSH) to conduct Medicaid eligibility determinations and one recommended that DSH hospitals and FQHCs are also ideal for outstationing sites in separate child health programs.

Other commenters believed that SCHIP plans should be subject to the Medicaid outstationing enrollment program requirements. One commenter noted that the requirement that States screen for Medicaid eligibility as part of the SCHIP application process makes it clear that State plans should be required to address how these requirements will be incorporated into the enrollment programs at FQHCs and DSH hospitals. Yet another commenter suggested that pediatricians' offices also serve as a prime location where families may receive help with the application process. Another commenter recommended that States consider outstationing eligibility workers at offices and clinics where uninsured families can be identified easily; and noted that monetary incentives can be offered to cover the cost of staff time associated with application assistance.

Response: We agree that outstationing eligibility workers is a promising outreach strategy for enrolling Medicaid and SCHIP-eligible children. ''Outstationing'' means locating eligibility workers or relying on other workers or volunteers, in locations other than welfare offices to assist with the initial processing of applications. (The final Medicaid eligibility determination must be made by the appropriate State agency.) States also can outstation eligibility workers in other locations and they can contract with community-based providers and organizations to assist with applications at other locations. Many locations, other than DSH hospitals and FQHCs, may be suitable for outstationing.

We disagree with the commenter's recommendation to include a full discussion of outstationing eligibility workers, and refer interested parties to the guidance issued on January 23, 1998, which provides the necessary detail. The Medicaid program already has specific regulations on this issue such as mandatory outstationing of workers at FQHCs and DSH hospitals, which can be found at 42 CFR 435.904. In separate child health programs, we encourage States to use outstationing, as it is one of many outreach strategies States have found to be valuable. Since Medicaid and SCHIP enrollment must be coordinated, Medicaid outstation sites provide a particularly important opportunity for enrolling children who are not eligible for Medicaid into SCHIP. In addition to Medicaid outstation sites, we recommend that States consider outstationing eligibility workers at other

sites that are frequented by families with children such as schools, child care centers, churches, Head Start centers, WIC offices, Job Corps sites, GED program, local Tribal organizations, Social Security offices, community health centers, disproportionate share hospitals and pediatricians' offices.

Comment: One commenter urged HCFA to adopt a requirement in the final rule that States include in the State plan an assessment of the extent to which procedural barriers may be discouraging enrollment or reenrollment of eligible children. For example, a survey of families once enrolled but failing to reenroll might indicate the need for longer enrollment periods, or the need for acceptance of self-declaration rather than actual verification of certain items like child care costs. This commenter suggested that the State plan could be a vehicle for a State to explain efforts made to examine these procedural barriers and indicate steps proposed to reduce them.

Response: We encourage States to assess and simplify their application and enrollment processes in an effort to reduce barriers to enrolling uninsured children. A burdensome application and enrollment process can be a significant barrier to successful enrollment. However, we are not requiring States to perform an assessment of procedural barriers in their State plan, although we encourage discussion of these issues in the annual report. Rather, we will work with States in a collaborative way to provide technical assistance and share successful procedures.

Comment: One commenter urged HCFA to encourage States to implement presumptive eligibility for both Medicaid and SCHIP.

Response: Information on presumptive eligibility is found in Subpart C and § 435.1101 and in our responses to comments on these provisions of the proposed regulation.

Comment: One commenter urged HCFA to reiterate to States the importance of assuring that they have properly implemented the delinking of TANF and Medicaid. The commenter noted that we will not be able to achieve the title XXI goal of covering more children, or of coordinating coverage among various health programs, if children continue to miss out on the health care coverage for which they are eligible as a result of inadequate implementation of delinking. This commenter requested that HCFA repeat the key elements of the discussion of ways to effectively implement delinking included in HHS' June 5, 1998, letter to Medicaid Directors and TANF Administrators and its March 22, 1999, Guide entitled Supporting Families in Transition. Furthermore, the commenter believed HCFA should stress that States must modify their computer systems to assure that families are not accountable for delinking, and assure that families do not lose Medicaid coverage inappropriately and to assure that families are informed about, and enrolled in, Transitional Medical Assistance whenever appropriate.

Response: Improving health care coverage through the delinking of Medicaid and TANF is a high priority in our efforts to reduce the number of uninsured children. Our guidance on this important initiative will be issued separately from this regulation.

Comment: Two commenters commended HCFA for the preamble discussion of ''enrollment simplification'' and HCFA's other efforts on this issue. However, this one commenter recommended that we clarify for States the parameters established by Federal law for taking steps to simplify application, enrollment, and redetermination procedures. This commenter recommended repeating the information provided in its September 10, 1998 letter to State officials regarding the minimum Federal requirements for the application and enrollment process for Medicaid and separate child health programs, with respect to simplification and opportunities to reduce verification requirements.

Response: The Federal requirements for the application and enrollment process for Medicaid and SCHIP provide a great deal of flexibility to States to design an application and enrollment process that is streamlined and simple, and avoids burdensome requirements for families that apply for benefits. As indicated in our September 10, 1998 letter to State officials, certain Federal rules apply to these processes. If a State chooses to develop a separate child health program, the only Federal requirements for the application and enrollment process are those listed in Subpart C for: (1) A screening and enrollment process designed by the State to ensure that Medicaid eligible children are identified and enrolled in Medicaid; and (2) obtaining proof of citizenship and verifying qualified alien status. The Federal requirements for an application and enrollment process in Medicaid are explained in 42 CFR 435.900. As many States' efforts to simplify application procedures demonstrate, States have broad flexibility under Federal law to simplify and streamline the enrollment procedures for both Medicaid and SCHIP.

Comment: One commenter urged HCFA to place greater emphasis on the ultimate goal of outreach—enrollment. In this commenter's view, the preamble language should be strengthened to encourage States to implement strategies for coordinating the enrollment processes of benefit programs such as WIC, Head Start, the School Lunch Program, subsidized child care and others with Medicaid and SCHIP enrollment. Efforts to enroll children in health coverage programs at the same time they enroll in other benefit programs should be encouraged.

Response: Thousands of low-income children are served by programs such as WIC, Head Start, the School Lunch Program, subsidized child care and the Child Support Enforcement program. We strongly encourage States to coordinate enrollment in other benefit programs that serve low-income children with Medicaid and SCHIP enrollment. For example, States may implement a referral system between the State's Medicaid agency, SCHIP agency (if different from the Medicaid agency) and other benefit program agencies. However, the coordination of these processes may only be applied to the extent that Medicaid and SCHIP rules allow. States must continue to meet the applicable Federal requirements for application and enrollment processes for Medicaid and SCHIP.

Comment: Two commenters recommended that HCFA state the rules relating to its child support enforcement policy under Medicaid and SCHIP. They request that HCFA should explicitly note the prohibition on denying Medicaid to children on the grounds that their parents have failed to cooperate with establishing paternity, or with medical support enforcement. They ask that HCFA highlight that States do not need to include questions about non-custodial parents on their joint or Medicaid applications, instead they can solicit such information at the time they notify families of their eligibility for coverage. HCFA should also reiterate that, regardless of when a State solicits such information, it must apprize families of the opportunity to show ''good cause'' for not providing the requested information.

Response: The rules for eligibility for SCHIP and our responses to comments on the proposed rules in this area, are found in Subpart C. Eligibility rules for Medicaid are issued under title XIX authority and are not discussed in this regulation.

Comment: One commenter suggested the use of licensed professional

insurance agents and brokers to enroll children. Insurance agents and brokers meet with uninsured adults every day, as well as the employers of many of the parents of uninsured children. Health insurance agents and brokers have a perfect opportunity to reach those that need the coverage the most, and since private health insurance plans already include a marketing component in their administrative cost, involving agents and brokers can be done with no extra cost to the program.

Response: As noted in § 457.340, States that implement separate child health programs may contract with independent entities to administer part or all of the eligibility determination process. A further discussion on the rules, and our responses to comments on the proposed rules pertaining to application processing is in Subpart C.

Comment: One commenter indicated that HCFA should include a description of the opportunity that States have to use innovative quality control projects to assure that allowing families to self-declare income does not increase the rate at which ineligible families get enrolled in coverage.

Response: Our requirements related to program integrity and responses to comments in this area are discussed in Subpart I.

12. Enrollment Assistance and Information Requirements (§ 457.110)

Section 2102(c) of the Act requires that State plans include procedures to inform families of the availability of child health assistance. In accordance with this provision, we proposed to require that a State have procedures to ensure that targeted low-income children are given information and assistance needed to access program benefits. Specifically, we proposed in § 457.110, that the State must make accurate, easily understood information available to families of targeted low-income children and provide assistance to them in making informed health care decisions about their health plans, professionals, and facilities. In order to assist families of targeted low-income children in making informed decisions about their health care, we proposed in § 457.110(b) to require that States have a mechanism in place to ensure that the type of benefits and amount, duration and scope of benefits available under SCHIP and the names and locations of current participating providers are made available to applicants and beneficiaries in a timely manner. This requirement also is consistent with the ''right to information'' provision of the President's Consumer Bill of Rights and Responsibilities and with the requirement in Section 2101(a) of the Act that child health assistance be provided in an effective and efficient manner.

We noted that the requirements set forth in this section apply to all States that are providing child health assistance, whether through a Medicaid expansion, a separate child health program, or a combination program, and whether they use fee-for-service or managed care delivery systems. Because Medicaid rules apply to States that implement Medicaid expansion programs, a State that is operating a Medicaid expansion program that uses managed care delivery systems would also be required to comply with the requirements of section 1932(a)(5) of the Social Security Act, enacted by section 4701(a)(5) of the BBA.

We proposed to require that information be easily understood and noted in the preamble that materials should be made available to applicants and beneficiaries in easily understood language and format. We noted in the preamble that the State should consider the special needs of those who, for example, are visually impaired or have limited reading proficiency, and the language barriers that may be faced by those who may use the information.

Comment: Several commenters expressed concern that the proposed rule did not expressly require States to provide information in a linguistically appropriate format, and one commenter recommended that HCFA add a requirement for linguistically appropriate information to the regulation. Several commenters stressed that HCFA should specify in the preamble that applicable title VI requirements related to linguistic accessibility to health care services and that HCFA requires States to communicate with enrollees in a language that they can understand.

One commenter recommended that HCFA provide examples of how States and contracted entities can comply with title VI requirements. Several commenters stated that HCFA should require States to take into account language in creating information materials. One commenter expressed concern about examples given in the preamble for overcoming language barriers. This commenter notes that two suggested methods should be used together as a part of a comprehensive plan to ensure linguistic access to services, but neither strategy alone would suffice to insulate the State from challenge under title VI.

Other commenters stated that HCFA should require States to provide translated oral and written notices including signage at key points of contact, informing potential applicants in their own language of their right to receive interpreter services free of charge. They further stated that bilingual enrollment workers and linguistically appropriate materials are necessary to ensure that limited English proficiency families make informed health care decisions. Another commenter feels that it is essential for HCFA to address the research-established higher risk for minority children to lack access to health insurance and health care in implementing SCHIP. This commenter noted that 14% of Americans speak a language other than English pursuant to Title VI of the Civil Rights Act. This commenter noted that HCFA has a responsibility to ensure that limited English proficient persons have a meaningful opportunity to participate in public programs.

Another commenter indicated that HCFA must elaborate on requirements to provide materials in alternative formats noted in the preamble and ensure that the rule includes an explicit reference to alternative formats. This commenter suggests that HCFA require materials be provided in accessible formats for persons with disabilities (e.g. tape recordings, large print, braille, etc.) and in appropriate reading levels for persons with limited literacy skills.

Response: After considering the commenters' concerns, we have taken the commenters' recommendation to add a linguistically appropriate requirement to the regulation. Section § 457.110 has been revised to require that the State must make accurate, easily understood, linguistically appropriate, information available to families of potential applicants, applicants, and enrollees, and provide assistance to these families in making informed health care decisions about their health plans, professionals, and facilities. In order to provide easily understood and linguistically appropriate information, States must assure meaningful communication for people who have limited English proficiency or have disabilities that impede their ability to communicate. This means that the State must assure that oral interpretation, sign language interpretation and auxiliary aids are provided to such potential applicants, applicants or enrollees. In addition, when necessary to ensure meaningful access, written information must be translated or made available in alternative formats such as large print or braille. ''For guidance in this area and for suggestions on how States can best meet title VI requirements, States should consult the DHHS Office for

Civil Rights' (OCR) ''Policy Guidance on the Title VI Prohibition Against National Origin Discrimination As It Affects Persons with Limited English Proficiency,'' (the LEP guidance) at 65 FR 52762 (August 30, 2000). The guidance is also available on OCR's web site at *www.hhs.gov/ocr.*

Comment: Two commenters urged HCFA to mandate language access policies by establishing numeric or proportional thresholds according to which States must provide translations of all written materials and by adopting minimum standards and procedures that must be met when those thresholds are crossed by a SCHIP program. One of these commenters asserted that it is important to require a numeric threshold rather than a proportion threshold as population densities vary greatly. Providing flexibility to States is important; however, flexibility should be granted in strategies to provide linguistically and culturally competent services, not in determining whether there is a need for these services in a particular state or service area, according to this commenter. This commenter recommended that States be required in their State plan to describe how they will target families who speak threshold languages and how linguistic services will be provided to ensure access to application and enrollment assistance.

Response: States must comply with all civil rights requirements, including those related to language access. Because States must already comply with all civil rights requirements, we are not specifying thresholds for translation of material. The Office for Civil Rights (OCR) has responsibility for and issues policy on these matters. States and other interested parties may contact OCR for information relating to compliance with title VI requirements.

Comment: Two commenters proposed that HCFA require States to describe in their plans the procedures they will use to identify population needs for specialized information techniques, and how they will develop effective informing procedures for persons whose primary language is not English or who have physical or mental disabilities which require special information techniques. The commenter felt that this is necessary in order for States to be in compliance (as required in proposed rule § 457.130) with title VI of the Civil Rights Act and with the Americans with Disabilities Act and Section 504 of the Rehabilitation Act of 1973.

Response: As discussed in previous responses, States are obligated to comply with civil rights requirements, including those related to language access. Because States must already comply with civil rights requirements as reflected in § 457.130, we are not further specifying procedures for identifying populations needing specialized information in this regulation.

Comment: One commenter recommended that HCFA prohibit States and contracted entities from requiring, suggesting, or encouraging beneficiaries to use family members or friends as translators except in cases of last resort. The commenter also recommended that the Department should prohibit the use of minors as translators in all instances.

Response: As noted above, the Office for Civil Rights recently issued guidance on the issue of translation services on August 30, 2000. The OCR guidance states that an enrollee/covered entity may not require an LEP person to use friends, minor children, or family members as interpreters. States and other interested parties may contact OCR for additional guidance on language access.

Comment: One commenter recommended that ''right to information'' principles for targeted low-income children be required for potential applicants as well. Information should be provided in an understandable format and in a language appropriate for the potential applicants as well as for the enrollees.

Response: We agree that it is important that potential applicants, as well as applicants and enrollees, have information about the program made available to them. Therefore, we have revised § 457.110(c) to require that, States must make accurate, easily understood, linguistically appropriate information available to families of potential applicants, applicants, and enrollees. States are encouraged to make information widely available, so that families have the opportunity to become familiar with the program.

Comment: One commenter supported the requirements in § 457.110 and the flexibility provided by suggestions in the preamble. This commenter believes that the proposed regulation fairly states the minimum information States must provide to prospective enrollees and enrollees. In this commenter's view, some of the preamble suggestions for additional information States might wish to provide are problematic and HCFA appropriately did not include these suggestions as requirements in the proposed rule. The commenter appreciates that the States are given the authority to determine how and when to provide materials in other languages and translation services.

Response: We note the commenter's support, but also need to make clear that States' discretion in this area is subject to the requirements of title VI.

Comment: One commenter recommended that HCFA add, in section 457.110(b)(1), cost sharing and other information that States must make available in order for families to make informed health care decisions.

One commenter suggested that HCFA include in the preamble a description of the types of more specific information that should be provided, such as access to information that assists health care consumers in making informed decisions and encourages accountability on the part of the health plans and providers. In this commenter's view, to alleviate concerns about overly burdensome requirements on States, additional categories of information could be made available to the public upon request.

Response: We have revised § 457.110(b) to require that certain information be made available to potential applicants, applicants, and enrollees. In addition to information on benefits and providers, § 457.110(b) requires that a State have a mechanism in place to make available information related to cost sharing, enrollment procedures, physician incentive plans, and review processes. We have added § 457.110(b)(2) to specify that cost-sharing requirements be made available. We have added § 457.110(b)(4) to require States to make available the circumstances under which enrollment caps or waiting lists may be instituted, including the process for deciding which children will be given priority for enrollment and how they will be informed of their status on a waiting list. We have also added § 457.110(b)(5) to require States to make available information on physician incentive plans described in § 422.210(b) of this chapter, as required by § 457.985 of this final rule. Finally, we have added § 457.110(b)(6) to require States to make available information on the process for review that is available to applicants and enrollees as described in § 457.1120. The information listed above is necessary to enable potential applicants, applicants and enrollees to make informed health care decisions.

In addition to the information that a State must make available, other basic information should be made available to families upon request. This information could include procedures for obtaining services, including authorization requirements; the extent to which after-hours and emergency services are provided; the rights and responsibilities of enrollees; any appeal rights that the

State chooses to make available to providers; with respect to managed care organizations and health care facilities, their licensure, certification, and accreditation status; and, with respect to health professionals, information that includes, but is not limited to, education and board certification and recertification. A State that provides services through a managed care delivery system should consider making additional information, such as the policy on referrals for specialty care and for other services not furnished by the enrollee's primary care physician, available to families of targeted low-income children.

Comment: Two commenters recommended that HCFA delete § 457.110. These commenters feel that States should have complete flexibility in the use of administrative dollars because they are capped by title XXI. According to this commenter, development of rules in this area is inappropriate and reduces State flexibility to design its program in the way that best serves the needs of that State's children. They note that States should be permitted to make these decisions and allowed to adopt commercial sector practices or practices more consistent with Medicaid.

Several commenters recommended that no specific requirements with respect to the information provided to families be adopted and that the level of assistance provided be determined by the State. These commenters indicated their belief that the proposed regulation is far too stringent and prescriptive regarding the level of enrollment assistance States are required to offer families. They noted that, in the commercial sector, health plans are not required to provide enrollment assistance to individuals. The commenters appreciated the authority provided to States to determine how and when to provide materials in other languages and translation materials and observed that States realize the importance of providing this information to families. However, the commenters noted that States are limited to a 10 percent expenditure allotment for enrollment, outreach and administration and that requiring additional material would be onerous.

Response: We disagree that the requirements set forth in § 457.110 are too prescriptive. Section 2102(c) of the Act requires that State plans include procedures to inform families of the availability of child health assistance under a State's program and to assist them in enrolling in such a program. We have provided sufficient flexibility to allow a State to design strategies that best meet the needs of families while setting minimum requirements consistent with these statutory provisions for the information that must be provided to assist families of targeted low-income children in making informed decisions about their health care.

We recognize that States have limited federal SCHIP matching funds available for administrative expenses. However, certain information must be provided to families to ensure that they are informed of the availability of child health assistance. We note that most private sector health plans routinely make available the information we have specified in this regulation to potential applicants and enrollees, including benefit descriptions and lists of participating providers. Moreover, a key goal of this program is to ensure that families are informed about available coverage and are encouraged to participate.

Comment: One commenter noted that the outreach and enrollment requirements are extensive considering the 10 percent cap and recommends modifying the rule to address the needs of applicants by requiring general information, or deleting the reference to applicants.

Response: We disagree that making this information available to applicants is not feasible due to the 10% cap on administrative spending. We are not requiring that the State provide each potential applicant with the required information, but to make the information available to potential applicants, and provide the information to applicants and enrollees in a timely manner. Potential applicants and applicants should have the opportunity to become familiar with the State's program so that they can make informed decisions about the program and selecting a health plan or provider. In the event that a potential applicant or an applicant becomes an enrollee, the child's family will already be informed about the services that are covered and how to access those services. This is particularly important if the child has immediate medical needs.

Comment: According to one commenter, providing current provider participation information is an impractical requirement. States should be free to update provider participation information on a periodic basis. Other commenters stated that it is difficult to distribute hard copy information of up-to-date provider lists to all enrollees; however, they suggest that web sites and toll-free numbers be listed as suggested methods of making up-to-date information available.

Response: States are required to have a mechanism to ensure that the names and locations of current participating providers are made available to applicants and enrollees. States may update directories on a periodic basis as long as there is another mechanism through which enrollees can obtain current information. For example, a State could use a telephone hotline to make current information available to applicants and enrollees.

Comment: One commenter recommended that the State should be required to distribute information that lists the enrollee's benefits and an updated provider directory listing available providers as soon as a child enrolls in SCHIP. According to this commenter, States should be required to consistently update a database for the provider directory since providers will change often and materials should be available in all languages enrollees speak.

Response: Under § 457.110(b), States must make information available to potential applicants, applicants and enrollees in a timely manner. States should provide this information, which includes benefit and provider information, within a reasonable amount of time after an individual is enrolled in SCHIP if the information is not provided before enrollment. Information should be provided to enrollees so that they have sufficient time to choose a primary care provider and a health plan where there is a choice. As indicated in the previous response, States must have a mechanism to ensure that current provider information is available. Furthermore, States are required by § 457.110(a) to make information available to families of potential applicants, applicants and enrollees in an easily understood, linguistically appropriate format. States must also meet more general civil rights requirements as specified under § 457.130.

Comment: One commenter encouraged States to make enrollment assistance available in providers' offices and indicated that enrollment assistance should also be provided in child care settings. All families applying for child care assistance should receive information about SCHIP and Medicaid according to this commenter.

Response: We encourage States to make information about enrollment procedures available to health care providers. States that implement separate child health programs are required under § 457.370 of this final regulation to provide application assistance and health care provider offices are often a logical place to

provide such assistance. Further information on this requirement is found in § 457.361 and in our responses to comments on that section. We also encourage States to make SCHIP outreach material available to families applying for or receiving child care assistance. Child care agencies often serve the same children who States are trying to reach through their child health outreach strategies. As noted in § 457.90, no single approach to reaching children is prescribed in this regulation and multiple approaches are likely to be most effective.

Comment: One commenter supported the requirement that States make accurate, easily understood information relevant to enrollment available to families of potentially eligible children. The commenter urged HCFA to make clear that such information should be available to adolescents, as well as their families. In this commenter's view, provider information should indicate providers specializing in, or with an interest in, adolescent care.

Response: As defined in § 457.10, a child is an individual under the age of 19. Hence, the term ''child'' includes adolescents within that age range. We encourage States to consider ways to reach out directly to adolescents, such as by providing age appropriate outreach and education materials directly to adolescents since they may obtain health care services independently of their parents or family members. Furthermore, adolescents should be provided information that assists them in identifying and linking up with providers that specialize in adolescent health care. This information should be freely available to anyone who requests it.

Comment: One commenter recommended that HCFA require States to inform and educate parents of children with special health needs about special services available for their children and how to access these services.

Response: We encourage States to consider the unique needs of families with children with special health needs when developing procedures to provide information to families. If applicable, States should provide information regarding supplemental benefits for special needs populations. Further discussion on assuring appropriate treatment for enrollees with chronic, complex or serious medical conditions is found in § 457.495(b) and in our response to comments on that section.

Comment: A commenter suggested that HCFA emphasize that States take special steps to target educational material to families of newborns to ensure enrollment during the crucial first months of life when screenings, vaccinations, and preventive care visits are vital.

Response: We encourage States to take additional steps, beyond making the information required at § 457.110(b) available, to educate special audiences. Families of newborns will benefit from educational programs designed to inform them of the advantages of enrolling eligible newborns in health insurance, including obtaining well-baby care and immunizations. As required in § 457.495, a State plan must include a description of the States' methods for assuring the quality and appropriateness of care, particularly with respect to providing well-baby/well-child care and childhood immunizations, as well as other areas highlighted by that section. A further discussion of State plan requirements relating to appropriateness of care is contained in § 457.735 and our responses to comments on that section.

Comment: Several commenters expressed concern that the proposed rules do not provide clear, detailed standards under § 457.110. These commenters expressed that it would be appropriate for HCFA to provide more detailed regulatory requirements as to what is meant by the timely provision of information, criteria for easily understood information, and direction as to format. They recommend that States should list providers by corporate name and popular name, by individual provider names, and by the entity (such as health center).

Response: States should have the flexibility to design a mechanism for providing information that will best meet the needs of potential applicants, applicants and enrollees, including whether there is a need to refer to providers by more than one name and their entity. In the spirit of State flexibility, we do not agree with the suggestion to further define timely provision of information, criteria for easily understood information, or direction as to format—aside from what has already been define in applicable Federal law. No one approach is most effective in providing information in all settings and to all audiences; therefore, we are not adopting this suggestion.

Comment: One commenter noted that the family needs to understand the consequences of applying for a separate child health program and being found eligible for Medicaid.

Response: The requirements for providing this information to applicants are found in subpart C, including § 457.360(a), relating to informed application decisions.

Comment: One commenter strongly supported the requirement that States provide specific benefit and provider information in an easily understood format and language. This commenter recommended that the list of other basic information, as stated in the supplementary information, include consent and confidentiality laws for minors and be included in the final language of § 457.110(b). Another commenter noted that the section regarding the integration of the Consumer Bill of Rights should include protections for families as parental consent will generally be a requisite for treatment under SCHIP.

Response: We note the commenter's support for the requirement to provide information in an easily understood format and language. However, we disagree with the recommendation of requiring a State to provide information on consent and confidentiality laws for minors. While we agree that this may be a good idea, we believe that requiring that such information be provided would be an undue burden on States, and therefore we have not amended the regulation text to require that States provide this information to applicants or enrollees. However, we note that in § 457.1110(b)(4), we require States to assure that all contractors protect the confidentiality of information about minors and the privacy of minors in accordance with applicable Federal and State law.

Comment: One commenter felt that consumer participation in treatment should be ''developmentally appropriate.'' The commenter recommended that HCFA add language about appropriate participation of guardians and parents and the family in general.

Response: We encourage States and providers to communicate in terms that can be understood by consumers with varied developmental levels. Further information on assuring quality and appropriateness of care is found in § 457.495 and the responses to comments on that section.

Comment: One commenter requested clarification of HCFA's intent and expectations in requiring States to assist families in making health care decisions. Several other commenters requested clarification that assisting families does not include decisions relating to the direct provision of care, and that these decisions should be made between parents and the health care provider.

Response: States should have the flexibility to design a mechanism to assist families in making informed health care decisions about their health

plans, professionals, and facilities that best meets the needs of the families in the State. No one approach may be the most effective in assisting families. Section § 457.110(a) requires that the State provide assistance to families in making informed health care decisions about their health plans, professionals, and facilities. All decisions regarding treatment options should be made between the patient, the family (as appropriate), and the health care provider. In order to assist families in making health care decisions, States must, at a minimum, have a mechanism in place to ensure that information is provided as required by § 457.110(b).

13. Public Involvement in Program Development (§ 457.120)

States are required under section 2107(c) of the Act to include in the State plan the process that the State used to accomplish public involvement in the design and implementation of the plan and the method to ensure ongoing public involvement. We proposed to implement this provision at § 457.120.

In the preamble to the proposed rule we encourage States to provide for participation from organizations and groups such as hospitals, community health centers, and other providers, enrollees, and advocacy groups. We also suggested mechanisms for encouraging public involvement such as through holding public meetings, establishing a child health commission, publishing notices in newspapers, or creating other methods for public access to materials. We indicated that States may use any process for public input that affords interested parties the opportunity to learn about the State plan and allow for public input in all phases of the program.

Comment: Several commenters strongly encouraged public participation in all aspects of planning, implementation, evaluation and monitoring of SCHIP. These commenters, including several States, specifically cited the value of participation from individuals, families, Native Americans, organizations concerned with the health of adolescents, and other stakeholders. They noted the ability of public participants to assist federal State and local officials in identifying the characteristics and needs of enrollees, suggesting effective program designs and implementation techniques, and gathering and reporting information on enrollees' experiences with SCHIP. These commenters therefore supported the proposed requirements that State plans describe the procedures to be used to involve the public in the design and implementation of the program and ensure ongoing public involvement, and also supported the public notice requirement for State plan amendments. They also supported the ideas and suggestions contained in the preamble to the proposed rule. Some commenters suggested strengthening the regulatory provisions by requiring States to engage in specific activities and collect public participation data to ensure that State programs are effectively involving the public.

Response: We agree that public involvement is integral to the success of SCHIP in every State and appreciate the support of the commenters. We have included the requirement at § 457.120 for initial and ongoing public involvement, consistent with the statute, in order to ensure that it takes place. Our early experience with SCHIP as well as our experience with other programs demonstrate the benefit of public participation in identifying and resolving issues.

We encourage States to take a thoughtful approach to ensuring ongoing public involvement once the State plan has been implemented. We believe that the most effective approach to ensuring public input is to allow States the flexibility to design a process that affords interested parties the opportunity to learn about, and comment on, proposed changes in the program and to identify problems and make suggestions for improvement to the administering agency. States should employ multiple methods of obtaining public input and provide for participation by a wide variety of stakeholders. To encourage public involvement, a State can—

- Hold periodic public hearings to provide a forum for comments when developing or implementing their State plans and plan amendments;
- Establish a child health commission or a consumer advisory committee that is responsible for soliciting broader public opinion about the State plan and formulating the development of program changes, and have their meetings open to members of the public;
- Make presentations to, and solicit input from, child health, consumer advisory or medical care advisory groups and provider groups;
- Publish notices in generally circulated newspapers advertising State plan or amendment development meetings so the public can provide input;
- Create a mechanism enabling the public to receive copies of working proposals, such as proposed State plan amendments, and provide ''stakeholders'' with the opportunity to submit comments to the State (such as mailing information to ''stakeholders,'' including providers and families likely to be served by SCHIP or posting information about proposed changes on a State web site);
- Use a process specified by the State legislature prior to submission of the proposal;
- Provide for formal notice of, and comment on, program changes in accordance with the State's administrative procedure act; and/or
- Any other similar process for public input that would afford an interested party the opportunity to learn about and comment on proposed changes in the program and to offer comments on how the program is operating and suggestions for improvements.

In addition, all State plans, amendments, annual reports and evaluations are made available to the public on the HCFA web site to ensure ongoing public participation. States have flexibility in the manner in which they choose to involve the public in learning about and commenting on program design and implementation. While we will monitor States' activities and effectiveness related to public involvement, we do not accept the suggestion to require collection of public participation data in this final rule.

Comment: One commenter appreciated the prompt posting of State plan information, approval and disapproval letters, amendment fact sheets, and summary information on the HCFA web site.

Response: We appreciate the commenter's support for the information posted on HCFA's web site.

Comment: Several commenters requested that HCFA further discuss the inclusion of various stakeholder groups into the public process. Some urged HCFA to discuss in the preamble ways to include parents of SCHIP children in the planning and monitoring of benefits and service deliver systems. Others suggested expanding the provisions of the rule to specify types of groups that should be involved, including parents, children, teachers, advocates, providers of services to low-income and uninsured children, agencies involved in the provision of medical and related services, managed care entities that hold SCHIP contracts, and the mental health and substance abuse communities. Some commenters also recommended including involvement by physicians' organizations and dentists. One commenter suggested ensuring that public participants should have experience in caring for, and knowledge about, adolescents. Several of the

commenters also recommended that the rule specify the aspects of the plan that should be subject to public input, and should include eligibility, benefits, program design, provider qualifications and payment, outreach and enrollment procedures, and family cost sharing.

Response: We encourage States to involve all ''stakeholders'' throughout the development and operation of the program. ''Stakeholders'' may include parents, children, teachers, advocates, the mental health and substance abuse community, dental providers, physicians and physicians' organizations, managed care entities, and other groups with experience in caring for and knowledge of children, including adolescents. We do not agree that the regulation should specify groups that must be involved nor those program elements for which public involvement is required, because appropriate involvement may vary based upon the program element under consideration and circumstances within a specific State. States may ensure public involvement through a variety of approaches, as noted above. As part of its ongoing method for ensuring public involvement, States are encouraged to consult with stakeholders in the development of annual reports and evaluations. As indicated in previous responses, each State must make a concerted effort to involve the public on an ongoing basis but should have the flexibility to design the processes for involving the public in light of the circumstances in each State.

Comment: One commenter and its member organizations urge strengthened and more detailed requirements for public input at the State level. One commenter strongly recommended more guidance to the States about required public participation in the development and implementation of their plans, including substantial changes to the plans. Although this commenter's State policy makers have kept a coalition of stakeholders (including consumer organizations and health care providers) informed about many changes and have solicited the coalition's input on a regular basis, they noted in their view that numerous major program decisions that could have a significant impact on consumers have been made without public input. This commenter noted that the State SCHIP legislation requires the State agency to adopt rules, which requires a formal notice and hearing process, but stated that the agency has not yet promulgated a single rule. Another commenter urged that HCFA require specific methods for soliciting and obtaining public input, even if States are permitted to select from among alternate specified methods. Some commenters urged HCFA to specifically enforce public input requirements, and to ensure that the public involvement is meaningful.

Response: We do not agree that mandating a particular set of procedures would necessarily ensure meaningful public involvement. Methods that work effectively in one State may not work or be utilized effectively in another State. It is vitally important that a State employ carefully considered methods to ensure involvement of a wide variety of interested parties. This variation across States necessitates allowing a State the flexibility to tailor its methods to the population it serves and other State characteristics. We encourage States to employ multiple methods of obtaining public input. We monitor compliance with all State plan and regulatory requirements, including those related to public involvement.

Comment: A commenter noted that, in the preamble to the proposed rule, HCFA encouraged States to create a mechanism enabling the public to receive copies of working proposals in order to provide comments to the States and that most States have posted their original State plans on the web or have made ordering information available to the public. But this commenter stated that States have not extended this same courtesy with proposed amendments of State plans. States are often unwilling to share proposed amendments and changes in the program until the amendment has been approved by HCFA. This practice inhibits public involvement in the development of the program in this commenter's view. This commenter urged that HCFA design procedures that enforce the requirement that States ensure ongoing public involvement in the amendment process.

Response: We encourage States to provide working copies of State plan amendments to interested parties so they may provide valuable input into the design of program changes. However, we are not requiring States to do so. States must have a method to ensure ongoing public involvement beyond the initial implementation of the program and we will monitor compliance with all requirements, including those related to ongoing public involvement. We would like to be informed if interested parties do not believe they have adequate means to provide input into the SCHIP design and implementation.

Comment: One commenter strongly encouraged HCFA to provide further elaboration in the rule itself on strategies that States should use to promote public involvement. Specifically, the commenter recommended that the final rule should require States to offer the public several different avenues for providing substantial input into the design and ongoing implementation of SCHIP, including public involvement in ''substantial'' State plan amendments. For example, the commenter noted that the final rule could specify that States can satisfy the requirement to involve the public in SCHIP by undertaking a number of the following activities: convening public hearings; advertising public hearings in generally circulated newspapers; making presentations to child health, consumer advisory or medical care advisory groups; mailing information about program implementation to stakeholders, including providers and families likely to be served by SCHIP; and posting information about the status of SCHIP implementation on a State web site. In this commenter's view, it is essential that the final rule do more than list possible examples of how States could comply with the public input requirement, and, in particular, not suggest that undertaking one of a long list of strategies will be sufficient.

Response: We encourage States to use multiple methods of obtaining public input. In a previous response in this section, we have provided further suggestions promoting public involvement and a number of these suggestions reflect this commenter's suggestions. However, as noted and explained previously, we have not revised the regulation to require or include specific methods for ensuring public involvement.

Comment: One commenter applauded HCFA's efforts to increase access to information and believes that requirements for State and local level input as the programs are developed and amended, including specification of a variety of clearly defined methods of providing input, can only help SCHIP.

Response: As indicated in previous responses in this section, we encourage States to take a thoughtful approach in developing methods to ensure public involvement, however, specifying methods in regulation is not necessarily the most effective way of ensuring public involvement within each State.

Comment: One commenter set forth the view that the methods described in the preamble for ensuring public involvement are excellent if used and publicized. This commenter recommended that States be required to report the methods used annually so that advocates and family members can understand the mechanisms for participation. In the view of this

commenter, small public notices are not a meaningful way to reach consumers and this commenter is using the web postings by HCFA to help educate parent leaders. This commenter encouraged families to go to the web site to find their States' annual report to help them understand the program and become involved in the SCHIP process. If the annual report contains no reference to public input, there is no opportunity for participation by consumers and the rules regarding public involvement are rendered useless, in this commenter's view.

Response: We appreciate the commenter's support of our suggested methods for public involvement. However, we disagree that the rules for public involvement are useless unless we require a description of the State's methods in the annual report. States are required to include in the State plan a description of the method the State uses to ensure ongoing public involvement and we will monitor compliance with this State plan requirement as we would monitor compliance with other Federal requirements. To reach a wide variety of stakeholders, we encourage States to use multiple methods of seeking input.

14. Provision of Child Health Assistance to American Indian and Alaska Native (AI/AN) Children (§ 457.125)

To implement section 2102(b)(3)(D) of the Act, we proposed to require a State in § 457.125(a) to include in its State plan a description of procedures used to ensure the provision of child health assistance to American Indian or Alaska Native children. We also requested in § 457.125(a) that the State officials responsible for SCHIP consult with Federally recognized Tribes and other Indian Tribes and organizations in the State on the development and implementation of the procedures used to ensure the provision of child health assistance to American Indian or Alaska Native children. Although not specified in the regulation, we had indicated in the preamble that such groups could include regional Indian health boards, urban Indian health organizations, non-Federally recognized Tribes, and units of the Indian Health Service.

We proposed in § 457.125(b) that we will not approve a State plan that imposes cost sharing on AI/AN children. In the preamble, we stated our view that the imposition of cost sharing on children in AI/AN families may adversely impact the State's ability to ensure coverage for this group as required under section 2102(b)(3)(D) of the Act. This provision applies to States that operate either a separate child health program or a Medicaid expansion program, including Medicaid expansion programs under a section 1115 demonstration project.

Please note that all comments and responses relating to the policy of prohibiting cost sharing for AI/AN children are addressed in the summary for Subpart E.

Comment: One commenting State agreed with the provision at § 457.125 that requires procedures to ensure that tribal children are offered SCHIP, and requests that States consult with federally recognized and other tribes. One commenter recommended that HCFA should strengthen § 457.125 by *requiring* State officials responsible for SCHIP to consult with federally recognized tribes and other Indian tribes and organizations in their States on the development and implementation of child health assistance to American Indian and Alaska Native children.

One commenter added that communication with various AI/AN groups (including IHS, tribal representatives, and urban Indian groups and organizations) is an effective way to accomplish the goal of enrolling AI/AN children in SCHIP. However, this commenter noted that the States should only be required to consult with Federally recognized Tribes. This commenter also noted that Federally recognized tribes should be the ones who ask that IHS or Indian organizations participate in coalitions or meetings to avoid confusion about who represents those tribes. In this commenter's view, federal agencies can enhance tribal/State relations by supporting tribal/State meetings and by providing technical assistance.

Response: We have taken these comments into consideration and agree with the recommendation to require interaction with Indian Tribes. We have moved and revised the provision at § 457.125(a) requesting that a State consult with Federally recognized Tribes and other Indian tribes and organizations in the State on the development and implementation of the procedures to ensure the provision of child health assistance to American Indian and Alaska Native (AI/AN) children. Section 2102(b)(3)(D) of the Act requires a State to include in its plan a description of procedures used to ensure the provision of child health assistance to AI/AN children. A State cannot meet the requirement for ensuring the provision of child health assistance to AI/AN children without interaction with Tribes. Additionally, Section 2102(b)(3)(D) of the Act requires that child health assistance is provided to Indians. We have, therefore, revised the language at § 457.120(c) to require interaction with ''Indian Tribes and organizations in the State'' as opposed to limiting the interaction to Federally recognized Tribes. The final language at § 457.120(c), given these revisions, requires that a State plan include a description of the method the State uses to ensure interaction with Indian Tribes and organizations in the State on the development and implementation of the procedures required in § 457.125(a) to ensure the provision of child health assistance to AI/AN children.

Given our broader definition of those Tribes that must be interacted with, we do not believe it is necessary to further interpret the definition of a ''Federally recognized Tribe'' or who should attend meetings. States are required to involve a range of other ''stakeholders'' pursuant to § 457.120 (a) and (b), as described earlier. We do support Tribal/State meetings related to SCHIP and are willing to provide technical assistance as needed in this area.

Comment: Multiple commenters expressed that States have a genuine interest in consulting with tribes and their related organizations to ensure that all children receive available health coverage, but caution against dual State and federal consultations that may result in confusion.

Response: The required interaction between States and Indian Tribes and other organizations in the State does not replace the federal government's consultation. The Federal government continues to be required to consult with Federally recognized Tribes. We have revised the language of the regulation to specify ''interaction'' to make clear that State actions do not replace the Federal consultation role.

Comment: One commenter urged that HCFA make federal matching funds available at the 100 percent rate for expenditures under separate child health programs for services to AI/AN children received through IHS facilities, the same rate available for such expenditures under Medicaid. According to this commenter, the inequitable treatment of separate child health programs will negatively affect the ability of such programs to serve more SCHIP-eligible children.

Response: Unlike Medicaid, title XXI does not provide the authority for Federal financial participation (FFP) at a level higher than the enhanced title XXI FMAP for any service including those provided at IHS or tribally-administered facilities. A statutory change by Congress would be required in order to permit 100 percent FFP for SCHIP services provided through IHS and tribal facilities.

15. Civil Rights Assurance (§ 457.130)

In § 457.130, we proposed to require the State plan to include an assurance that the State will comply with all applicable civil rights requirements. This assurance is necessary for all programs involving continuing Federal financial assistance in accordance with 45 CFR 80.4 and 84.5. These civil rights requirements include title VI of the Civil Rights Act of 1964, title II of the Americans with Disabilities Act of 1990, section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, 45 CFR part 80, part 84 and part 91, and 28 CFR part 35.

Comment: One commenter noted that this section correctly reminds States that they are required to comply with civil rights laws. However, the commenter noted that this section of the regulation and the preamble should explain that States will violate civil rights laws if they fail to provide linguistically appropriate and accessible services. The commenter recommended that the final regulation should provide more information on each of the listed civil rights statutes and should include examples of violations and compliance. Many other commenters made similar recommendations.

Response: Because primary authority within the Department of Health and Human Services for enforcement of civil rights requirements is held by the Office for Civil Rights, interested parties should contact the Office for Civil Rights directly for more information on compliance with these requirements. States are required by civil rights law to provide linguistically appropriate and linguistically accessible services, as described in the response to the following comment.

Comment: Several commenters noted their view that it is very important for HCFA to articulate clearly the States' obligations under current law (Title VI, 45 CFR Part 80) to provide linguistic access. Three commenters specifically recommended that HCFA, at a minimum, should incorporate in this regulation the standards for providing linguistic and cultural access to services set forth in a 1998 Guidance Memorandum issued by OCR. These commenters also suggested that even stronger standards than those provided by the Guidance Memorandum are often necessary and recommended that HCFA mandate aggressive language access policies by establishing numeric or proportional thresholds, and then mandate minimum standards and procedures that must be adopted when those thresholds are met. They recommended that HCFA also should give consideration to ensuring the cultural and linguistic competency of a SCHIP program. They noted that, for example, it cannot be assumed that because a worker is bilingual, he or she is sufficiently familiar with medical terms and concepts in both languages to provide competent translation services.

Several commenters recommended that the Department should also prohibit States and participating contractors from requiring, suggesting, or encouraging beneficiaries to use family members or friends as interpreters (which should only be done as a last resort), and absolutely prohibit the use of minors as interpreters, regardless of the enrollee's willingness. In the view of these commenters, there also should be explicit instructions to provide clear, translated signage and written materials informing applicants and clients of their right to receive bilingual or interpreter services. A different commenter agreed with the above recommendation and emphasized that access to SCHIP-covered services needs to be provided regardless of the number of individuals from a given language group who live in a given service area and regardless of how obscure the language is. Another commenter also suggested that the States and the Department analyze gaps in data needed for establishing the above described thresholds, and that States and the Department should consider encouraging providers to have paid, trained interpreters or bilingual providers on staff because face-to-face interpretive services are more effective.

Yet another commenter also suggested the adoption of minimum standards for the provision of SCHIP services to persons with limited English proficiency (LEP). This commenter suggested that these minimum standards should include: written policies and procedures on the development, dissemination and use of medical interpreter services; cultural competency standards and training; notice of the right to a free interpreter at all points of contact; prohibition on the use of minors as interpreters and the use of family and friends as a last resort for interpretation and only after being given notice of the right to a free interpreter.

Other commenters suggested that HCFA give examples of how States and contracted entities can comply with title VI, such as providing bilingual workers selected through formal criteria for translation vendors, and linguistically appropriate materials that include accommodations (such as oral, audio, or video formats) for limited English proficiency speakers who do not read well in their primary language or whose languages lack a written version.

Response: A State's obligation to provide linguistically appropriate communication and services flows from a federal fund recipient's obligation to ensure equal access under title VI. Further discussion of language access is found in the responses to comments on § 457.110(a).

Comment: One commenter is concerned that the section does not address the civil rights duties of contractors. Many States contract and sub-contract with entities to administer their programs. This commenter recommended that § 457.130 explain that contracted entities are also required to comply with civil rights laws. In addition, the commenter felt the following sections, and the discussions of each in the preamble, should emphasize that the Department requires contracting entities to comply with civil rights protections: § 457.940 (procurement standards); § 457.945 (certification for contracts and proposals), § 457.950 (contract and payment requirements including certification of payment information). Other commenters agreed with the recommendation that this section should address the civil rights duties of contractors and that the other sections in Subpart I should be amended similarly as well.

Response: A State's contractors, subcontractors and grantees are required to comply with all civil rights laws. When the State contracts with other entities, the State must ensure that its contractors comply with all applicable laws. Because § 457.130 already requires a State to provide an assurance that the State will comply with all applicable civil rights laws, we do not agree that Subpart I should be amended. Section 457.130 already places an obligation on a State to assure that it performs SCHIP-related activities in accordance with applicable federal laws.

Comment: A couple of commenters requested that HCFA amend many other sections to ''incorporate enrollment assistance.'' Specifically, the commenters recommended requiring that States:

- Provide bilingual outreach workers, linguistically appropriate materials, and culturally appropriate strategies when needed (§ 457.90);
- Provide translated oral and written notices, including signage at key points of contact informing potential applicants in their own language of their right to receive interpreter services free of charge (§ 457.110);
- Include the use of bilingual workers, translators, and linguistically

appropriate materials for limited English proficiency populations as required under title VI, in application assistance (§ 457.361(a));

• Take reasonable steps to convey information about notices of rights and responsibilities and decisions concerning eligibility in a culturally and linguistically appropriate manner to ensure that all applicants, including those who are limited English proficiency, are given notice of, and understand, their rights, responsibilities, and decisions concerning their eligibility (§ 457.361(b), (c));

• Provide bilingual workers and linguistically appropriate materials regarding grievances and appeals when needed (§ 457.365);

• Provide notice to beneficiaries about their rights to linguistic access to services (§ 457.995).

Other commenters urged that cultural competency and linguistic accessibility requirements be incorporated throughout the provisions on information, choice of providers and plans, access to emergency services, participation in treatment decisions, respect and nondiscrimination, and grievances and appeals.

Response: A State must comply with civil rights requirements in the operation of all elements of its program. We do not agree that other sections of the regulation, as suggested by the commenter, should be amended since a State must provide an assurance pursuant to § 457.130 that the State plan will be conducted in compliance with all civil rights requirements.

Comment: One commenter noted that, without explanation, HCFA dropped sexual orientation, genetic information, and source of payment as part of the civil rights assurance in its effort to integrate the Consumer Bill of Rights. This commenter requested that HCFA include the source of payment in the final regulation, as it is a major source of discrimination in access to dental services.

Response: The assurance of compliance with civil rights law seeks to assure that the State and its contractors comply with applicable civil rights laws and regulations, without specifying particular policies, procedures, or actions that would constitute a violation of those laws. Generally, to the extent that actions of the State or its contractors based on sexual orientation, genetic information or source of payment discriminate against individuals based on race, ethnicity, color, sex, age or disability, those actions most likely would constitute a violation of the civil rights laws and regulations. States and organizations should contact the Office for Civil Rights (OCR) for more information regarding specific prohibited actions under the civil rights laws and regulations enforced by OCR.

Comment: One commenter asked whether States will be able to sign the civil rights assurance if HCFA implements § 457.125 regarding cost sharing for AI/AN children.

Response: As further discussed in § 457.535, the exemption of AI/AN families from cost sharing is consistent with title VI of the Civil Rights Act of 1964. Therefore, the implementation of § 457.125 will not affect a State's ability to provide an assurance that it will comply with applicable civil rights requirements.

16. Assurance of Compliance With Other Provisions (§ 457.135)

In accordance with section 2107(e) of the Act, we proposed in § 457.135 to require that the State plan include an assurance that the State will comply under title XXI with the following provisions of titles XIX and XI of the Social Security Act:

• Section 1902(a)(4)(C) (relating to conflict of interest standards).

• Paragraphs (2), (16) and (17) of section 1903(i) (relating to limitations on payment).

• Section 1903(w) (relating to limitations on provider donations and taxes).

• Section 1132 (relating to periods within which claims must be filed).

Section 2107(e)(2)(A) of the Act also provides that section 1115 of Act, pertaining to research and demonstration waivers, applies to title XXI. This provision grants the Secretary the same section 1115 waiver authority in title XXI programs as in title XIX programs. In the preamble to the proposed rule, we discussed in detail the extent to which waivers of both title XIX and title XXI provisions should be granted under SCHIP. Specifically, we stated that while the law permits the Secretary to use section 1115 authority to waive provisions of title XXI in order to pursue research and demonstration projects, we do not believe it would be reasonable to grant waivers under section 1115 before States have experience in operating their new title XXI programs and can effectively design and monitor the results of demonstration proposals. We stated that we would consider a section 1115 demonstration proposal for waiver of title XXI provisions only after a State has had at least one year of SCHIP experience and has conducted an evaluation of that experience. We invited comments on the best approach to considering section 1115 waivers of title XXI provisions.

We noted that because both the Federal government and the States have substantial experience in administering title XIX, we believed that we were in a position to consider and grant waivers of title XIX provisions even when the demonstration project involves the SCHIP-related enhanced match. We stated that we would consider a request for section 1115 waivers of title XIX provisions applicable to Medicaid expansion programs without any additional experience with the program.

We only received comments in this section related to our statements in the preamble regarding consideration of section 1115 demonstrations. Therefore, we are implementing the above described regulatory provisions as set forth in the proposed rule. We will be considering those comments as we develop our policies on section 1115 demonstration projects under title XXI.

17. Budget (§ 457.140)

Section 2107(d) of the Act specifies that a State plan must include a description of the budget, updated periodically as necessary, including details on the planned use of funds and the sources of the non-Federal share of plan expenditures, including any requirements for cost sharing by enrollees. We proposed in § 457.140 that the State plan must include a budget that describes both planned use of funds and sources of the non-Federal share of plan expenditures (including any requirements for cost sharing by beneficiaries) for a 3-year period. We also proposed to require that an amended budget included in a State plan amendment include the required description for a 3-year period. We proposed that the planned use of funds include the projected amount to be spent on health services, the projected amount to be spent on administrative costs, and assumptions on which the budget is based.

Please note that additional comments on budget, particularly related to State plan amendments, are addressed in the comments and responses to § 457.60.

Comment: One commenter believed that budget issues did not necessarily tie well with the submittal of plan amendments. For example, a State may go several years without submitting a plan amendment. Several commenters suggested that budget data would best be gathered through the annual reporting process through which States are required to update budget estimates on a yearly basis.

Another commenter stated that the submission of a three-year budget, to the extent that it requires specific budget items, has the potential for being burdensome. This commenter, along with another, expressed that a two-year budget estimate should be sufficient for federal planning purposes. One State indicated that it operates on an annual budgetary cycle and that all budgets are developed by the legislature and approved by the Executive branch annually, so the State does not have any legal authority to develop three-year budget projections.

Response: We agree with the first commenters' suggestion and have reconsidered the requirement at proposed § 457.140 that the State plan, or plan amendment as required at § 457.60(b), must include a budget that describes the State's planned expenditures for a three-year period. We have revised § 457.140 to require that the State plan or plan amendment include a budget that describes the State's planned expenditures for a one-year period. Furthermore, because we are requiring that the budget be updated periodically through the annual report and through quarterly financial reporting, we have revised the requirement at proposed § 457.60(b), (now § 457.60(d)) to require a one-year budget only with State plan amendments that have a significant budgetary impact. Examples of these types of amendments would be those that related to eligibility, as required by § 457.60(b)(1), or cost sharing as required by § 457.60(b)(6) or benefits as required by § 457.60(b)(4). For example, if the amendment added or dropped a package of dental benefits that would have an impact on expenditures, the State would need to submit an amended budget with the amendment. The description of the budget must be submitted in accordance with § 457.60(d) and must continue to meet the requirements of § 457.140(a) and (b). The changes to these provisions will relieve States from having to provide budget descriptions with all State plan amendments. At the same time, we will continue to require a description of planned expenditures for a three-year period each year through the annual report from every State with an approved State plan.

Because States have up to three years to spend each annual allotment, a three-year budget is useful to show if States are planning to use their unused allotments in the succeeding two fiscal years and if they, therefore, anticipate a short fall in Federal funding. We realize that a State must base the required information on projections and that the budget projections submitted to HCFA are not approved by a State's legislature. However, it is important to have this information to ensure the State has adequately planned for its program and to analyze spending of the allotments.

18. HCFA Review of State Plan Material (§ 457.150)

Section 2106 of the Act provides the Secretary of DHHS with the authority to approve and disapprove State plans and plan amendments. The authority vested in the Secretary under title XXI has been delegated to the Administrator of HCFA with the limitation that no State plan or plan amendment will be disapproved without consultation and discussion by the Administrator with the Secretary. We also described this delegation of authority at proposed § 457.150(c).

Under the authority of section 2106 of the Act, we proposed at § 457.150(a) to specify that HCFA reviews, approves and disapproves all State plans and plan amendments. We noted in the preamble to the proposed regulation that the Center for Medicaid and State Operations within HCFA has the primary responsibility for administering the Federal aspects of title XXI. We also noted therein that we would continue to work jointly with the Health Resources and Services Administration (HRSA) to implement and monitor the new program as a part of the Department's overall strategy to support coordination with other Federal and State health programs in providing outreach to uninsured children and promoting coordination of care and other public health interventions. Consistent with the Department's strategy, the current State plan and plan amendment review process involves collaboration with other agencies within the Department and Administration as well. The approval or disapproval of all State plans or amendments presently requires consensus among all of the participating Department components.

Section 2106 does not speak of partial approval or disapproval of a State plan or plan amendment. Thus, at § 457.150(b) we proposed that HCFA approves or disapproves the State plan or plan amendment only in its entirety. We noted in preamble to the proposed regulation that as appropriate and feasible, States may withdraw portions of a pending State plan or plan amendment that may lead to delay in its approval or disapproval. In § 457.150(d), we proposed that the HCFA Administrator designate an official to receive the initial submission of a State plan. In § 457.150(e), we proposed that the HCFA Administrator designate an individual to coordinate HCFA's review for each State that submits a State plan.

Comment: Many commenters questioned the necessity of approving or disapproving a State plan or amendment only in its entirety as provided under proposed § 457.150(b). In the opinion of these commenters, this provision may detrimentally affect what States submit. In these commenters' view, even though a State may have an innovative idea that has come out of the development and public consultation process, it may be reluctant to ''push the envelope'' with the idea for fear that it may hold up a larger state plan or plan amendment. If only a single provision is preventing approval, it would be more effective to approve the rest of the submission and then work with the State on the questionable provision. One of these commenters noted their view that this requirement limits the State flexibility that Congress envisioned in passing title XXI.

A different commenter believed this provision to be administratively burdensome because it encourages States to submit each component of an amendment separately rather than one complete document that provides a more comprehensive picture of the program. This commenter also requested that HCFA approve sections of a plan amendment and allow the State to implement the changes while other sections are under review. Yet another commenter also indicated their belief that the approval process should have more flexibility. If a State plan or plan amendment can be implemented without inclusion of that part, this commenter believes that the entire plan or plan amendment should not be held up for that one small part. Another State concurred with this view. One more commenter says that the provision may be an impediment to, or cause delay in, making innovative changes to a State's program. In this commenter's view, States will be forced to prepare amendments in a piecemeal fashion, causing more work and a greater administrative burden. It would be more efficient for States to be allowed to submit comprehensive program changes that HCFA can approve or deny in part according to this commenter.

Response: HCFA approves or disapproves the State plan or plan amendment only in its entirety because section 2106 does not permit the Secretary to partially approve or disapprove a State plan or plan amendment. Additionally, it would be administratively burdensome for HCFA to track and monitor only portions of approved State plans or plan amendments. However, States may

withdraw or change portions of a proposed State plan or plan amendment at any time during the review process. States need not submit components of a State plan amendment separately, because States may withdraw portions of a pending State plan amendment that may lead to delay in its approval or disapproval of the amendment. Additionally, States have the option to split a single State plan amendment into separate amendments during the review process. Given these options, we do not agree that this provision necessarily limits State flexibility or increases administrative burden and we will work with States to prevent this from occurring.

Comment: Several commenters asserted that the regulations should not provide for review of whether previously approved State plan material complies with title XXI requirements, unless federal law or regulations change. These commenters read section 2106 to mean that, once a State plan provision has been approved, the provision cannot be revoked unless the statute is amended. These commenters specifically argued that new regulations or guidance documents do not provide a basis for revoking approval of a State plan provision. And these commenters assert that disturbing previously approved State plan provisions could disrupt the stability of programs and continuity of care for children. Some commenters, while generally agreeing, indicated that, at a minimum, States should have a reasonable time to come into compliance.

Response: We disagree that the scope of HCFA's authority to determine whether previously approved material continues to meet the requirements for approval should be restricted to changes in statutory or regulatory requirements. Sections 2101(b) and 2101(a)(1) require State plans to be consistent with the requirements of title XXI. Accordingly, we base approval or disapproval of State plan and plan amendments on relevant Federal statutes, including title XXI and title XIX, regulations, and guidelines issued by HCFA to aid in the interpretation of the statutes and regulations. Regulations and guidelines are issued by HCFA in order to implement relevant statutes.

States may continue to rely on approval of a State plan or plan amendment and the receipt of federal matching funds associated with such approval. States will be given an opportunity to correct any parts of the State plan that no longer meet the conditions for approval. Compliance actions will not be imposed without the opportunity for correction afforded by section 2106(d)(2) of the Act and subpart B of part 457 implementing that section of the Act.

19. Notice and Timing of HCFA Action on State Plan Material (§ 457.160)

Section 2106(c) sets forth requirements relating to notice and timing of State plan material. In § 457.160(a), we proposed that the HCFA Administrator will send written notification of the approval or disapproval of a State plan or plan amendment. While section 2106(c)(2) only requires that written notification be sent for disapproval and requests for additional information, we proposed to require that written notification be sent for approvals as well.

In § 457.160(b)(2), we proposed that the State plan or plan amendment be considered received on the day the designated official or individual, as designated pursuant to § 457.150(d) and (e), receives an electronic, fax or hard copy of the complete plan or plan amendment. The complete plan includes any referenced documentation, such as attachments, benefits plans or actuarial analyses.

As required by section 2106(c)(2), a State plan or plan amendment will be considered approved unless HCFA, within 90 days after receipt of the State plan or plan amendment, sends the State written notice of disapproval or written notice of any additional information it needs in order to make a final determination. The Act does not specify calendar days or business days. We proposed to measure the 90-day review period using calendar days. The 90-day review period would not expire until 12:00 a.m. eastern time on the 91st countable calendar day after receipt (except that the 90-day period cannot stop or end on a non-business day), as calculated using the rules set forth in the proposed regulation and discussed below.

Section 2106(c) sets forth requirements relating to notice and timing of action on State plan material. In § 457.160(b)(3), we proposed that if HCFA provides written notice requesting additional information, the 90-day review period is stopped on the day HCFA sends the written request for additional information. This written request will be considered sent on the day that the letter is signed and dated except if that day is a weekend or Federal holiday, in which case the review period will stop on the next business day. We proposed that the review period will resume on the next calendar day after the complete additional information is received by the designated individual, unless the State's response is received after 5:00 p.m. eastern time on a day prior to a non-business day or any time on a non-business day, in which case the review period will resume on the following business day. We proposed in § 457.160(b)(4) that the 90-day review period cannot stop or end on a non-business day. HCFA will not stop a review period on a weekend or holiday. If the 90th day of a review period is scheduled to be on a weekend or holiday, then the 90th day will be the following business day. Additionally, in § 457.160(b)(5), we proposed that HCFA may send written notice of its need for additional information (and therefore, stop the 90-day review period) as many times as necessary to obtain the necessary information for making a final decision whether to approve the State plan or plan amendment.

Comment: One commenter supported HCFA's proposal to send written notification of State plan approvals even though the statute requires only written notification of disapprovals.

Response: We note the commenter's support.

Comment: One commenter agreed with HCFA's use of 90 calendar days. One commenter proposed that some allowance should be made for expedited approval of State plan amendments because SCHIP programs are such a high priority for the States and the federal government. This commenter expressed the opinion that allowing for more than 90 days each time federal approval is needed, even for simple changes, is a deterrent to quick, innovative program adjustments. They recommended that HCFA should strive for expeditious responses to State plan amendments and, whenever possible, should take action in fewer than 90 days.

Response: We appreciate the support of the first commenter. As for the expedited approval of State plan amendments, section 2106(c)(2) of the Act provides that a State plan or plan amendment will be considered approved unless HCFA, within 90 days after receipt of the State plan or plan amendment, sends the State written notice of disapproval or written notice of any additional information it needs in order to make a final determination. We make every attempt to expedite responses to State plan amendments and recognize their importance to the States and the Federal government. The 90-day time frame is the outer time limit for action; it does not preclude action in a shorter time period and we will strive to take quicker action whenever possible.

Comment: One commenter proposed that the State plan or amendment be

considered received by HCFA the day it is delivered to the HCFA office rather than the day it is received by a specified individual. In this commenter's view, the State should not be penalized for delays in HCFA's internal delivery system. In this State's case, two weeks after the amendment was delivered to the HCFA Central Office, the Regional Office reported to the State that the amendment had not been received by the Central Office. The State was able to obtain a signed cartage statement indicating that it had been delivered to the office and thereby protected the submission date.

Response: We disagree with the commenter's suggestion that a State plan or plan amendment be considered received by HCFA on the day is it delivered to HCFA. As set forth in § 457.160(b)(2), a State plan or plan amendment is considered received on the day the designated individual or official receives an electronic, fax or paper copy of the complete material. This is intended to simplify administration of the program. At this point in the program, each State has received correspondence notifying it of the identity of the designated individual. If the designated individual is unavailable during regular business hours, another HCFA employee will act in place of the designated individual to ensure that the review period is counted as if the designated individual was in the office. However, in cases where States send an amendment to an individual or address other than the one designated, HCFA cannot begin the review until the amendment is received by the designated individual.

Comment: One commenter disagreed with this provision that provides that if HCFA requests additional information, the 90 day review period stops but resumes on the next calendar day after HCFA receives all of the requested information. The commenter recommended that HCFA adopt the approach used in Medicaid under 42 CFR 430.16(a)(2) which states that if HCFA requests additional information, the 90 day review period for HCFA action on the plan or plan amendment begins on the day it receives that information. The commenter reasoned that under proposed § 457.150(b), ''HCFA approves or disapproves the State plan or plan amendment only in its entirety''. Yet under proposed § 457.160(b)(3), if HCFA has determined that additional information is needed, HCFA will have fewer than 90 days to review that information once it is submitted. Although this commenter indicated that it understands the strong interest in moving quickly to implement SCHIP, the commenter saw no reason to accelerate a review process when the initial State submission was inadequate or incomplete. The commenter felt that using the current Medicaid standard would promote consistency and ensure that HCFA has sufficient time for review.

Response: We are committed to expeditious review of State plans and plan amendments. The process set forth in § 457.160(b)(3), that the 90 day review period resumes on the next calendar day after HCFA receives all requested information, will help ensure an expeditious review. We are not using the review period policies in effect under Medicaid, as the Medicaid statute differs from title XXI in this regard and we believe the speedier and more flexible process described in § 457.160(b)(3) will more effectively implement title XXI objectives. To allow us the maximum review time within the review period, we have set forth rules that the review period be started (or restarted) on the first full day following receipt of the plan (or additional information) and the review period will resume on the following business day if the response is received after 5 p.m. eastern time on a day prior to a non-business day or any time on a non-business day.

Comment: One commenter requested that HCFA make every effort to request all necessary information initially so that multiple stoppages of the 90 day clock are less likely to occur. Another commenter wrote that HCFA should not have unlimited ability to stop the clock.

Response: HCFA's formal request for information may include a description of specific issues that need clarification, an outline of additional information required, or a request for resolution of any inconsistencies of the plan with title XXI provisions. We will continue to make every effort to identify those issues for which we need additional information early in the review process. However, many times a State's response will trigger further questions. By allowing the review period to be stopped as many times as necessary to obtain the information needed to make a decision, States are provided ample opportunity to demonstrate compliance with the requirements of the program.

20. Withdrawal Process (§ 457.170)

In § 457.170, we proposed to allow a State to withdraw its State plan or State plan amendment at any time during the review process by providing written notice to HCFA of the withdrawal. This proposed process is consistent with the process for withdrawal of a proposed Medicaid State plan amendment.

Comment: A number of commenters suggested that a State be allowed to withdraw any portion of a proposed submitted plan (and not just a whole plan or amendment) in order to expedite the approval process when a limited number of its provisions are slowing down the plan review process.

Response: In our review of State plans and plan amendments, we have allowed and will continue to allow a State to withdraw a portion of its proposed State plan or proposed plan amendment. In order to clarify this provision, we have revised § 457.170(a) to require that a State may withdraw its proposed State plan or proposed plan amendment, or any portion of its State plan or plan amendment, at any time during the review process by providing written notice to HCFA of the withdrawal.

Comment: One commenter recommended that the State be required to provide public notice and a meaningful opportunity for public input prior to any withdrawal.

Response: We encourage States to involve the public in all phases of the program, including, to the extent feasible, prior to withdrawal of a proposed State plan amendment.

Comment: One commenter suggested that we clarify that a State may withdraw its approved State plan at any time if the State chooses to discontinue its program.

Response: A State may withdraw a proposed State plan or plan amendment by providing written notice to HCFA of the withdrawal in the form of a State plan amendment. We have added a provision at § 457.170(b) to clarify that a State may request withdrawal of an approved State plan by submitting a State plan amendment to HCFA as required by § 457.60. Because withdrawal of a State plan is a restriction on eligibility, a State plan amendment to request withdrawal of an approved State plan must be submitted in accordance with requirements set forth in § 457.65(b), including those related to the provision of prior public notice. Although HCFA does not have authority to deny such a State plan amendment request, this requirement conforms with the requirements of section 2106(b)(3) relating to State plan amendments that restrict eligibility. We note that withdrawal of a Medicaid expansion program may also require an amendment to the title XIX State plan.

21. Administrative and Judicial Review of Action on State Plan Material (§ 457.190)

Under Section 2107(e)(2)(B) of the Act, a State dissatisfied with the Administrator's action on State plan

material has a right to administrative review and judicial review. In § 457.190(a), we proposed a procedure for administrative review. Specifically, we proposed to require that any State dissatisfied with the Administrator's action on State plan material under § 457.150 may, within 60 days after receipt of the notice of final determination provided under § 457.160(a), request that the Administrator reconsider whether the State plan or plan amendment conforms with the requirements for approval. Additionally, we proposed that the procedures for hearings and judicial review be the same procedures used in Medicaid which are set forth in regulations at part 430, subpart D. We also proposed that HCFA will not delay the denial of Federal funds, if required by the Administrator's original determination, pending a hearing decision. If the Administrator determines that the original decision was incorrect, HCFA will pay the State a lump sum equal to any funds incorrectly denied.

Comment: One commenter supported the proposed procedure for administrative and judicial review.

Response: We note the support of the commenter.

C. Subpart C—State Plan Requirements: Eligibility, Screening, Applications, and Enrollment

1. Basis, Scope, and Applicability (§ 457.300)

This subpart interprets and implements provisions of section 2102 of the Act which relate to eligibility standards and methodologies and to coordination with other public health insurance programs; section 2105(c)(6)(B), which precludes payment for expenditures for child health assistance provided to children eligible for coverage under other Federal health care programs other than programs operated or financed by the Indian Health Service; and section 2110(b), which defines the term ''targeted low-income child.'' This subpart sets forth the requirements relating to eligibility standards and to screening, application and enrollment procedures. We proposed that the requirements of this subpart apply to a separate child health program and, with respect to the definition of targeted low-income child only, to a Medicaid expansion program.

As discussed in the response to the first comment below, we have removed from the proposed definition of ''optional targeted low income child'' for purposes of a Medicaid expansion the cross reference to § 457.310(a) in subpart C and have revised the definition of ''optional targeted low-income child'', which is now located at §§ 435.4 and 436.3 of this chapter. Comments regarding optional targeted low-income children for purposes of a Medicaid expansion program are addressed in the preamble to subpart M. Conforming changes have been made to the definition of ''targeted low-income child'' at § 457.310. This subpart now applies only to a separate child health program.

We received no comments on § 457.300 and, with the exception of the one change noted, are implementing it as proposed. General comments on subpart C are discussed in detail below.

Comment: We received two requests that the Medicaid regulations clarify the definition of ''optional targeted low-income child.'' The commenters are of the opinion that the cross-reference to the title XXI regulations is confusing. They note that some provisions in title XXI, such as permitting States to limit eligibility by geographic region, do not apply in Medicaid.

Response: We accept the commenters' request to clarify the definition of optional targeted low-income child in the Medicaid regulations, rather than cross-reference § 457.310(a). In proposed § 435.229(a), the cross-reference to § 457.310(a) incorporated provisions of the definition of targeted low-income child that only apply in a separate child health program. We have removed the cross-reference to § 457.310(a) and added a specific Medicaid definition of optional targeted low-income child in § 435.4 (and in § 436.3 for Guam, Puerto Rico, and the Virgin Islands).

Comment: We received a number of comments recognizing that certain policies were statutory and urging HCFA to seek statutory changes. The suggested changes included the following:

Allow a State the option to keep a pregnant teen enrolled in a separate child health program even if she becomes eligible for Medicaid as a pregnant woman.

Allow States to deem an infant eligible for a separate child health program for a full year if the birth is covered by a separate child health program.

Response: We will take these suggestions into consideration in developing future legislative proposals and appreciate the commenters' recognition that these issues are driven by the statute.

Comment: Several commenters were concerned about the interaction of various public programs. Two urged HCFA to reiterate the importance of ensuring the Medicaid eligibility is not tied to eligibility for Temporary Assistance for Needy Families (TANF) under the Personal Responsibility and Work Opportunity Reconciliation Act (PRWORA).

Response: Under the welfare reform provisions of PRWORA, the link between Medicaid and cash assistance (previously given as Aid To Families with Dependent Children, or AFDC) was severed. This ''delinking'' of Medicaid from cash assistance assured Medicaid eligibility for low-income families regardless of whether the family is receiving welfare payments, and offers States new opportunities to provide a broader range of low-income families health care coverage. In an effort to help States better understand their opportunities and responsibilities under the law, DHHS, HCFA, and the Administration on Children and Families (ACF) have issued substantial guidance on how to implement the delinking provisions, including fact sheets, letters to State Medicaid and TANF Directors, updates to the State Medicaid Manual, and the publication of a 28-page, plain-English guide entitled, ''Supporting Families in Transition: A Guide to Expanding Health Coverage in the Post-Welfare Reform World.'' State Medicaid Director letters dated October 4, 1996, February 5, 1997, April 1, 1997, September 22, 1997, and August 17, 1998 dealt with the implementation of the section 1931 eligibility category; letters dated February 6, 1997 and April 22, 1997 discussed redetermination procedures; and eight additional letters covered immigration, outreach and enrollment, MEQC errors, and the availability of the $500 million delinkage fund. Last fall, at the direction of President Clinton, HCFA conducted comprehensive on-site visits in all States to review State TANF and Medicaid application and enrollment policies and procedures. HCFA is currently finishing the ensuing reports and working with the States to address problems that have been identified. An April 7, 2000 letter to State Medicaid Directors requires States to take steps to identify and reinstate individuals who have been terminated improperly from Medicaid and to ensure that their computer systems are not improperly denying or terminating persons from Medicaid. The letter also provides important guidance regarding redetermination. A series of Questions and Answers concerning this letter can be found under the heading ''Welfare Reform and Medicaid'' on HCFA's web

site at: *http://www.hcfa.gov/medicaid/medicaid.htm.*

Based on the findings of HCFA's reviews and the reviews that States are undertaking to comply with the April 7, 2000 guidance, HCFA is providing further guidance and technical assistance to States in the areas of application and notice simplification, outreach to eligible families, and modification of computer systems, among others. HCFA, in partnership with ACF, the Food and Nutrition Service, the American Public Human Services Association, and the National Governors Association, is also disseminating best practices so that States can assist one another as they move forward to correct problems and improve participation among eligible low-income families.

Comment: We received one comment urging HCFA to include information about presumptive eligibility under a separate child health program in the preamble to the SCHIP financial regulation. Another urged HCFA to encourage States to provide presumptive eligibility for children as this is particularly important to children experiencing a mental health crisis.

Response: States have the authority to implement a presumptive eligibility procedure under its separate child health program. This was implicit under title XXI as originally enacted and now, with the enactment of the Benefits Improvement and Protection Act of 2000(BIPA) (Pub. L. 106–554), the authority to implement presumptive eligibility procedures in separate child health programs is explicit.

Under section 803 of BIPA, States have the option to establish a presumptive eligibility procedure and, consistent with the flexibility now granted States under the Medicaid presumptive eligibility option (see section 708 of BIPA, amending section 1920A(b)(3)(A)(i) of title XIX), States have broad discretion to determine which entities shall determine presumptive eligibility, subject to the approval of the Secretary. For example, States can rely on health care providers, child care providers, WIC, or Head Start centers, or the contractors that may be doing the initial SCHIP/Medicaid eligibility screen.

Under the presumptive eligibility established under Medicaid and carried over to SCHIP under the BIPA legislation, a family has until the end of the month following the month in which the presumptive eligibility determination is made to submit an application for the separate child health program (or the presumptive eligibility application may serve as the application for the separate child health program, at State option). If an application is filed, the presumptive eligibility period continues until the State makes a determination of eligibility under the separate child health program (subject to the Medicaid screening requirements). In accordance with section 457.355, if a child enrolled in a separate child health program on a presumptive basis is later determined to have been eligible for the separate child health program, the costs for that child during the presumptive eligibility period will be considered expenditures for child health assistance for targeted low-income children and subject to the enhanced FMAP. If the child is found to have been Medicaid-eligible during the period of presumptive eligibility, the costs for the child during the presumptive eligibility period can be considered Medicaid program expenditures, subject to the appropriate Medicaid FMAP (the enhanced match rate or the regular match rate, depending on whether the child is a optional targeted low-income child).

We have revised the policy stated in the preamble of the proposed rule regarding children who are enrolled through presumptive eligibility, but who are later not found to be eligible under the separate child health program or Medicaid. In the proposed rule, we noted that the costs for coverage of such children during the presumptive period must be claimed as SCHIP administrative expenditures, subject to the enhanced match and the 10 percent cap. BIPA, however, authorizes presumptive eligibility under separate child health programs in accordance with section 1920A of the Act, and the statute now allows health coverage expenditures for children during the presumptive eligibility period to be treated as health coverage for targeted low-income children whether or not the child is ultimately found eligible for the separate child health program, as long as the State implements presumptive eligibility in accordance with section 1920A and section 435.1101 of this part. This preserves State flexibility to design presumptive eligibility procedures and allows States that adopt the presumptive eligibility option in accordance with section 435.1101 to no longer be constrained by the 10 percent cap.

Comment: One commenter thought that greater coordination among HCFA, the Office of Child Support Enforcement (OCSE), State child support agencies, and SCHIP stakeholders would increase the likelihood of children receiving the best available health care. The commenter noted that many children who qualify for SCHIP are members of single-parent families and could benefit from the services of the child support program. Conversely, SCHIP programs can ensure that children have access to quality health care when a noncustodial parent's employer does not offer health insurance, the health insurance is available only at a prohibitive cost, or it is not reasonably accessible to the child. Another commenter suggested that the preamble explicitly note the prohibition on denying Medicaid to children on the grounds that their parents have failed to cooperate with establishing paternity or with medical support enforcement and also highlight that States do not need to include questions about noncustodial parents on their joint applications, but rather can solicit such information at the time that they notify the family of eligibility.

Response: We agree that it is important that children benefit from the services of the child support program. HCFA has issued guidance to States under title XIX about the importance of informing families who receive Medicaid about available State Child Support Enforcement services. We have instructed State Medicaid agencies to coordinate with State CSE agencies to ensure that children who could benefit from these services receive them. We encourage States to inform families who apply for coverage under their separate child health programs about CSE services.

CSE agencies can also serve as a source of information about available health care coverage for families who seek CSE services. In many cases, families are not able to secure health care coverage through a child's absent parent. In such cases, CSE can help the family obtain coverage through SCHIP or Medicaid if the State promotes coordination between its CSE and child health coverage. Several States have reported taking such steps as part of their outreach and coordination activities.

While child support services can provide important support to many families, questions about absent parents on a child health application can be a barrier to enrollment. Under Medicaid, the recent guidance issued to State Medicaid agencies reiterates that cooperation of a parent with the establishment of paternity and pursuit of support cannot be made a condition of a child's eligibility for Medicaid. Moreover, the guidance informs States that they are not required to request information about an absent parent on a Medicaid application (or a joint Medicaid/separate child health program

application) that is only for a child and not for the parent.

Comment: One commenter felt that the eligibility screens and information requirements in the proposed regulations went beyond the statutory requirements, are excessively burdensome and will make it impossible to effectively coordinate with other programs, such as the school lunch program, Head Start, or WIC.

Response: We disagree with the commenter's assertion that the regulations have created barriers to enrollment in the SCHIP program. We have provided States with considerable flexibility with respect to how to meet the requirements of the statute, and have worked in this final rule to further expand that flexibility in many cases. The statute specifically requires that States screen all applicant children for Medicaid eligibility and enroll them in Medicaid if appropriate. To that end we have encouraged, and the majority of States have adopted, joint applications which significantly decrease the complexity of the application and enrollment process. We have permitted States flexibility with respect to the design of their applications and their application processes, although we encourage States to streamline the enrollment process in SCHIP and Medicaid (for example, elimination of assets tests, using mail-in applications, minimizing verification requirements) to enable families to access coverage under a separate child health program or Medicaid as quickly and easily as possible. We acknowledge the difficulties that exist in coordinating different public programs and have provided flexibility wherever possible; but that flexibility is constrained by the statutory provisions that are designed to ensure that children are enrolled in the appropriate program. States have taken advantage of the flexibility permitted to design varied and effective coordination procedures. We are committed to working closely with the States to help them implement procedures that work effectively for them and to share their ideas and experiences with other States.

2. Definitions and Use of Terms (§ 457.301)

This section includes the definitions and terms used in this subpart. Because of the unique Federal-State relationship that is the basis for this program and in keeping with our commitment to State flexibility, we determined that many terms should be left to the States to define. For purposes of this subpart, we proposed to define the terms ''employment with a public agency,'' ''public agency,'' and ''State health benefits plan.''

We proposed to define ''public agency'' to include a State, county, city or other type of municipal agency, including a public school district, transportation district, irrigation district, or any other type of public entity. We proposed to define the term ''employment with a public agency'' as employment with an entity under a contract with a public agency. The term was intended to include both direct and indirect employment because we did not wish to influence or restrict the organizational flexibility of State and local governmental units. We proposed to define the term ''State health benefits plan'' as a plan that is offered or organized by the State government on behalf of State employees or other public agency employees within the State.

Comment: Commenters objected to the definition of ''employment with a public agency'' as being too inclusive. They noted particular concern about the inclusion of ''entities contracting with a public agency'' in the definition. Commenters felt the inclusion of this group could unfairly deny coverage to children in families who are not State employees.

Response: We are deleting our proposed definition of ''employment with a public agency'' in § 457.301. In § 457.310(c)(1)(i), we will track the statutory language at section 2110 (b)(2)(B), which excludes from eligibility ''a child who is a member of a family that is eligible for health benefits coverage under a State health benefits plan on the basis of a family member's employment with a public agency in the State.'' State law will determine whether parents employed by contracting agencies are employed by a public agency and whether their children are eligible for health benefits coverage under a State health benefits plan. If the State determines that a child is eligible for health benefits coverage under a State health benefits plan on the basis of a family member's employment with a public agency in the State, then the child is ineligible for coverage under a separate child health program. In addition, we have revised the definition of ''State health benefits plan'' to clarify that we would not consider a benefit plan with no State contribution toward the cost of coverage and in which no State employees participate as a State health benefits plan.

3. State Plan Provisions (§ 457.305)

In accordance with the requirements of section 2102(b)(1)(A) of the Act, we proposed to require that the State plan include a description of the State's eligibility standards.

Comment: Several organizations commented that HCFA should require States that limit the number of children who can enroll in a separate child health program to describe their procedures for deciding which children will be given priority for enrollment and how States will ensure that equal access is provided to children with pre-existing conditions; their processes for discontinuing enrollment if program funds are depleted; how they will comply with the prohibition on enrolling children at higher income levels without covering children at lower income levels; how the waiting lists will be fairly administered. The commenters also suggested that we require these States to maintain sufficient records to document that favoritism or discrimination does not occur in selecting individuals for enrollment. Additionally, commenters suggested that § 457.305 or § 457.350, should specifically require that a Medicaid screen be conducted before a child is placed on a waiting list.

Response: States are required under § 457.305 to include as part of their State plan a description of their standards for determining eligibility. We are clarifying in regulation text that this must include a description of the processes, if any, for instituting enrollment caps, establishing waiting lists, deciding which children will be given priority for enrollment. This clarification of the regulation text conforms with actual HCFA practice. HCFA has requested States that have adopted enrollment caps to describe in their State plans their policies for establishing enrollment caps and waiting lists and for enrolling children from any waiting lists. We also have added a provision at § 457.350(h) requiring that applicants must be screened for Medicaid prior to being placed on a waiting list due to an enrollment cap. Not doing so would place Medicaid-eligible children on a waiting list and undermine a fundamental goal of the statute—to enroll children in health insurance programs for which they are eligible. In this case, arrangements must be made for the joint application to be processed promptly by the Medicaid program.

States must afford every individual the opportunity to apply for child health assistance without delay in accordance with § 457.340, and facilitate Medicaid enrollment, if applicable, in accordance with § 457.350, prior to placing a child on a waiting list for a separate child health program. We have amended the language of § 457.305 (relating to State

plan requirements) to reflect this requirement.

If, after a State plan is approved by HCFA, the State opts to restrict eligibility by discontinuing enrollment, by establishing an enrollment cap, or by instituting a waiting list, the State must submit a State plan amendment requesting approval for the eligibility changes as required by § 457.60(a). Because we believe these changes in enrollment procedures constitute restrictions of eligibility, the amendment must be submitted in accordance with the requirements at § 457.65(d). With respect to public input, HCFA also requires in § 457.120 that States ensure ongoing public involvement once the State plan has been submitted.

4. Targeted Low-Income Child (§ 457.310)

In accordance with § 2110(b) of the Act, we proposed to define a targeted low-income child as a child who meets the eligibility requirements established in the State plan pursuant to § 457.320 as well as certain other statutory conditions specified in this section. At § 457.310(b), we set forth proposed standards for targeted low-income children that relate to financial need and eligibility for other health coverage, including coverage under a State health benefits plan. In addition, we set forth exclusions from the category of targeted low-income children.

With regard to financial need, we proposed that a child who resides in a State with a Medicaid applicable income level, must have: (1) family income at or below 200 percent of the Federal poverty line; or (2) family income that either exceeds the Medicaid applicable income level (but by not more than 50 percentage points) or does not exceed the Medicaid applicable income level determined as of June 1, 1997. We left States the discretion to define ''income'' and ''family'' for purposes of determining financial need.

We note that we have modified § 457.310(b)(1) to clarify the definition of targeted low-income child. We made technical corrections, in accordance with section 2110(b) to indicate that a targeted low-income child may reside in a State that does not have a Medicaid applicable income level and that a targeted low-income child may have a family income at or below 200 percent of the Federal poverty line for a family of the size involved, whether or not the State has a Medicaid applicable income level. In addition, we have revised proposed § 457.310(b)(1)(iii), now § 457.310(b)(1)(iii)(B), for purposes of clarity. A targeted low-income child who resides in a State that has a Medicaid applicable income level, may have income that does not exceed the income level that has been specified under the policies of the State plan under title XIX on June 1, 1997. This provision effectively allows children who became eligible for Medicaid as a result of an expansion of Medicaid that was effective between March 31 and June 1, 1997 to be considered targeted low-income children. It also means that children who were below the Medicaid applicable income level but were not Medicaid eligible due to financial reasons that were not related to income (e.g. due to an assets test) can be covered by SCHIP.

With regard to other coverage, we proposed that a targeted low-income child must not be found eligible for Medicaid (determined either through the Medicaid application process or the screening process discussed later in this preamble); or covered under a group health plan or under health insurance coverage, unless the health insurance coverage has been in operation since before July 1, 1997, and is administered by a State that receives no Federal funds for the program's operation. However, we proposed that we would not consider a child to be covered under a group health plan if the child did not have reasonable access to care under that plan.

With regard to exclusions, we proposed at § 457.310(c)(1) that a targeted low-income child may not be a member of a family eligible for health benefits coverage under a State health benefits plan on the basis of a family member's employment with a public agency so long as more than a nominal contribution to the cost of the health benefit plan is available from the State or public agency with respect to the child. We proposed to set the nominal contribution at $10.

Section 2110(b)(2)(A) of the Act excludes from the definition of targeted low-income child a child who is an inmate of a public institution or who is a patient in an institution for mental diseases (IMD). We proposed to use the Medicaid definition of IMD set forth at § 435.1009, which provides, in relevant part, that an IMD ''means a hospital, nursing facility, or other institution of more than 16 beds that is primarily engaged in providing diagnosis, treatment or care of persons with mental diseases, including medical attention, nursing care and related services.''

We proposed to apply the IMD eligibility exclusion any time an eligibility determination is made, including the time of application or any periodic review of eligibility (for example, at the end of an enrollment period). Therefore, a child who is an inpatient in an IMD at the time of application, or during any eligibility determination, would be ineligible for coverage under a separate child health program. If a child who is enrolled in a separate child health program subsequently requires inpatient services in an IMD, the IMD services would be covered to the extent that the separate program includes coverage for such services. However, eligibility would end at the time of redetermination if the child resides in an IMD at that time. We stated that we were reviewing the IMD policy and considering various options. We solicited comments on an appropriate way to address this issue.

We proposed to use the Medicaid definition of ''inmate of a public institution'' set forth at § 435.1009. Accordingly, we stated in the preamble to the proposed regulation that when determining eligibility for a separate child health program, an individual is an inmate when serving time for a criminal offense or confined involuntarily in State or Federal prisons, jails, detention facilities, or other penal facilities. We also stated in the preamble to the proposed regulation that a facility is a public institution if it is run, or administratively controlled by, a governmental agency.

Under Medicaid, FFP is not available for medical care provided to inmates of public institutions, except when the inmate is a patient in a medical institution. We proposed to allow this same exception for a separate child health program because we believe an inmate residing in a penal institution who is subsequently discharged or temporarily transferred to a medical institution for treatment is no longer an ''inmate.'' Therefore, an inmate who becomes an inpatient in a medical institution that is not part of the penal system (that is, is admitted as an inpatient in a hospital, nursing facility, juvenile psychiatric facility, or intermediate care facility that is not part of the penal system), would be eligible for a separate child health program (subject to meeting other eligibility requirements), and the State would receive FFP for medical care provided to that child. If the child is taken out of the medical institution and returned to a penal institution, the child again would be excluded from eligibility for the separate child health program.

Comment: Numerous commenters supported the proposed policy that a child would not be considered covered under a group health plan if the child did not have reasonable access to care under that plan and several others

requested further clarification. A third group of commenters also recommended that States should be allowed to determine when a plan is inaccessible.

Response: The intention of the ''reasonable access to care'' standard is to provide relief for children who are covered by a health maintenance organization or managed care entity not in close geographic proximity through the employer of a non-custodial parent and cannot get treatment in the locality in which they reside due to service area or other restrictions. HCFA recognizes that it is often difficult for such children to be removed from coverage under their non-custodial parent's health plan, because it is often court-mandated coverage and the custodial parent may not be able to terminate such coverage. We therefore defined these children as lacking ''reasonable access to care.'' While we recognize that health coverage that is unaffordable due to high premiums or deductibles also presents issues of access, the statute precludes children who are covered under a group health plan or under health insurance coverage (as defined under HIPAA and reflected in our definitions) from receiving coverage under a separate child health program. We note that some States have established eligibility for children whose families have dropped such unaffordable coverage and it is within their discretion to adopt such procedures. However, we believe that to permit children who are currently enrolled in a group health plan or other health insurance coverage, other than children who do not have reasonable geographic access to coverage, to enroll in a separate child health program would contradict the statute. We have revised § 457.310(b)(2)(ii) to clarify that a child would not be considered covered under a group health plan if the child did not have reasonable geographic access to care under that plan.

Comment: Several commenters requested additional guidance on whether children covered under a plan which provides limited benefits only, such as policies covering only school sports injuries, vision, dental, or catastrophic care, or those with high deductibles, have access to insurance. One commenter requested that HCFA allow States to consider a child's access to dental services when making eligibility determinations. Clarification also was requested on whether school health insurance is considered creditable coverage.

Response: Section 2110(b)(1)(C) of the Act excludes from the definition of targeted low-income children a child who is ''covered under a group health plan or under health insurance coverage'' as those terms are defined in § 102 of the Health Insurance Portability and Accountability Act (HIPAA), which added section 2791 to the Public Health Service Act (PHSA), 42 U.S.C. 300gg–91(c). HIPAA and the implementing regulations (found at 45 CFR 146.145 and 148.220), in turn, exempt certain ''excepted benefits'' from some of the requirements of HIPAA to which group health plans and group health insurance are otherwise subject. Consistent with this treatment under HIPAA, a group health plan or group health insurance which meets the definition of ''excepted benefits'' also will not be considered as a group health plan or health insurance coverage for eligibility purposes. Under section 2110(b)(1)(C) of title XXI, a child with coverage under a group health plan or group health insurance coverage that is included under ''excepted benefits'' coverage may be provided with SCHIP funds, provided the child meets the other eligibility requirements of the separate program.

Policies that are limited to dental or vision benefits are among the ''excepted benefits'' identified in HIPAA. Therefore, a child with coverage under a limited-scope dental or vision plan would not be precluded from receiving coverage under a separate child health plan. Similarly, school health insurance policies with very restrictive coverage—for example, coverage limited to treating an injury incurred in a school sports event—would not preclude Title XXI eligibility, so long as they meet the definition of ''excepted benefits'' in HIPAA.

Comment: Two commenters requested that HCFA allow children to receive vision or dental services through a separate child health program when these services are not provided by the child's current health plan.

Response: With respect to coverage of vision and dental services, the statute does not permit States to provide coverage to children under separate child health programs when these children have other health insurance coverage, as defined by HIPAA even when coverage for certain services is limited. States that are concerned about ensuring that children receive such services may wish to consider expanding eligibility under Medicaid, which does not exclude children with other health insurance coverage from eligibility, or providing for such coverage with State-only funds.

Comment: One commenter noted that the exclusion of children of public employees places an additional administrative burden on States because they must verify whether the child has access to the State employee benefit system before a child may enroll in a separate child health program. Commenters also pointed out that under State welfare reform programs, many former welfare recipients are placed in entry-level State positions and State employee coverage is not necessarily affordable for them.

Response: We recognize that premiums and deductibles may present barriers to access to health coverage for children eligible for State health benefit coverage. However, the statute specifically prohibits coverage under a separate child health program of children who are eligible for health benefits coverage under a State health benefits plan. We have provided greater flexibility on this issue in the regulation, but we believe any further flexibility would violate the statutory prohibition. The verification requirements are subject to State discretion and the State may accept the individual's statement about eligibility for health benefits coverage under a State health benefits plan. Therefore, we do not agree that verification requirements necessarily create an undue burden on States. In any event, we do not have the statutory authority to permit eligibility for children of public employees who have access to coverage under a State health benefits plan.

Comment: Many commenters requested that HCFA clarify the proposed nominal contribution of $10 for children of public employees by indicating whether this is an amount per child, per family, per month, or per year. Other commenters offered alternative suggestions for what could be considered ''nominal,'' including: allow flexibility among states; $15–$20; 5% or 10% of the family's income or a standard related to their ability to pay; 25–50% of the child's premium; 50% of the cost of the child's coverage; or 60% of the cost of family coverage (consistent with the standard set for employer-sponsored insurance). One commenter requested clarification on how a nominal State contribution of $10 could be verified.

Response: We agree that we were unclear in the proposed regulation regarding the definition of nominal contribution and have clarified in the final regulation that the $10 contribution is per family, per month. While we appreciate the numerous suggestions submitted by commenters for alternative definitions of a ''nominal'' contribution, we did not change the $10 level in the final regulation. In selecting this level, we were attempting to offer States some

flexibility in determining what constitutes eligibility for a State health benefits plan, within the limits on eligibility for a separate child health program imposed by the statute. In our opinion, the $10 nominal contribution achieves this balance. We have also added to the regulation text the ''maintenance of effort'' provision discussed in the preamble to the proposed rule to indicate that if more than a nominal contribution was available on November 8, 1999, the child is considered eligible for a State health benefits plan. The contribution with respect to dependent coverage is calculated by deducting the amount the State or public agency contributes toward coverage for the employee only from the amount the State or public agency contributes toward coverage of the family.

For example, if a State contributes $100 per month to cover State workers themselves, but contributes $150 per month to cover the cost of the State workers themselves and their dependents, then the contribution toward dependent coverage would be $50 and would clearly exceed the $10 nominal contribution amount. A more complicated scenario that has arisen with certain States occurs when States offer flexible spending accounts in which employees are given a defined contribution amount and can choose from an array of health insurance options. Under these flexible spending plans, the State employees usually choose from plans that have a range of costs, some of which cost less than the State contribution, and some of which cost more than the State contribution. In such cases, if the State contributes $100 toward the cost of insuring the State workers themselves, and there are insurance options available that only cost $85 per month, then the extra $15 dollars that the employees keep could be used to cover the cost of dependents and would be considered a contribution toward family coverage that exceeded the $10 minimum contribution amount. If the cheapest health insurance option under such a scenario were $95, then the contribution toward dependents would be $5 and would be below the $10 nominal amount.

We also have clarified the language in § 457.310(c)(1)(i) to state that a targeted low-income child must not be eligible for coverage under a State health benefits plan on the basis of a family member's employment with a public agency even if the family declines to accept such coverage. We have clarified this language to reflect the clear intent of the statute that the child's eligibility for coverage is the determining factor in this case.

Comment: Several commenters requested clarification on the adoption of the Medicaid definition of ''inmate of a public institution.'' Commenters noted that, to date, the Medicaid policy has been unclear with unresolved issues, and one commenter queried whether the discussion in the preamble of the proposed regulations makes the stated policy official for Medicaid. Two commenters supported the policy that a child is no longer considered an inmate if the child is discharged from a public institution for treatment in a hospital. One commenter also requested that the term ''penal'' be included in the preamble and the regulation, and that the definition explain that this refers only to children who are incarcerated after sentencing. One organization requested that the term ''inmate of a public institution'' not be used because it makes it problematic for ensuring that children in the juvenile justice system, who are not always serving time for a criminal offense but may be awaiting trial, receive adequate care. The organization believes that there is no rationale for making ineligible a child who is temporarily confined.

Response: We have not accepted the commenters' suggestion to revise the definition of ''inmate of a public institution.'' This term is used in both title XIX and title XXI and is included in the Medicaid regulation at § 435.1009. For purposes of consistency it is appropriate that the term be defined for separate child health programs in these regulations as it has been defined in Medicaid.

Further, neither the statute nor the Medicaid definition differentiate between temporary confinement and incarceration after sentencing. However, as explained in the preamble to the NPRM, there is a distinction between the status of children under title XXI and under title XIX. Under title XXI, children who are ''inmates of a public institution'' are not eligible for a separate child health program. In contrast, under title XIX such children are eligible for Medicaid, but no FFP is provided for services provided while the child is in the institution. States may address the issue of temporary confinements by promptly enrolling or reenrolling children into the separate child health program when the child is discharged, as long as the child meets other eligibility requirements. We emphasize that the regulations in this subpart apply only to separate child health programs under title XXI. They do not establish Medicaid policy with respect to the definition of ''inmate of a public institution.''

Comment: We received many comments on the proposed policy related to a patient in an institution for mental diseases (IMD) and the requirement that a determination be made at the time of initial application or any redetermination. One State specifically supported this flexibility. Another pointed out that the proposed policy was inconsistent with the Medicaid policy and did not see why this situation was any different than other changes in living arrangements. Another said that the proposal to deny eligibility conflicts with § 457.402(a)(9) which includes IMD services in the definition of ''child health assistance,'' and that denial of eligibility is not a reasonable compromise between these two provisions. This commenter recommended that States be allowed to decide which provision best fits their programs. One commented that this provision of the regulation should be withdrawn because HCFA has not finalized its guidance for Medicaid. Several organizations disagreed with the proposed policy based on the potential negative effect on the child. One of these commenters recommended that the child remain eligible for a separate child health program until one year of creditable coverage has been secured for that child. One commented that it is unfair to cover some children and not others and that the policy on IMDs makes it very difficult to set accurate budget estimates and managed care rates. Another suggested that the exclusion apply only at the time of application so that the practitioner would not avoid referring a child for IMD services because the child might lose eligibility during his or her stay. This organization also said that this would allow consistent continued eligibility during an IMD stay for children who have been determined eligible for an SCHIP Medicaid expansion or separate child health program. Several commenters were concerned about continuity of care if the child lost eligibility at redetermination and commented that the policy was in conflict with the policy to allow a spend down when the spend down was met by the family paying for the IMD. Several commenters expressed support for the policy in the proposed regulation. One noted that children are often in an IMD for a short period. One organization commented that separate child health programs should continue to cover IMD services unless the child is determined not to be eligible for the program.

Response: We have carefully considered the range of comments on

this point and have adopted the policy set forth in the proposed rule as the final policy with respect to children who are patients in IMDs. As was described in the proposed rule, the IMD eligibility exclusion applies any time an eligibility determination is made, either at the time of application or during any periodic review of eligibility. We believe that this is the most reasonable interpretation of section 2110(b)(2)(A) of the Act, which excludes eligibility for residents in an IMD, in light of sections 2110(a)(10) and (18), which allow for coverage of inpatient mental health and substance abuse treatment services, including services furnished in a State-operated mental hospital. We also recognize that this policy may be perceived as treating children with similar needs inequitably based on the particular point in time at which their eligibility is being determined. However, we believe that this is the most reasonable way to implement the two statutory requirements cited above.

We recognize the concern raised by some commenters that this policy differs from Medicaid rules on the IMD exclusion, and in response we note that the different treatment is due to differences between title XIX and title XXI; title XXI mandates an eligibility exclusion for residents in an IMD, while title XIX provides for a restriction on payment for services provided to IMD residents. We must also point out that in Medicaid expansion programs, Medicaid rules will continue to apply and IMD residents will be eligible for the Medicaid expansion program, but no Federal matching funds will be available for any services provided to the individual while residing in an IMD, unless the facility meets the requirements of subpart D of 42 CFR 441 to qualify as an inpatient psychiatric facility for individuals under the age of 21.

5. Other Eligibility Standards (§ 457.320)

Section 2102(b)(1)(B) of the Act sets forth the parameters for other eligibility standards a State may use under a separate child health program. With certain exceptions, the State may establish different standards for different groups of children. Such standards may include those related to geographic areas served by the plan, age, income and resources (including any standards relating to spend downs and disposition of resources), residency, disability status (so long as any standard relating to disability does not restrict eligibility), access to other health coverage and duration of eligibility. We set forth these provisions at proposed § 457.320(a).

In addition, under the statute, the State may not use eligibility standards that discriminate on the basis of diagnosis, cover children with higher family income without covering children with a lower family income within any defined group of covered targeted low-income children, or deny eligibility on the basis of a preexisting medical condition. We set forth these provisions at § 457.320(b). We also proposed that States may not condition eligibility on any individual providing a social security number; exclude AI/AN children based on eligibility for, or access to, medical care funded by the Indian Health Service; exclude individuals based on citizenship or nationality, to the extent that the children are U.S. citizens, U.S. nationals or qualified aliens (except that, in establishing eligibility for a separate child health program, we proposed that States must obtain proof of citizenship and verify qualified alien status in accordance with section 432 of PRWORA); or violate any other Federal laws pertaining to eligibility for a separate child health program.

In addition to the revisions made to this section based on the comments discussed below, we clarified the language in § 457.320(b) to prohibit States from establishing eligibility standards or methodologies which would result in any of the prohibitions listed. ''Standards'' traditionally have referred to the income eligibility level (for example, 133 percent of the Federal poverty level). ''Methodologies'' includes the deductions, exemptions and exclusions applied to a family's gross income to arrive at the income to be compared against the standard in determining eligibility. This is a technical change necessary to implement the intent of the statute that States not be permitted to cover children in families with a higher income without covering children in families with a lower income.

Comment: One commenter expressed concern that allowing eligibility standards related to geographic area, age, income, resources, and so forth will allow States to limit the scope of coverage to a smaller population, thereby defeating the goal of covering the maximum number of children. They recommend that HCFA ensure that States are maximizing, not minimizing, the number of children covered. Two commenters were specifically concerned that standards related to geography might encourage States to exclude hard-to-serve areas such as rural areas, although they recognized this provision was statutory.

Response: The flexibility afforded to States in establishing eligibility standards was granted by Congress under section 2102(b)(1)(A) of the Act. Although a primary purpose of SCHIP is to extend health insurance coverage to as many uninsured children as possible, States are explicitly allowed by the law to adopt certain eligibility rules. We note that to date, States have generally designed and implemented broad coverage for children and we are hopeful that this will continue to be the case.

Comment: We received a few comments related to terminating benefits when a child reaches age 19. One commenter objected to terminating benefits when a child reached age 19, while another specifically supported doing so. A third commented that it would be clearer to say ''not to exceed 19 years of age'' than ''not to exceed 18 years of age.''

Response: Section 2110(c)(1) of the Act defines a ''child'' as an individual under 19 years of age. There is no statutory authority for payment to States for child health assistance provided to children who have reached age 19.

Comment: Several commenters expressed support for allowing States to define income and for allowing States flexibility in verifying income and establishing periods of review. One strongly supported allowing States to determine family composition as well as whose income will be counted and under what circumstances, because this approach could provide a basis for teens (without family support) to enroll themselves.

Response: We appreciate the support and agree that allowing States to define ''family'' and ''income'' might provide States the flexibility to provide coverage to certain teens who are without family support.

Comment: One commenter requested that HCFA point out the advantage of using the same definition of income for separate child health programs and Medicaid.

Response: We urge States to use the same definition of income and the same methods of determining income for both separate child health programs and Medicaid. As discussed later in this preamble, using the same definitions and methodologies simplifies the screening process and helps ensure that children are enrolled in the correct program. HCFA can help States to identify ways to simplify Medicaid methodologies and to align the rules adopted for Medicaid and a separate child health program.

Comment: One commenter expressed concern that allowing States to use gross

or net income as countable when determining whether the countable income is below the eligibility standard will result in State differences and families may be convinced to move to another State for coverage.

Response: Given the flexibility authorized by law, income tests would vary from State to State even if States were required to use the same method of arriving at countable income because the income standards to which the countable income is compared vary widely. Income standards (and often methodologies) for most Federally-assisted, means-tested programs vary from State to State. Research in this area indicates that individuals move to be with family or for employment and generally do not move for the purpose of receiving means-tested benefits. Income standards vary widely in Medicaid and there has been no evidence that this has resulted in families moving from State to State.

Comment: Two commenters specifically supported eliminating pre-existing conditions as a reason for denial and stated that such a policy is important to children with special needs. Two additional commenters stated that if States may not deny eligibility based on preexisting conditions, it may conflict with contracts between a separate child health program and a health plan or with premium assistance programs.

Response: Section 2102(b)(1)(B)(ii) of the Act prohibits the denial of coverage based on preexisting conditions and § 2103(f)(1)(A) prohibits eligibility restrictions based on a child's preexisting condition. We agree that this prohibition is very important in providing health care to low-income children with special needs and have included it at § 457.320(b)(2) of the regulations. States that have contracts with health plans which restrict eligibility based on preexisting conditions will have to renegotiate the contracts or otherwise ensure that the affected children are provided with care that meet the standards of title XXI.

One limited exception to this rule is permitted. Under § 2103(f)(1)(B) of Title XXI, if a State child health plan provides for benefits through payment for, or a contract with, a group health plan or group health insurance, the plan may permit the imposition of those preexisting conditions which are permitted under HIPAA. This permits the imposition of preexisting conditions consistent with the requirements of such plans when the State is providing premium assistance through SCHIP to subsidize child or family coverage under a group health plan or group health insurance pursuant to § 2105(c)(3) of the statute.

Comment: We received one comment specifically supporting State latitude to establish eligibility based on State-established disability criteria. Another commenter recommended that we add a new § 457.320(b)(4) to specifically prohibit the use of eligibility standards that discriminate on the basis of diagnosis in accordance with section 2102(b)(1)(A).

Response: Section 2102(b)(1)(A) of the Act provides that an eligibility standard based on disability may not ''restrict eligibility,'' although States may provide additional benefits to children with disabilities. This provision was included in the regulation at § 457.320(b)(3). Section 2102(b)(1)(A) of the Act also provides that no eligibility standard may discriminate on the basis of diagnosis. We have revised the regulation at § 457.320(b)(3), as suggested, to specifically prohibit discrimination on the basis of diagnosis. Therefore, a State may establish eligibility standards that are based on or related to the loss of certain functional abilities, whether physical or mental, if those standards result in children with disabilities qualifying for coverage. A State cannot, however, establish eligibility standards based on or related to a specific disease.

Comment: We received a significant number of comments urging HCFA to add specific residency requirements. Many of the commenters were concerned about children of migrant workers and homeless children. One commenter specifically urged HCFA to require States to set forth rules and procedures for resolving residency disputes. One recommended that the regulations explicitly provide that families involved in work of a transient nature be allowed to choose to establish residency in the State where they work or in one particular State. One commenter recommended that States be required to expedite enrollment of migrant children. One recommended that States be prohibited from the following: denying eligibility to a child in an institution on the grounds that a child did not establish residency in the State before entering the institution; denying or terminating eligibility because of temporary absence; or denying eligibility because residence was not maintained permanently or at a fixed address.

Response: Because Congress has specifically allowed States flexibility to establish standards, we do not establish general residency rules for States. However, we share the commenters' concern that certain children may be unable to establish eligibility in any State because of disputes over residency and do not believe that allowing such a result would be consistent with the overall intent of title XXI and the requirement that SCHIP be administered in an effective and efficient manner. We have revised paragraph (a)(7) and added a new paragraph (d) to § 457.320 to specify residency rules in limited circumstances. In the case of migrant workers, when the child of a parent or caretaker who is involved in work of a transient nature, such that the child's physical location changes periodically from one State to another, the parent or caretaker may select either their home State or the State where they are currently working as the State of residence for the child. For example, if a migrant family moves temporarily from Florida to North Carolina and then returns to Florida during the course of a year as a result of the parents' transient employment, the parents can claim either Florida or North Carolina as the child's State of residence.

In other instances, where two or more States cannot resolve which is the State of residence, the State where a non-institutionalized child is physically located shall be deemed the State of residence. In cases of disputed residency involving an institutionalized child, the State of residence is the parent's or caretaker's State of residence at the time of placement. We believe that a child who is placed in an out-of-State institution should remain the responsibility of the State of residence at the time of placement. Similarly, in cases of disputed residency involving a child who is in State custody, the State of residence is the State which has the legal custody of the child. As indicated in the preamble to the proposed rule, under Shapiro v. Thompson (394 US 618), a State cannot impose a durational residency requirement. We have also added this prohibition to § 457.320(d).

We have not imposed further residency rules. However, we strongly recommend that States establish written inter-State agreements related to disputed residency. We note that the rules contained in § 457.320(d)(2) of this regulation apply only if the States involved cannot come to agreement with respect to a child's residency.

Comment: We solicited comments on our proposal that the eligibility standard relating to duration of eligibility not allow States to impose a maximum length durational requirement or any similar requirement. We received three comments in response, and all three recommended that the regulations make it clear that States are prohibited from

imposing time limits or lifetime caps on eligibility.

Response: Under section 2102(b)(1)(A) of the Act, States have considerable flexibility in setting the standards used to determine the eligibility of targeted low-income children, including those related to duration of eligibility. This enables States to establish the period of time for which a child determined eligible for the State's separate child health program can remain covered prior to requiring a redetermination or renewal of eligibility. At the same time, it is important to ensure that States can identify children enrolled in a separate child health program who become ineligible due to a change in circumstances. Therefore, we have retained the provision in proposed § 457.320(a)(10) and moved it to § 457.320(e)(2) to require that States redetermine a child's eligibility at least every 12 months. Note that termination of a child's eligibility at the end of the specified period (e.g. after a redetermination review) would constitute a ''denial of eligibility'' subject to the requirements of § 457.340(d) of this subpart and subpart K.

We agree that durational limits on eligibility are contrary to the intent of the program. We have added a new subsection § 457.320(e)(1) to include a prohibition against imposing time limits, including lifetime caps, on a child's eligibility for coverage. That is, a State cannot deny eligibility to a child because he or she has previously received benefits. The prohibition against lifetime caps or other time limits on coverage is consistent with Congressional intent to provide meaningful health care for children and will prevent unequal treatment of similarly-situated children simply because one child has been enrolled in the program longer than the other. It will also prevent the possibility of jeopardizing the health of low-income children by terminating or denying health care on the basis of circumstances unrelated to the child's needs. The prohibition against durational limits on eligibility does not prevent a State from limiting enrollment based on budget constraints, or capping overall program enrollment due to lack of funds. This is reflected in §§ 457.305(b) and 457.350(e). In addition, we have added a definition of ''enrollment cap'' in § 457.10 of subpart A.

Comment: One commenter specifically supported the concept of 12 months of continuous eligibility. Another recommended that the regulations be more specific about the duration of eligibility. This commenter recommended an annual time period because health care should not be interrupted when income fluctuates, which the commenter believes happens frequently with the population being served. One commenter objected to requiring any interim screening process during an established 12-month continuous eligibility period.

Response: We see no basis to prohibit State review of eligibility on a less than annual basis. We do encourage States to establish an annual period of review and to adopt continuous eligibility rules to avoid interruptions in a child's health care because of minor fluctuations in income. Frequent reviews can be a barrier to enrollment and redetermination and can reinforce the ''welfare stigma.'' In addition, research shows that many children lose coverage at the time of redetermination.

Between the scheduled reviews, regular, periodic screenings are not required. A child always has the right to file for and become eligible for Medicaid if family income changes, and the State is required to take action on the application, even if the child is covered by a separate child health program. If a child enrolled in a separate child health program does not file an application for Medicaid, the State is not required to screen the child for Medicaid eligibility until the next scheduled redetermination, regardless of changes in the child's circumstances (other than reaching age 19).

Comment: We received a significant number of comments on the discussion about pregnant teens included in the preamble, many of which expressed support for our position.

One commenter suggested that Illinois KidCare is a good model under which a pregnant teen is automatically transferred to the Moms and Babies Medicaid Program. Another recommended that HCFA clearly state an expectation that States provide information to teenage enrollees on the possible benefits of seeking Medicaid if they are pregnant, rather than simply urging them to do so. One commenter recommended that States be required to inform pregnant teens about the differences between their Medicaid and separate child health programs. This commenter also asserted that the benefits of keeping a trusted health care provider may override the benefits of broader coverage and lower out-of-pocket expenses and that States, therefore, should inform pregnant teenagers of the possibility that changing from one program to the other may require the teen also to change doctors. Two commenters recommended that it be made clear that States providing information about Medicaid and the opportunity to apply for Medicaid cannot be held responsible for any individual who does not complete the Medicaid application process.

Several commenters objected to the recommendation that pregnant teens switch to Medicaid midyear. They argued that this unnecessarily disrupts continuity of care and has negative effects on pregnant teens. One of these commenters recommended that pregnant adolescents in their second or third trimester and adolescents with high-risk pregnancies be allowed to continue to see their treating provider through pregnancy and the 60-day postpartum period. Another commenter stated that the regulation related to monitoring pregnant teens and moving them to Medicaid in the middle of an eligibility period goes beyond statutory authority.

One commenter contended that all benchmark programs require pregnancy services and commented that establishing procedures for managed care contractors to notify the State of a teen's pregnancy would be cumbersome, expensive and a potential violation of the family's confidentiality.

Finally, one commenter was concerned that the discussion about pregnant teens not appear to foreclose separate child health programs from adopting pregnancy-related benefits for pregnant teens who are not eligible for Medicaid.

Response: We appreciate the comments, and we wish to clarify a number of points. In drawing attention to pregnant teens, it was not our intent to impose additional or unnecessary requirements on States nor to promote procedures that would disrupt the medical care of pregnant teens. Our intent was to ensure that pregnant teens are provided with sufficient, clear information about Medicaid to make an informed choice about staying in the separate child health program or applying for Medicaid. States are not required to monitor teens for pregnancy and cannot be held responsible for teens who choose not to apply for Medicaid. Managed care contractors in separate child health programs are not required to notify the State when a teen becomes pregnant. Finally, States may provide the same pregnancy-related services under separate child health programs that they do under Medicaid. We urge States to do this, but pregnancy-related services are not mandatory under separate child health programs. We also urge States to make every effort to rely

on the same plans and providers in their separate child health programs and Medicaid so that children who switch between programs because of changes in circumstances, including pregnancy, need not change providers.

While States are not under an obligation to ensure that teens enrolled in separate child health programs become enrolled in Medicaid if they become pregnant, we remind States that there are advantages to Medicaid for a pregnant teen even when the benefit package is the same. First, cost-sharing is prohibited for pregnancy-related services under Medicaid and premiums are prohibited if the woman's net family income is at or below 150 percent of the Federal poverty level. (Above that level premiums are limited to 10 percent of the amount by which the family income exceeds 150 percent of the Federal poverty level.) In addition, a child born to a woman who is eligible for and receiving Medicaid on the day the infant is born is deemed to have filed an application and been found eligible for Medicaid. That infant remains eligible for one year if residing with the mother, regardless of family circumstances. If the delivery is covered by a separate child health program because the mother does not apply for Medicaid, the infant might not be eligible for Medicaid instead of automatically eligible as would be the case had the delivery been covered by Medicaid.

Comment: Two commenters recommended that HCFA encourage States that have separate child health programs to provide newborn infants the same eligibility protections granted under Medicaid. Another recommended that HCFA allow pre-enrollment of newborns or automatic enrollment of newborns of pregnant teens enrolled in a separate child health program.

Response: The statute does not provide for automatic and continuous eligibility for infants under a separate child health program as it does under Medicaid. Moreover, it is also likely that due to higher income standards that most States apply in Medicaid, many infants born to teens enrolled in a separate child health program will be eligible for Medicaid and therefore not eligible for a separate child health program.

However, as discussed elsewhere in this preamble (in response to comments under both §§ 457.300 and 457.360), we have determined that States may use ''presumptive eligibility'' to enroll children in a separate child health program pending completion of the application process for Medicaid or the separate plan. We recognize the need of infants to have immediate coverage and consider the automatic enrollment of newborns born to mothers covered by a separate child health program at the time of the delivery into the separate program as an example of such presumptive eligibility. Presumptive eligibility is time-limited, however, and States choosing to enroll these newborns must formally determine the infant's eligibility (including screening the infant for Medicaid eligibility) within the time frame set for completing the application process and determining eligibility.

As noted earlier, if the infant is ultimately found not to be eligible for Medicaid, costs of services provided during the period of presumptive eligibility may be treated as health coverage for targeted low-income children whether or not the child is ultimately found eligible for the separate child health program, as long as the State implements presumptive eligibility in accordance with section 1920A and section 435.1101 of this part. Thus, States that adopt the presumptive eligibility option in accordance with section 435.1101 to no longer be constrained by the 10 percent cap.

Alternatively, States can develop an administrative process to identify, prior to birth, an infant as a Medicaid-eligible individual as soon as he or she is born, as we understand some States have done. This would ensure that Medicaid coverage and services are immediately available to a Medicaid-eligible newborn child.

Comment: We received a large number of comments related to obtaining social security numbers (SSNs) during the application process. Many commenters specifically supported the prohibition against requiring the SSN in separate child health programs. Two requested clarification as to whether an SSN can be required on a joint SCHIP/Medicaid application. A few recommended that SSNs be required for applicants as long as there is a Medicaid screen and enroll requirement. One commenter did not advocate asking for an SSN, but commented that the policy for separate child health programs and Medicaid should be consistent because families prefer to give all information at one time and having a distinction between the requirements for the two programs hinders States' efforts to create a seamless program.

Some commenters indicated that the prohibition against requiring SSNs for a separate child health program while requiring it for Medicaid will cause referral, tracking and coordination problems; handicap enrollment in States using a joint application; make it difficult to implement the screen and enroll provision; reinforce stereotypes; and prevent automatic income verification in States that have reduced the documentation requirements. Another added that this prohibition will impede efforts to identify children with access to State health benefits.

Finally, another commenter suggested that Medicaid medical support cooperation requirements include providing information about noncustodial parents and that this ''section may be construed as excusing a Medicaid applicant from having to provide an SSN for all family members, including noncustodial parents absent from the home.''

Response: The requirements and prohibitions related to the use of a social security number are statutory. The Privacy Act makes it unlawful for States to deny benefits to an individual based upon that individual's failure to disclose his or her social security number, unless such disclosure is required by Federal law or was part of a Federal, State or local system of records in operation before January 1, 1975. Section 1137(a)(1) of the Social Security Act requires States to condition eligibility for specific benefit programs, including Medicaid, upon an applicant (and only the applicant) furnishing his or her SSN. Because SCHIP is not one of the programs identified in section 1137 of the Act, and Title XXI does not require applicants to disclose their SSNs, States are prohibited under the Privacy Act from requiring applicants to do so.

Thus, only the SSN of the individual who is applying for Medicaid (including a Medicaid expansion program under title XXI) can and must be required as a condition of eligibility. Children applying for coverage under a separate child health program cannot be required to provide a SSN, and States cannot require other individuals not applying for coverage, including a parent, to provide a SSN as a condition of the child's eligibility for either a Medicaid expansion program or separate child health program.

We recognize that these statutory provisions can be difficult to reconcile in practice. Under the law, a joint Medicaid/SCHIP application must indicate clearly that the SSN is only needed for Medicaid and not for coverage under a separate child health program, but a family often will not know if their child is or is not Medicaid-eligible. A State may request the SSN for all applicant children as long as the State makes it clear that family members are not required to provide the SSN and that the child's eligibility under the

separate child health program will not be affected if the child's SSN is not provided. However, the State must also inform the family that Medicaid eligibility cannot be determined without the SSN and that the child cannot be enrolled in the separate child health program if the child otherwise meets the eligibility standards for Medicaid.

Comment: A significant number of commenters objected to the verification requirements pertaining to citizenship and alien status. Most of these commenters requested that subsection § 457.320(c) be deleted. A number of the commenters pointed out that we proposed to require that States follow INS rules which were not yet mandatory. Additionally, they argued that the requirement in § 457.320(b)(6) that States abide by all applicable Federal laws and regulations would be sufficient. Several commenters objected to the verification requirements for a number of reasons. A significant number of them commented that the procedures are too burdensome. One commenter felt that proof of citizenship might discourage some citizens who do not have birth certificates from applying. Another commented that requiring proof and verification of alien status would delay access to care for alien children who are otherwise eligible.

Response: Section 432 of the PRWORA requires verification of citizenship for applicants of all ''Federal public benefits'' as defined in section 401 of the PRWORA. However, proposed regulations published by the Department of Justice, which is responsible for enforcing the verification provision, provide that a State may accept self-declaration of citizenship provided that (1) the federal agency administering the program has promulgated a regulation which permits States to accept self-declaration of citizenship and (2) the State implements fair and nondiscriminatory procedures for ensuring the integrity of the program at issue with respect to the citizenship requirement.

Requiring documented proof of citizenship can be a time-consuming and difficult process for many applicants, and therefore could create a significant barrier to enrollment. It also can create a significant administrative burden for the State. Therefore, consistent with the statutory intent to promote access to and enrollment in separate child health programs and HCFA's policy to provide States with flexibility to simplify their application processes and eliminate barriers to enrollment wherever possible, we have modified § 457.320(c). The regulation permits States to accept self-declaration of citizenship, provided that they have implemented effective, fair and nondiscriminatory procedures for ensuring the integrity of their application process with respect to self-declaration of citizenship.

For example, a State could implement a system to randomly check the documentation of some applicants and terminate the eligibility of any applicants found to have provided a false declaration. If the percentage of false declarations was found to be high, the State would need to take appropriate measures to remedy the problem—including, if necessary, requiring documentation to verify the citizenship of every applicant.

Comment: One commenter asked for clarification of the difference between ''proof'' and ''verification.''

Response: We have used ''proof'' to refer to documents provided by individuals. ''Verification'' is used to refer to the process of comparing the information in the ''proof'' to the INS records. An individual may be considered eligible based on ''proof'' while the information is being verified.

Comment: Several commenters urged that the regulations specifically prohibit requests for information about the citizenship or immigration status of non-applicants, including parents. One commenter indicated that States should be prohibited from verifying the status of any non-applicant when the information is voluntarily provided.

Response: Information about the citizenship or alien status of a non-applicant cannot be required as a condition of eligibility. States may request this information if it reasonably relates to a State eligibility standard and it is made clear that the provision of this information is optional and that refusing to provide the information will not affect the eligibility of applicants. We strongly urge States not to request this information nor to verify it if voluntarily provided, as this has been found to be a strong deterrent to alien parents filing applications on behalf of their citizen children.

Comment: One commenter recommended that HCFA issue, through letter or manual and web site, Medicaid guidance on the categories of immigrants eligible for Medicaid and that these regulations reference that guidance.

Response: Section 3210 of the State Medicaid Manual, which is available through links set for in HCFA's web site at *www.hcfa.gov,* discusses immigrant eligibility for Medicaid following passage of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, although it does not reflect changes to immigrant eligibility contained in the Balanced Budget Act of 1997. We also have posted a fact sheet on the section of our web page addressing Medicaid and welfare reform. The fact sheet is entitled, ''The Link between Medicaid Coverage and the Immigration Provisions of the Personal Responsibility and Work Opportunity Act of 1996.'' Guidance to State Medicaid Directors dated December 8, 1997 discusses changes in immigrant eligibility for Medicaid under the Balanced Budget Act of 1997. Finally, guidance dated January 14, 1998 discusses immigrant eligibility for benefits under title XXI. This guidance (in the form of ''Dear State Medicaid Director or Dear State Health Official letters) can be found at *www.hcfa.gov.*

We will consider issuing more detailed instructions pertaining to the eligibility of immigrants for Medicaid and separate child health programs and posting such guidance on our web site.

6. Application and Enrollment in a Separate Child Health Program (§ 457.340)

We proposed to require that the State afford every individual the opportunity to apply for child health assistance without delay. Section 2101(a) of the Act requires States to provide child health assistance to uninsured, low-income children in an effective and efficient manner. The opportunity to apply without delay is necessary for an effective and efficient program. Because we have determined that proposed § 457.361 ''Application for and enrollment in SCHIP,'' is closely related to this section, in this final rule we have incorporated the provisions of proposed § 457.361 into this section. We will respond to the comments concerning § 457.340 of the proposed rule here, and to those concerning § 457.361 of the proposed rule below, under § 457.361.

Comment: We received a number of comments on this section. Many commenters were concerned about the complexity of the application process, particularly when States have a separate child health program. Several commenters recommended that HCFA require States to certify that they have conducted a review of their Medicaid and Title XXI application and redetermination procedures and have eliminated any unnecessary procedural barriers that discourage eligible children from enrolling in and retaining coverage. If differences remain, States should be required to identify in their State plan the reasons for the differences and explain how they are consistent with the coordination goals of title XXI.

Other commenters added that families should not be forced to understand and navigate two sets of application, enrollment and redetermination procedures.

Several commenters focused on joint applications for Medicaid and separate child health programs. One commenter asked HCFA to highlight that States can use a joint application and a single agency. Another urged HCFA to require a joint application process or, at a minimum, to conduct rigorous oversight of the screen and enroll procedures. A third specifically indicated that HCFA should require States to have a single form for children who are applying for both programs, that it be limited to four pages, that States be required to accept mail-in applications and that States notify families when their application has been received. Yet another stated that the burden should rest with the State that chooses not to have a joint application to establish that its application procedures are effective. This commenter also recommended that HCFA require that the same verification procedures be used for both programs and that families not have to take any additional steps in order for their application to be processed by Medicaid.

One commenter felt that the regulations should define a joint application process rather than referring to joint forms. This commenter believes that applicants should be subject to the same requirements and procedures—including a single application, the same verification requirements, and common entry points—for both programs, and that nothing additional should be required for children to enroll in Medicaid under one of the categories identified in § 457.350(c)(2).

One commenter felt that States also should be required to certify that they have eliminated any unnecessary procedural barriers to children making a transition between regular Medicaid and a Title XXI-funded program when they lose eligibility for one program and become eligible for the other. Another thought it would be useful for HCFA to mention that flexibility regarding the eligibility determination process is not limited to contractors. Provider employees or outstationed workers at provider locations are also capable of making these determinations under a separate child health program.

Two commenters emphasized the importance of States applying any simplifications adopted in the application process for Medicaid or a separate state program to children whose families also are on Food Stamps or TANF. Some States which generally allow families to apply for Medicaid on behalf of their children through a mail-in application reportedly do not accept mail-in applications from families who already happen to be receiving Food Stamps or TANF. In this commenter's view, such policies create inequities and impose unnecessary procedural barriers to Medicaid enrollment and HCFA should encourage States to review whether they have any such policies, and to eliminate them whenever possible.

Other commenters recommended that HCFA place emphasis not only on helping families to apply for coverage, but also on helping them to remain enrolled in coverage. They felt that the simplification strategies listed by HCFA should also include States' adopting the same redetermination period in Medicaid and separate child health programs, and reducing verification requirements for redeterminations as well as for the initial application.

Response: States are required to establish a program that is ''effective and efficient'' and a process that allows every individual to apply for child health assistance without delay. Mail-in, joint program application forms, common entry points and applicable procedures, single agency oversight and administration, and simplified and consistent program rules and documentation requirements are several ways that States can facilitate families' ability to apply for the appropriate health coverage program as expeditiously as possible. These procedures can also simplify administration for States. While we are not requiring that States use any specific mechanism, States that do not take steps to streamline, align, and coordinate their enrollment process will have a more difficult time ensuring that children can apply for health insurance coverage without delay and that their application is assessed in an effective and efficient manner.

We encourage, but do not require, States to use a joint application for their separate child health program and Medicaid programs and to simplify the application as much as possible. We agree with the comment that States should construct a joint application process, rather than just a joint application. States that have adopted the same or similar rules relating to application interviews, verification and managed care enrollment have an easier time coordinating the enrollment process. We note that most States with separate child health programs report they use a joint child health application and that joint applications do not necessarily need to cover all possible Medicaid eligibility groups.

Section 2102(c) requires coordination of the administration of SCHIP with other public and private health insurance programs, and we also will be monitoring States' coordination of enrollment in their separate child health program and Medicaid programs, including children's transitions from one program to the other. HCFA will pay particular attention to outcomes in States that lack many of the elements of a streamlined and coordinated system. When appropriate, such monitoring will include requests for States to identify the number of children found potentially eligible for Medicaid, the percentage of those children who have been determined eligible for and enrolled in Medicaid, and the percent determined eligible for and enrolled in the separate child health program. These data will help States and HCFA determine whether the State has developed an effective method to coordinate enrollment and ensure that children are enrolled in the appropriate program.

While States have and will continue to have the flexibility to design their own unique application and enrollment systems, States will be held accountable to ensure that children are afforded the opportunity to apply for the appropriate program in a timely and efficient manner. We believe that most States have developed coordinated enrollment procedures and are continuing to improve their systems to promote enrollment of eligible children, and we will continue to work with the States in developing effective systems.

It is also true, as a few commenters pointed out, that eligibility determination for a separate child health program may be performed by a wide range of entities, as determined by the State. For example, State Medicaid agencies, health care plans and providers, and outstationed State or local eligibility workers also may determine eligibility.

Finally, we agree with the last two points made by the commenters. First, we agree that States' simplifying both initial application and redetermination processes is critical. Second, we also agree that States can reduce barriers to accessing health care for all families by applying any simplifications adopted in the application process for Medicaid and the separate child health program to the application process for children whose families also happen to be receiving, or applying for, Food Stamps or TANF benefits, and we encourage States to do so.

Comment: Several commenters requested that States be given flexibility to use the application for a program other than Medicaid or SCHIP.

Response: States may use a joint application with other programs. Proposed § 457.340(b) was confusing and may have implied that States do not retain discretion over whether or not to combine the applications of different programs. Because we do not want to preclude States from including programs other than Medicaid and SCHIP in a joint application and because a regulation is not needed to allow States to adopt a joint application, we have eliminated § 457.340(b). This in no way implies that States are prohibited from using joint applications. In fact, we continue to strongly encourage States to consider how joint applications might promote coverage of eligible children.

For example, the application for Medicaid and/or a separate child health program may be combined with an application for child care assistance or WIC. Joint applications can be an effective outreach and enrollment tool because they can help States reach families that are being served by other programs. States that use a joint application, however, must develop a process that allows every individual to apply for child health assistance without delay. If the application for the separate child health program and/or Medicaid is combined with an application for other services or benefits and sufficient information is provided to make a determination of eligibility for child health coverage, that determination must not be held up because of information (or action) which is needed for the other program. Joint program applications, while an effective tool, must not result in delays that would be contrary to the intent of the statute and this section.

Comment: One organization commented that the regulations should clarify that underlying the provision at proposed § 457.340(a) regarding the opportunity to apply without delay are title VI of the Civil Rights Act and the Americans with Disabilities Act.

Response: Underlying the provision that individuals be able to apply without delay is section 2101(a) of the Act, which requires States to provide child health assistance to uninsured, low-income children in an effective and efficient manner. The opportunity to apply without delay is necessary for an effective and efficient program.

Of course, this opportunity must be available to all children, regardless of their race, sex, ethnicity, national origin or disability status. Thus, the civil rights laws must be adhered to in implementing this requirement, but are not the only statutory authority for this provision.

Comment: One commenter expressed strong support for the requirement that every individual be afforded the right to apply. The commenter asserted that adolescents not living with their parents should be allowed to file their own applications and recommended that HCFA, through the preamble, encourage States to adopt policies that facilitate the filing of applications by adolescents themselves.

Response: As required by this section, States must afford every individual, including adolescents, the opportunity to apply for child health assistance without delay. We encourage States to consider how they might best ensure that adolescents, including those who are not living with their parents or caretakers, can apply for SCHIP. States can also allow adolescents to sign their own applications; but this is a matter of State law and we cannot require States to permit minors to do so.

Comment: One commenter stated that the regulations should address methods for allowing families to report changes in circumstances in an efficient, family-friendly manner, such as not requiring the family to complete a new application when circumstances change.

Response: Section 2101(a) of the Act requires that child health assistance be provided in an effective and efficient manner. A reporting system which requires that a child reapply every time there is a change in family circumstances affecting eligibility would not constitute effective and efficient administration. The precise manner in which an individual reports changes is subject to State discretion, as is the form used for periodic redetermination. States should develop methods of reporting changes that pose as few barriers to uninterrupted eligibility as possible and do not require families to resubmit information that has not changed. States that have opted to provide continuous eligibility generally do not require reporting of any changes in circumstances except at regularly scheduled redeterminations.

7. Eligibility Screening and Facilitating Medicaid Enrollment (§ 457.350)

Sections 2102(b)(3)(A) and (B) of the Act require that a State plan include a description of screening procedures used, at intake and at any redetermination, to ensure that only children who meet the definition of a targeted low-income child receive child health assistance under the plan, and that all children who are eligible for Medicaid are enrolled in that program. In accordance with the statutory provisions, we proposed at § 457.350(a) that a State plan must include a description of these screening procedures.

More specifically, section 2110(b)(1)(C) of the Act provides that children who would be eligible, if they applied, for Medicaid are not eligible for coverage under a separate child health program. Section 2102(b)(3)(B) provides that States have a responsibility to actually enroll children who have applied for a separate child health program in Medicaid if they are Medicaid-eligible.

As stated in previous guidance, referrals to Medicaid do not satisfy this ''screen and enroll'' requirement. In accordance with the statute, we proposed to require States to use screening procedures that identify any child who is potentially eligible for Medicaid under one of the poverty-level-related groups described in section 1902(l) of the Act. However, since States are not mandated to cover children below the age of 19 who were born before October 1, 1983 under the poverty-level-related Medicaid groups, we also proposed at § 457.350(c) to require, at a minimum, that a State use screening procedures that identify any child who is ineligible for Medicaid under the poverty level related groups solely because of age but is potentially eligible under the highest categorical income standard used under the State's title XIX State plan for children under age 19 born before October 1, 1983. In almost all circumstances, we expected that the highest categorical income standard used for such older children will be the standard used for the optional categorically needy group of children eligible under section 1902(a)(10)(A)(ii)(I) of the Act. These children are sometimes referred to as ''Ribicoff children.'' (See § 435.222.) Mandatory coverage of the older children in poverty-level related groups is being phased in and by October 1, 2002, all children under age 19 will be included in the poverty-level-related groups in all States.

In the preamble of the proposed rule, we encouraged States to identify any pregnant child who is eligible for Medicaid as a poverty-level pregnant woman described in section 1902(1)(1)(A) of the Act even though she is not eligible for Medicaid as a child. We noted that Medicaid coverage, cost-sharing rules and eligibility rules pertaining to infants may be more advantageous to a pregnant teen than coverage under a separate child health program.

We proposed at § 457.350(d) that to identify children who are potentially eligible for Medicaid, States must either initially apply a gross income test and then use an adjusted income test for applicants whose State-defined income exceeds the initial test, or use only the adjusted income test for all applicants. We set forth the initial gross income test and the adjusted income test at proposed § 457.350(d)(1) and (2) respectively.

As indicated in section 2102(b)(3)(B) of the Act, Congress intended that children eligible for Medicaid be enrolled in the Medicaid program. We proposed at § 457.350(e)(1) that, for a child found potentially eligible for Medicaid, the State must not enroll the child in the separate child health program unless a Medicaid application for that child is completed and subsequently denied.

At § 457.350(e)(2) we proposed that the State must determine or redetermine the eligibility of such a child for the separate child health program if (1) an application for Medicaid has been completed and the child is found ineligible for Medicaid or (2) the child's circumstances change and another screen shows the child is ineligible for Medicaid. Finally, at § 457.350(e)(3), we proposed that if a child is found through a State screening process to be potentially eligible for Medicaid but fails to complete the Medicaid application process for any reason, the child cannot be enrolled in a separate child health program. Enrollment in a separate child health program for such a child can occur only after the Medicaid agency determines that a child who has been screened and found likely to be eligible for Medicaid is not in fact eligible for Medicaid under other eligibility categories.

We also proposed to require at § 457.350(f) (§ 457.350(g) in this final regulation) that States choosing not to screen for Medicaid eligibility under all possible groups provide certain written information to all families of children who, through the screening process, appear unlikely to be found eligible for Medicaid. We proposed that the following information must be provided to the person applying for the child: (1) a statement that, based on a limited review, the child does not appear to be eligible for Medicaid but that a final determination of Medicaid eligibility can only be made based on a review of a full Medicaid application; (2) information about Medicaid benefits (if such information has not already been provided); and (3) information about how and where to apply for Medicaid.

We have incorporated the provisions of proposed § 457.360, ''Facilitating Medicaid enrollment,'' into § 457.350 because the requirements of both sections relate to the steps which the State or contractor responsible for determining eligibility under a separate child health program must take to comply with the ''screen and enroll'' requirements of Title XXI. In § 457.350(a), we therefore have added a requirement that the State plan include a description of the procedures the State will use to ensure that enrollment in Medicaid is facilitated for children screened potentially eligible for Medicaid and who are then determined by the State Medicaid agency to be eligible for Medicaid.

We will respond to the comments on the proposed § 457.360 in our discussion of § 457.360 rather than in our discussion of this section. Also, note that the obligations of the Medicaid agency in meeting the screen and enroll requirements are set forth in a new § 431.636, which is discussed further in subpart M of this preamble, ''Expanded coverage of children under Medicaid and Medicaid coordination.''

We noted in the preamble that there is great concern among a number of States and others that children will go without health care because of these screen and enroll policies. The concern centers around the perceived stigma of Medicaid. Some families may refuse to apply for Medicaid because they associate it with ''welfare.'' Some families may not complete the Medicaid application process because it may be more complicated than the application process for a separate child health program, may require more documentation, or may otherwise be seen as more invasive into personal lives. We solicited comments on the extent of these problems and possible solutions. We received many comments concerning the screen and enroll requirements. These comments are addressed below.

Comment: One commenter indicated that the term ''found eligible'' should be used consistently. The regulations should not say that a child is ''found eligible'' for Medicaid through the screening process and then indicate that when the Medicaid application is processed the child is not ''found eligible'' for Medicaid.

Response: We agree with the comment. A child who has been found through the screening process to be potentially eligible for Medicaid has not been determined eligible for Medicaid. We have revised the regulations to use the terms consistently. As revised, the term ''found eligible'' is only used when a final action has been taken on a Medicaid application and the child has been enrolled in Medicaid. The term ''potentially eligible'' is used when a screening indicates that a child appears to be eligible for Medicaid and therefore may not be enrolled in a separate child health program until action is taken on his or her Medicaid application.

Comment: One commenter suggested that the regulations require that States provide comprehensive training to eligibility determination workers (and other workers as appropriate) in both Medicaid and a separate child health program to ensure that all potentially eligible applicants are afforded the right to apply and that no eligible children are terminated inadvertently or inappropriately.

Response: One aspect of minimizing barriers and assuring appropriate action with respect to applications is providing adequate training to eligibility workers. States will need to ensure that such training has been, and continues to be, provided, as appropriate.

Comment: A significant number of commenters supported the policy that a child could be ''found ineligible'' for Medicaid through either a regular Medicaid application or through a screening rather than requiring that an actual Medicaid application be filed and a formal determination be made that the child is Medicaid-ineligible.

Response: The clear intent of title XXI is to provide benefits only to children who do not meet Medicaid eligibility requirements in effect before title XXI was enacted. This policy ensures that SCHIP funds will be used to cover only newly eligible children and not supplant funds already available through Medicaid to cover eligible children at the applicable Medicaid FMAP. This policy also ensures that children who are eligible for Medicaid benefits and cost-sharing protections receive the benefits and protections to which they are entitled. At the same time, Congress intended for children to be able to apply for, and obtain, health care insurance as quickly as possible, without lengthy delay. Requiring a formal denial by the State Medicaid agency in all cases would not promote the intent of the law. Permitting children who are found unlikely to be eligible for Medicaid through a screening process to proceed with their application under a separate child health program without a formal Medicaid determination be made, best balances these two goals.

Comment: Some commenters were concerned that States would make the Medicaid application process difficult and unfriendly while making the

application for a separate child health program simple so that families would choose to apply for the separate program but not Medicaid, and that the State would get the enhanced Federal match. One commenter particularly supported the policy that refusal to apply for Medicaid affects eligibility for a separate child health program. A number of other commenters objected to the policy of denying eligibility for a separate program when a child is found potentially eligible for Medicaid but the family makes an informed choice not to apply for Medicaid or chooses not to complete the Medicaid application process. One commenter argued that this policy goes beyond statutory authority. Most of those objecting to the policy expressed concern that it would result in children going without health coverage at all.

Response: How well the screening process works depends in large part on State Medicaid application rules and procedures. States have broad discretion under federal law to simplify and streamline their enrollment processes. We encourage States to simplify the Medicaid application process and to make the division between separate child health programs and Medicaid appear seamless, and many States have done so.

While we recognize that some families may decide to go without insurance rather than apply for Medicaid, we believe that it would be contrary to the statutory purposes to permit States to enroll children in a separate child health program who have been found potentially eligible for Medicaid through a screening process. As many States have demonstrated, States have the flexibility to address most, if not all, of the reasons why families might prefer not to apply for Medicaid. If families are reluctant to apply for Medicaid, the State may need to reexamine the Medicaid application and redetermination process, as well as its outreach and marketing strategies, to assess how barriers to participation can be eliminated. For example, States have shown that families are more likely to complete the Medicaid application process if face-to-face interviews are eliminated, resource tests for children are dropped and documentation requirements are reduced. If a joint application process and a single program name are used, the procedures can be made seamless and the difference between separate child health programs and Medicaid made almost invisible to the family. States are continuing to experiment with different ways to promote seamless enrollment and coverage systems.

HCFA will be focusing considerable attention over the coming months on ways to help States develop seamless, family-friendly application and eligibility determination systems and to promote best practices across States. These practices will not only help States meet the screen and enroll requirements, but also will help States identify and enroll the millions of uninsured children who are eligible for, but not enrolled in, Medicaid.

Comment: Many of those commenting on the screening requirements were concerned that not all children who are eligible for Medicaid will be identified. A number of commenters disagreed with the policy that the screening process only needs to screen for eligibility under the children's poverty level groups described in 1902(l). Quite a few were concerned that children with special needs who might qualify for Medicaid under another eligibility group will end up enrolled in a separate child health program that may provide less coverage than Medicaid. Some urged HCFA to require that States ask whether a child is disabled or has special needs. Others disagreed with the statement in the preamble that requiring States to screen for eligibility under all possible groups would place an unreasonable administrative burden on States. These commenters pointed out that States have considerable flexibility to simplify eligibility under Medicaid, particularly under section 1931.

One commenter noted that screening and determining eligibility are not the same. This commenter suggested that it is quite feasible to devise a simple, short list of questions to screen for eligibility in non-poverty related groups, and that the regulations should require that States screen considering the most liberal income eligibility standard for the child given the child's age, disability and the family's prior eligibility for § 1931. One commenter suggested that States be required to screen for eligibility for children under sections 1931 and 4913 of the Balanced Budget Act of 1997. Four others suggested that the regulations should require States to screen considering the highest effective income threshold, taking income disregards into account.

One commenter expressed concern about the extent to which income exclusions and disregards must be applied in the screening process. This commenter suggested that the screening should include only the standard deductions applicable to all poverty-level Medicaid eligibility groups. Another commenter stated that requiring independent entities to be knowledgeable about income exclusions under other Federal statutes, particularly those which are not likely to be encountered, is contrary to simplification.

Finally, one commenter was concerned that a pregnant teen who could be eligible for Medicaid as a pregnant woman might be found ineligible for both a separate child health program and Medicaid if the screening process did not include a method of identifying pregnant teens.

Response: We have tried to balance the statutory screen and enroll requirements with the requirement that child health benefits be provided in an ''effective and efficient manner,'' taking into consideration the fact that screening may be done by entities that may not be familiar with the intricacies of Medicaid eligibility. For this reason, we have not required a full Medicaid application or a formal decision on such an application before a child can be eligible for a separate child health program.

We have, however, reevaluated our position on screening for eligibility under section 1931 of the Act in light of the fact that in some States the highest eligibility threshold for non-disabled children is applied through the § 1931 eligibility group. We also recognize that some States expanded Medicaid eligibility through the authority of section 1115 of the Act, resulting in a higher eligibility threshold for some children. We have revised § 457.350(b) (proposed § 457.350(c)) to require that a State that has used the flexibility provided under § 1931 to expand eligibility must screen for eligibility under one of the poverty level groups described in section 1902(l), section 1931 of the Act, or a Medicaid demonstration project under section 1115 of the Act, whichever standard generally results in a higher income eligibility level.

States that have expanded eligibility under section 1931 beyond the poverty level category generally have adopted similar income eligibility rules; at a minimum, the section 1931 income methodologies are not likely to be significantly more complicated than the poverty level rules. Further, States need not screen families under both section 1931 and section 1902(l). Rather, they must screen under whichever methodology generally results in a higher income eligibility level for the age group of the child applying for assistance.

Because we are requiring States to screen under whichever methodology generally results in a higher income eligibility level, States do not have to apply every income and resource disregard used under its State plan.

Disregards that apply only in very limited circumstances need not be routinely used in the screening process. For example, many families applying for coverage under section 1931 would be expected to have earned income, so earned-income disregards must be applied in the screening process. However, few applicant families would be expected to have income-producing property. Thus, a State that disregards such income under section 1931 would not have to apply this disregard in the screening process.

We had included proposed § 457.350(c)(2) in the proposed rule to ensure that the children eligible for Medicaid under section 1902(a)(10)(A)(ii)(I) (the ''Ribicoff children'') would not be missed in the screening process. However, most of these children will be identified under the revised § 457.350(b). Therefore, cognizant of the need to keep the screening process as simple as possible, we have removed proposed § 457.350(c)(2) from the final regulation.

We share the commenters' concern about children with disabilities being left out of the screening process and strongly encourage States to screen for children who might be eligible for Medicaid on the basis of disability. Questions about a child's potential disability may be included on the separate child health or joint SCHIP/Medicaid application for follow-up. We require States to ensure that parents are provided with information about all Medicaid eligibility categories and coverage, are encouraged to apply for Medicaid under other eligibility categories and are offered assistance in applying for Medicaid. However, we do not agree with the comment that a child should be denied coverage under a separate child health program unless a full Medicaid disability determination has been made. The definition of disability for Medicaid purposes is not easily understood by people unfamiliar with Medicaid eligibility rules, and screening for eligibility based on disability could be very time-consuming. We note that States have 90 days, rather than 45, to determine Medicaid eligibility when disability is involved. Moreover, particularly in light of recent State Medicaid expansions, most children who would be eligible for Medicaid on the basis of disability will also meet the eligibility requirements as a poverty level child.

We also do not specifically require States to screen for eligibility under section 4913 of the BBA. The State is responsible for ensuring that disabled children who lost SSI because of the change in the definition of childhood disability (''section 4913 children'') are aware of their right to Medicaid benefits. States must identify and provide coverage for section 4913 children, but it is highly unlikely that a child who would be eligible as a section 4913 child would not be identified in the screening process as potentially Medicaid eligible on the basis of his/her income alone. In any event, Medicaid confidentiality rules do not allow States to provide lists of section 4913 children to entities that determine eligibility for a separate child health program but that do not also determine Medicaid eligibility.

Comment: One commenter pointed out that a screening based on income alone would be insufficient in a State that continues to apply a resource test to children under Medicaid. They recommended that § 457.350 be revised to clarify that, in such situations, States must evaluate whether children meet both income and resource tests for Medicaid eligibility.

Response: We agree that, in States that continue to apply a resource test to children under Medicaid, when an income screen indicates that a child is potentially income eligible for Medicaid, the State must also screen for Medicaid eligibility under the applicable Medicaid resource test. A resource screen limits those cases in which a child is found potentially eligible for Medicaid based on an income test, but is then reviewed under Medicaid rules and found ineligible based on resources (and is then sent back to the separate child health program for another eligibility review). We have added a new paragraph (d) to § 457.350 to include this requirement. If a State continues to apply a resource test for children under the eligibility groups described in § 457.350(b) (§ 457.350(c) in the proposed rule) and a child has been determined potentially income eligible for Medicaid, the State must also screen for Medicaid eligibility by comparing the family's countable resources to the appropriate Medicaid resource standard. In conducting the screening, the State must apply Medicaid policies related to resource requirements, including policies related to resource exclusions and disregards and policies related to resources for particular Medicaid eligibility groups. However, in an effort to balance the statutory mandate that children eligible for Medicaid not be enrolled in a separate child health program with the need to keep the screening process as simple as possible, States need not take into account disregards that apply only in very limited circumstances in the screening process. Any resource exclusions and disregards which the State does not plan to use in the screening process must be identified in the State plan.

Since most States no longer apply a resource test to children, this added screening requirement will not affect most States. State experience indicates that children who are income eligible seldom have resources in excess of the resource standard previously used, with the possible exception of a car that is usually needed for transportation to and from work. States have found that requiring information about resources that are highly unlikely to make a child ineligible, or that rarely provide a family with a greater ability to purchase health coverage, is an unnecessary administrative burden, a barrier to eligibility, and helps to reinforce the ''welfare stigma.'' HCFA encourages the few States with resource requirements for children to eliminate or otherwise simplify any remaining resource tests under both Medicaid and separate child health programs. However, any State that retains a resource test for Medicaid must screen all applicants who appear income-eligible for Medicaid for eligibility under the applicable resource test.

Comment: One commenter indicated that screening is particularly difficult when an employer-sponsored model is used for SCHIP. This commenter suggested that States be given the option to accept a lower Federal match, for example, the Medicaid match, in lieu of meeting the Medicaid screen and enroll requirements.

Response: We do not have the statutory authority to provide a lower match in lieu of meeting the Medicaid screen and enroll requirements. Furthermore, because eligibility determinations are distinct from determinations about the kind of coverage an eligible child will receive, there does not seem to be any reason why the screen and enroll requirements would present any particular problems for States with premium assistance programs. States are required to screen all children applying for coverage under a separate child health program.

Comment: We received a significant number of comments concerning the requirement that certain information about Medicaid be provided to families if a State uses a screening procedure other than a full determination of Medicaid eligibility. Many commented that this requirement is administratively burdensome, a waste of administrative resources, exceeds statutory authority, and is contrary to the purpose and goal of the separate child health program option provided by Congress. Some

commenters believed that this requirement would mean that a full Medicaid determination needs to be made in every case. Others were concerned that it would be confusing to families whose children were found eligible for a separate child health program, would slow down the eligibility determination process, and would create a barrier to access in situations where the family did not want Medicaid. Several commenters stated that there is no evidence that Medicaid-eligible children are being missed in the screening process and that to the contrary, State-based evidence suggests that many more such children are being found than anticipated.

Other commenters did not think that the notice requirements went far enough and they urged HCFA to require that the information provided describe disability-based, medically-needy and § 1925 transitional Medicaid eligibility. One commenter recommended that proposed § 457.350(f)(1) be revised to read ''based on limited review, we could not tell if your child is eligible for Medicaid.'' Another recommended adding ''and orally in a manner that is literacy and language appropriate'' to the lead-in to the required list of notifications. One commenter recommended that the final rule include an example of notice language to be sent to children who are determined unlikely to be Medicaid-eligible as a result of a limited screening process. Several others questioned whether the cost of providing the information about Medicaid would be an SCHIP administrative cost subject to the 10 percent cap on administrative expenses.

Response: Providing information about Medicaid will not necessarily create a barrier to enrollment. Families are entitled to have complete information on which to base a decision about applying for coverage. We are pleased that reports from many States indicate that many Medicaid-eligible children are being found through the screening process. However, the results across all States are not uniform and there is no way to know how many other Medicaid-eligible children are not being identified. Because all families are entitled to have information on their child's eligibility for coverage, we are retaining this provision with clarification.

We agree that families need to understand that no formal determination of the child's Medicaid eligibility has been made, nor has the child been screened under all Medicaid eligibility categories. We note that a Medicaid determination does not need to be made in every case, but rather only for those children screened as potentially eligible for Medicaid using the joint application, and that a Medicaid eligibility determination can only be issued by the State agency designated to make the determination. In the instance where the same agency that makes the Medicaid determination of eligibility also determines eligibility for the separate child health program, a determination of Medicaid eligibility must be issued, in addition to the notice required at § 457.350(e).

We have clarified the language of proposed § 457.350(f) at § 457.350(g)(1) of this final rule to provide that the State must inform the family, in writing, that based on a limited review, the child does not appear to be eligible for Medicaid, but that Medicaid eligibility can only be determined from a full review of a Medicaid application under all Medicaid eligibility groups. We have not included actual or proposed notice language in the final rule. Due to the differences in Medicaid programs, the language necessarily will vary from State to State. However, we are working to identify good notice language and best practices and will disseminate this material to States.

We expect that the information will be comprehensive and include information about Medicaid eligibility based on disability, pregnancy, excessive medical expenses, or unemployment of the family wage earner. We also expect that this information will be provided in a simple and straightforward manner that can be understood by the average applicant and that meets all applicable civil rights requirements, including the Americans with Disabilities Act (ADA). The information can be provided along with other information conveyed to SCHIP applicants or it can be a separate notice. The cost of providing information about Medicaid eligibility need not be a SCHIP administrative expense subject to the 10 percent cap. A State may choose to charge the cost of providing information about Medicaid as an administrative expense under title XIX.

Comment: A few commenters indicated that the regulations should make it clear that a child can be enrolled in a separate child health program while undertaking the full Medicaid application process. Other commenters recommended enrolling a child in a separate child health program for 45 days to allow processing of the Medicaid application.

Response: As discussed above, at its option, a State may provisionally enroll or retain current enrollment of a child who has been found potentially eligible for Medicaid in a separate child health program, for a limited period of time, as specified by the State, pending a final eligibility decision. However, the child cannot be ''eligible'' for the separate program unless a Medicaid application is completed and a determination made that the child is not eligible for Medicaid.

As noted above, we have revised our policy based on the recent enactment of BIPA to permit health coverage expenditures for children during the presumptive eligibility period to be treated as health coverage for targeted low-income children whether or not the child is ultimately found eligible for the separate child health program, as long as the State implements presumptive eligibility in accordance with section 1920A and § 435.1101 of this part. This preserves State flexibility to design presumptive eligibility procedures and allows States that adopt the presumptive eligibility option in accordance with § 435.1101 to no longer be constrained by the 10 percent cap.

Comment: We received several comments urging HCFA to emphasize opportunities for simplifying the screen and enroll process and making the process ''family-friendly.'' Among the suggestions were: using a joint application or a single State agency; avoiding confusing options for families to opt in or out of Medicaid; eliminating age-based rules; adopting the same verification requirements as Medicaid; adopting the same income and resource methodologies as Medicaid; eliminating documentation requirements in Medicaid that are not required by the separate child health program; and requiring that any simplifications in the application process that States adopt for Medicaid or a separate child health program not be denied to children whose families also happen to be TANF or Food Stamp applicants or recipients.

Response: The suggested simplifications are ways in which confusing options and complex procedures can be eliminated and the screen and enroll process be made ''family-friendly.'' We encourage States to adopt these simplifications. As States experiment with new ways to coordinate their child health coverage programs, they are finding that alignment of program rules and procedures can greatly simplify the task of coordinating enrollment. As for children who are also applying for, or are receiving, Food Stamps or TANF, we emphasize that, while States may use joint child health, Medicaid, Food Stamp and TANF applications, they cannot condition Medicaid eligibility on Food Stamp or TANF requirements that

do not apply to Medicaid. For example, if a State Medicaid program does not require a face-to-face interview to determine a child's eligibility for Medicaid, a child applying for Medicaid and Food Stamps on a joint application cannot be denied Medicaid simply because the child's family does not comply with the Food Stamp interview requirement. Similarly, States cannot condition eligibility for a separate child health program on Food Stamp or TANF requirements that do not apply to that program.

Comment: Many of those who commented on the screen and enroll process were concerned generally about families ''falling through the cracks'' because of the back and forth between separate child health programs and Medicaid or going without any health care for a period of time because of the process requirements. One commenter was particularly concerned about children leaving State custody from foster care or the juvenile justice system, who are at great risk of failing to apply for health coverage after they leave State custody. A significant number suggested that the regulations provide that a State cannot require a child to reapply for a separate child health program if the child is screened potentially eligible for Medicaid, but later determined ineligible for Medicaid. Most suggested that the separate child health program application should be suspended or provisionally denied when a child is found to be potentially eligible for Medicaid, pending a final Medicaid eligibility determination.

Other commenters found the distinction between joint and separate applications confusing with respect to the screening requirements. The commenters requested clarification as to whether the procedures for use of joint applications also apply to separate child health programs.

Response: There are many policies and procedures that States with separate child health programs can adopt to ensure that children do not ''fall through the cracks.'' When a child is identified through screening as potentially eligible for Medicaid, States may suspend, deny or provisionally deny the separate child health application. Alternatively, if the State has established a presumptive eligibility process for a separate child health program, the State may enroll an applicant in the separate child health program pending the formal determination of Medicaid eligibility; we have added a new section § 457.355 to reflect this option. It should also be noted that we have revised our policy to allow health coverage expenditures for children during the presumptive eligibility period to be treated as health coverage for targeted low-income children whether or not the child is ultimately found eligible for the separate child health program, as long as the State implements presumptive eligibility in accordance with section 1920A and section 435.1101 of this part. This preserves State flexibility to design presumptive eligibility procedures and allows States that adopt the presumptive eligibility option in accordance with section 435.1101 to no longer be constrained by the 10 percent cap.

We also have clarified the regulations at § 457.350(f)(5) (§ 457.350(e)(2) in the proposed regulations) to require that, if a child screened potentially eligible for Medicaid is ultimately determined not to be eligible for Medicaid, once the State agency or contractor that determines eligibility for the separate child health program has knowledge of the Medicaid determination, the child's original application for the separate child health program must be reopened or reactivated and his/her eligibility under the separate child health program determined without a new application. We believe that most States currently follow this procedure to ensure that the screening process does not improperly deny coverage under the separate child health program.

As discussed below, we have also added a rule directed to the Medicaid agency that requires that agency to promptly inform the SCHIP agency or contractor when a child who has been screened as potentially eligible for Medicaid is found ineligible for Medicaid (see section 431.636 of this chapter).

We have clarified § 457.350(f)(1) (§ 457.350(e)(1) in the proposed rules) to indicate that a State may suspend, provisionally deny or deny the application of a child screened potentially eligible for Medicaid. (Note that to provisionally deny an application is the same as finding the child provisionally ineligible for the separate child health program.) Putting the application into suspense for a reasonable period of time before taking action on it would preserve the child's initial application date and ensure follow-up on the part of the State agency or contractor after the specified time period had elapsed or the agency or contractor learned that the child has been determined ineligible for Medicaid, whichever is sooner. If a State provisionally denies the application and the child is subsequently determined ineligible for Medicaid, the child's initial application would be reactivated as soon as the State agency or contractor that determines eligibility for the separate child health program learns of the denial of Medicaid eligibility. In either case, the family would not need to provide any additional information (unless there has been a change in circumstances that could affect eligibility).

In most circumstances, no further action on the part of the family will be necessary to reactivate or reopen the application for the separate child health program following a denial of Medicaid eligibility. For example, in States in which the State Medicaid agency also determines eligibility for the separate child health program, no further action on the part of the family will be required. Similarly, States that use a joint application and that closely coordinate the eligibility determination process (for example, through electronic transfers or by co-locating eligibility workers) can ensure that Medicaid determinations for children identified as potentially Medicaid-eligible can be made quickly and that the decision (and underlying information) can also be conveyed quickly back to the workers responsible for determining eligibility for the separate program.

We agree that the screening requirements are the same whether a joint application or separate applications are used, although the procedures States will need to adopt to meet these requirements will vary depending on whether a joint application is used. Therefore, we have deleted proposed § 457.350(b) to eliminate confusion. All States, including those that use a joint application, are required to meet the screening requirements in § 457.350.

We have added a new subparagraph § 457.350(f) to clarify the State's responsibilities for ensuring that the Medicaid application process for a child screened potentially eligible for Medicaid is initiated and, if eligible, that the child is enrolled in Medicaid, as required by section 2102(b)(3)(B) of the Act.

In general, in States that use a joint application, the State agency or contractor that conducts the screening shall promptly transmit the application and all relevant documentation to the appropriate Medicaid office or Medicaid staff to make the Medicaid eligibility determination, in accordance with the requirements of § 431.636, a new provision which sets forth the Medicaid agency's responsibilities with respect to the screen and enroll requirements of title XXI. Because the agency administering the separate child health program may not be the agency

authorized to make Medicaid determinations in the State, it is at the point when the joint application form is transmitted to the Medicaid office from the separate program that it becomes a Medicaid application. We have added the definition of ''joint application'' at § 457.301 to clarify this point and to facilitate the processing of joint applications. Specifically, we define a joint application as a form used to apply for a separate child health program that, when transmitted to the Medicaid agency following a screening that shows the child is potentially eligible for Medicaid, may also be used to apply for Medicaid. We encourage States that use a separate application for a separate child health program to design their applications so that families can easily waive confidentiality under SCHIP to allow the agency or contractor that conducts the screening to transfer information to the Medicaid agency when a child has been found potentially eligible for Medicaid.

In States which do not use a joint application for Medicaid and separate child health programs, the State agency or contractor that conducts the screening shall (1) inform the applicant that the child is potentially eligible for Medicaid; (2) provide the applicant with a Medicaid application and offer assistance in completing the application, including providing information about what, if any further information and/or documentation is needed to complete the Medicaid application process; and (3)promptly transmit the application and all other relevant information, including the results of the screening process, to the Medicaid agency for a final determination of Medicaid eligibility, in accordance with § 431.636.

It should be noted that under most circumstances, the term ''promptly'' means that the entire process (including screening and facilitation between SCHIP and Medicaid) for determining eligibility should be completed within the 45 day period. However, we recognize that there are cases where the timing of the process is beyond the control of the separate child health program. For example, if the process for determining Medicaid eligibility after a screen reveals that the family's income has changed, making them eligible for the separate child health program, we understand that the need to transfer paperwork back and forth between programs can take additional time beyond the 45 days.

Alternatively, under § 457.350(f), the State can establish other procedures to eliminate duplicative requests for information and documentation and ensure that the applications and all relevant documents of children screened potentially eligible for Medicaid are transmitted to the Medicaid agency or staff and that, if eligible, such children are enrolled in Medicaid in a timely manner.

We also have added a section § 457.353(a) to require that States monitor and establish a mechanism to evaluate (1) the process established in accordance with § 457.350 to ensure that children who are screened potentially eligible for Medicaid apply for and, if eligible, enroll in that program and (2) the process established to ensure that the applications for a separate program of children who are screened potentially eligible, but ultimately determined by the Medicaid agency not to be eligible, for Medicaid are processed in accordance with § 457.340 of this subpart.

Data collection will need to be a part of any mechanism developed to effectively evaluate the screen and enroll process. For example, States will need to collect data on the number and percent of children applying for a separate child health program who are screened potentially eligible for Medicaid; the number of those screened potentially eligible for Medicaid who ultimately are determined to be eligible versus the number determined not to be eligible for Medicaid; the number of those children ultimately determined not to be eligible for Medicaid whose applications for the separate child health program are processed; etc. These data will help States and HCFA evaluate whether the procedures States adopt are accomplishing the goal of enrolling children in the appropriate program or whether modifications are needed.

We have modified the language in § 457.350(f)(5)(ii) to clarify that States must determine or redetermine the eligibility of a child initially screened eligible for Medicaid if the child's circumstances change and under § 457.350(e) another screening shows that the child does not appear to be eligible for Medicaid. We have added the phrase ''does not appear to be'' to reflect the fact that only the State Medicaid agency is authorized to actually determine that a child is ineligible for Medicaid. Contractors can only make a determination as to the likelihood of the child's eligibility for purposes of proceeding with the application for a separate child health program.

Second, we have added a new subparagraph at § 457.350(f)(5)(iii) to clarify that, in determining or redetermining the eligibility for a separate child health program of a child screened potentially eligible, but ultimately determined not eligible, for Medicaid, the child may not be required to complete a new application, although it may supplement the information on the initial application to account for any changes in the child's circumstances or other factors that may affect eligibility.

We also have added a new subsection § 457.350(h) to require that States which have instituted a waiting list for the separate child health program develop procedures to ensure that the screen and enroll procedures set forth in § 457.350 have been complied with before a child is placed on the waiting list. This ensures that children who are eligible for Medicaid are not placed on a waiting list if a State has closed enrollment for its separate child health program. These requirements ensure that eligible children are enrolled in the appropriate program without delay and without unnecessary paperwork barriers. At the same time, they give States ample leeway to design the system that works best for them. No one system is prescribed, but States will need to monitor and evaluate how well their system is working, and they will be held accountable for ensuring that the system they have designed and implemented complies with the statutory and regulatory requirements.

Comment: We received one comment that the regulations should clearly indicate that a State may cease accepting applications for its separate child health program when enrollment is closed.

Response: The State may stop accepting applications as one method of administering an enrollment cap. If the State is using a joint application, which is also an application for Medicaid, then the State must have provisions to assure that the Medicaid eligibility determination process is initiated, even if enrollment in the separate child health program has been suspended. If, after a State plan that does not authorize an enrollment cap is approved by HCFA, the State opts to restrict eligibility by discontinuing enrollment, the State must submit a State plan amendment in accordance with §§ 457.60 and 457.65 of this final rule.

Comment: Two commenters suggested that the preamble reiterate that a child who must meet a spend down does not have ''other coverage'' and may be eligible for the separate child health program.

Response: We have not required States to screen for Medicaid eligibility under the medically needy groups described in section 1902(a)(10)(C) of the Act because of the uncertainty inherent in determining whether and

when a spend down has been met. A child who is not yet ''medically needy'' because he or she has not yet met the spend down requirements is not considered to be eligible for Medicaid for purposes of the screening requirement. However, an individual who could be eligible for Medicaid as medically needy with a spend down has a right to apply for Medicaid, and should be informed of the spend down category. If a child is eligible without a spend down or if it is determined that the spend down has been met, then the child would be eligible for Medicaid and would not be eligible for the separate child health program. Information about the State's medically needy program must be included in the information provided to applicants for a separate child health program.

Comment: In response to our request for comments on the extent of the Medicaid ''stigma'' problem and possible solutions, several commenters noted that poor coordination between separate child health programs and Medicaid expansions contributes to the stigmatization of Medicaid. One commenter noted that many working people take pride in their achievements and posited that they prefer to pay their own way rather than participate in what they perceive as a public assistance program. This commenter felt that people's desire for self-reliance is not an attitude that public policy can (or should) change.

According to the commenters, a program is more likely to be successful in insuring children if these attitudes are taken into account. Two commenters said that negative reactions to Medicaid are due to its historic association with welfare; discourteous or intrusive treatment by workers; difficult application processes; negative treatment by providers; negative personal experiences and those of friends and neighbors.

Several commenters suggested that the stigma can be alleviated by having a simple, joint enrollment process and creating a seamless environment. One commenter suggested that a non-public entity be allowed to enroll children in Medicaid. Another recommended that HCFA encourage States to offer applicants a choice of settings in which to be enrolled, because reliance on a public monopoly reinforces the stigma. Additional suggestions included giving both programs one name; adopting a joint application; eliminating asset tests; encouraging presumptive eligibility; expanding outreach and enrollment sites; eliminating face-to-face requirements; and offering a single application site. One commenter also recommended that HCFA continue to research best practices and promote them.

One commenter suggested that ensuring that providers in both programs are paid adequately and that provider networks in both programs provide convenient access to high quality services is a critical step as well. We received one suggestion that HCFA assess the barriers to Medicaid enrollment in each State and develop and implement a State-specific plan to address and remove such barriers. Several commenters asserted that the situation is difficult to resolve given the current statutory requirements and suggested that HCFA fund a study and make suggestions for legislative changes.

Response: We appreciate the responses on the stigma issue and have incorporated many of them in our guidance and suggestions to the States. We will continue to research and promote best practices and note that many States have successfully eliminated or greatly limited the welfare stigma which sometimes is associated with Medicaid and have converted Medicaid to a program that operates as, and is perceived to be, a health insurance program.

We encourage States to continue to simplify their processes and eliminate barriers to facilitate enrollment and retention among eligible individuals. We also encourage States to employ outreach efforts geared toward changing the perception that Medicaid is ''welfare.'' We urge States to make clear in all their informational materials about the TANF cash assistance program that coverage under Medicaid or a separate child health program is not linked to TANF eligibility or enrollment and that, whether or not families apply for or receive TANF assistance, they are encouraged to apply for Medicaid and any separate child health program.

8. Facilitating Medicaid Enrollment(§ 457.360)

Under section 2102(b)(3)(B) of the Act, States are required to ensure that children found through the screening process described above to be eligible for Medicaid apply for and are actually enrolled in Medicaid. We proposed in § 457.360(a) that the State plan must describe the reasonable procedures to be adopted to ensure that children found through the screening to be potentially eligible for Medicaid actually apply for and are enrolled in Medicaid, if eligible. Under proposed § 457.360(b), States must establish a process to initiate the Medicaid enrollment process for potentially Medicaid eligible children and several options for States are provided.

We also proposed to require at § 457.360(c) that a State ensure that families have an opportunity to make an informed decision about whether to complete the Medicaid application process by providing full and complete information, in writing, about (1) the State's Medicaid program, including the benefits covered and restrictions on cost-sharing; and (2) the effect on eligibility for coverage under the separate child health program of neither applying for Medicaid nor completing the Medicaid application process.

Comment: We received one comment that States should not be required to ''ensure'' that children enroll in Medicaid because States cannot dictate to families, but can only assist them.

Response: The statute specifically requires that States ''ensure'' that children are enrolled. It is correct that a family cannot be forced to apply for Medicaid and that States cannot ultimately ''ensure'' that an eligible child is enrolled. However, it is the responsibility of the State to remove barriers to enrollment, adopt procedures that promote enrollment of eligible children, and ensure that the family understands the benefits of Medicaid and the consequences of not applying for Medicaid.

Comment: We received a number of comments pertaining to the information about Medicaid which must be provided to families. One commenter stated that it was not reasonable to expect States to ''ensure'' that a family's decision not to apply for Medicaid is an informed decision and that this could lead to costly litigation over whether the State has taken sufficient measures. A significant number of commenters were concerned that States would be required to provide ''reams'' of in-depth information about Medicaid and commented that general information ordinarily provided to any family interested in applying for Medicaid should be sufficient. Finally, one commenter recommended that information about the benefits of Medicaid be provided to adolescents in a format and language that can be easily understood by both the adolescent and the family.

Response: Sufficient information must be provided to families to enable them to make an informed decision about completing an application for Medicaid. We agree that information about Medicaid eligibility and the benefits of Medicaid should also be in a format that adolescents can understand as appropriate. We also note that the provision of information to families

under proposed § 457.360(c), section § 457.350(g) of the final rule, only applies for States that use a separate application for their separate child health plan and those using a joint application which permits families to check a box on the application to elect not to apply for Medicaid.

In some cases, the general information provided ordinarily to any family interested in applying for Medicaid may provide sufficient information about Medicaid itself for these purposes. However, the State must also inform the family about the effect on eligibility for the separate child health program if the family chooses not to apply for Medicaid or not to complete the Medicaid application process, as many families will not realize that they do not have a choice between programs.

We have reconsidered the use of the term ''ensure'' because we agree that States cannot ''ensure'' that a decision is an informed one, no matter how much or how understandable the available information. States can only make the information available in an accessible way. We have revised the regulation at new § 457.350(g) (proposed § 457.360(c)) to require that States provide sufficient information to enable the family to make an informed decision.

Comment: One commenter suggested that, because Medicaid eligibility may result in automatic referral to CSE, States should inform families applying for the separate child health program about the rights and responsibilities associated with being found eligible for Medicaid, including the assignment of medical support rights and the right to claim an exemption from the cooperation requirements. The commenter is concerned that a mother applying for SCHIP, where there is no need for contact with the noncustodial parent, may not mention that she has been subject to domestic abuse at the time of applying, and might be automatically referred to CSE when there is good cause for not being referred.

Response: A Medicaid application for a child should not result in a referral to the CSE agency absent the cooperation of a parent. We agree that whenever a Medicaid or separate child health program application is filed, the family should be informed about the services offered by the CSE, its opportunity to take advantage of these services, and whether additional information will be required. Cooperation with establishing paternity and pursuing medical support is *not* a condition of a child's eligibility for Medicaid. Parents can be asked whether they would like to pursue medical support through CSE, but a cooperation in obtaining CSE cannot be required as a condition of a child's eligibility for Medicaid. If a parent also is applying for Medicaid, the parent should be informed of the acceptable reasons for refusing to cooperate and of the distinct consequences for the parent's and child's eligibility of not cooperating if none of the acceptable reasons applies.

Comment: One commenter noted that States should be given flexibility in the areas of application and enrollment. Another commented that the proposed regulations are overly prescriptive and exceed statutory authority by requiring States and SCHIP applicants to go through a tedious and administratively difficult process of obtaining a written waiver from applicants stating they do not wish to apply for Medicaid or complete a Medicaid application as required in proposed § 457.360(c).

Response: As discussed in the responses to several comments below, States have a great deal of flexibility in the areas of application and enrollment. There is no requirement that SCHIP programs ask families for a waiver; in fact, under title XXI, States do not have the option of enrolling children in the separate program if a Medicaid screen indicated the child may be eligible for Medicaid, even if a family waived their right to apply for Medicaid. States must inform families about the consequences for the child's coverage of not applying for Medicaid and develop systems to facilitate seamless enrollment in Medicaid for eligible children pursuant to § 457.350. Under § 457.350(f)(1), the State could suspend the child's application for the separate program unless or until a completed Medicaid application for that child is denied. This would preserve the child's initial application date and ensure follow-up on the part of the State SCHIP agency after the specified time period had elapsed.

Alternatively, a State may deny, or provisionally deny, the separate child health program application. As discussed earlier, if a State provisionally denies the application and the child is subsequently determined ineligible for Medicaid, the child's initial separate child health program application should be reactivated as soon as the SCHIP agency learns of the denial of Medicaid eligibility. The family would not need to provide any additional information (unless there has been a change in circumstances that could affect eligibility). If the child chooses not to apply for Medicaid, the denial or provisional denial under a separate child health program will stand (unless the child's circumstances change and a new screen shows that the child no longer appears potentially eligible for Medicaid).

Comment: Several commenters were concerned that the application process for Medicaid would be a barrier to enrollment in a separate child health program. Some expressed concern that the proposed rule would fail to prevent States from using unnecessary administrative barriers and hostile or adversarial treatment by Medicaid eligibility workers as a means of discouraging families from successfully completing a Medicaid application and one urged HCFA to prevent States from requiring that applicants screened potentially Medicaid-eligible go through complicated, time-consuming and demeaning processes. Two recommended that HCFA prohibit States from making the process for applying for Medicaid more burdensome, onerous or time-consuming than the process for applying for a separate child health program. A few urged that the screen and enroll requirements be enforced, monitored, and evaluated to ensure that all children eligible for Medicaid are reached. One of the commenters urged HCFA to set high standards to ensure that States actually enroll screened children in Medicaid.

Response: Section 2102(b)(3)(B) of the Act requires States to describe in their State plan their procedures for ensuring that children screened potentially eligible for medical assistance under the State Medicaid plan under title XIX are enrolled in Medicaid. We have implemented that statutory provision at § 457.350(a)(1). A simple referral to the Medicaid agency is not enough to meet this requirement. In § 457.350, we require that States take reasonable action to facilitate the Medicaid application process and to promote enrollment of eligible children into Medicaid.

We do not have the statutory authority to require any particular application process, or that the Medicaid application process be no more difficult than the application procedures for separate child health programs. However, we appreciate the commenters' concerns and encourage States to examine their administrative systems and to simplify and minimize barriers in their application and enrollment processes for both Medicaid and separate child health programs to the extent possible. We are pleased that most States are moving in this direction and will continue to provide technical assistance on this matter as needed.

Given Congressional concern that title XXI funds not be used to supplant existing health insurance coverage, ensuring compliance with the screen and enroll requirements of title XXI is a high priority for HCFA and will be strictly monitored, evaluated, and enforced. As previously discussed, we have added a new § 457.353(a) to require States to monitor and establish a mechanism to evaluate the processes adopted by the State to implement the screen and enroll provisions of § 457.350.

Comment: Two commenters recommended that States be required to send a notice after an initial screen finds potential Medicaid eligibility.

Response: The State needs to provide written notice of any determination of eligibility under § 457.340(d). If the State determines that an applicant is ineligible for coverage under its separate child health program, the State must provide written notice of that determination. In addition, under § 457.350(g) the State must provide families with information to enable them to make an informed decision about applying for Medicaid; and under § 457.350(f)(3), if a State does not use a joint application for Medicaid and its separate child health program, applicants that are screened potentially Medicaid-eligible must be given notice that they have been found potentially eligible for Medicaid, and be offered assistance in completing a Medicaid application (if necessary), and provided information about what is required to complete the Medicaid application process.

Comment: We received two comments related to the effective date of an application. One commenter requested that the regulations clarify that if a joint application is used, the date of the application for a separate child health program is also the date of application for Medicaid. One commenter believed that if an application for the separate child health program is denied, the State must provide notice to the applicant and must also continue to process the Medicaid application within the 45-day time frame.

Response: If a State uses a joint application for Medicaid and its separate child health program, the date of application for Medicaid may or may not be the same as the date of application for the separate program. As indicated earlier, this is because the State agency that determines eligibility for Medicaid may not be the same entity that determines eligibility for the separate program. In some cases, it may not be reasonable to hold the Medicaid agency responsible for determining eligibility within 45 days when it could not have initiated the determination process until the application was transmitted from the entity administering the separate child health program.

The SCHIP entity's responsibility in this case is to promptly transmit the application to the Medicaid agency immediately following the screen. Under most circumstances, the term ''promptly'' means that the entire process (including screening and facilitation between the separate child health program and Medicaid) should be completed within 45 days. However, we recognize that there are also circumstances where the timing of the process is beyond the control of the separate child health program and the separate child health program. For example, if the process for determining Medicaid eligibility after a screen reveals that the child's family income has changed, making them eligible for the separate child health program, we understand that the transfer back and forth between programs can take additional time.

If a State uses separate applications for its separate child health program and Medicaid, States can but are not required to establish the date the separate application was filed as the effective date of filing for Medicaid. States have flexibility under the Medicaid program to establish the effective date of a Medicaid application. The regulations at § 431.636 of this chapter do require that the SCHIP agency and the Medicaid agency coordinate to design and implement procedures that are developed to coordinate eligibility to ensure that eligible children are enrolled in the appropriate program in a timely manner.

Comment: Two commenters recommended that the regulations require that, even if a separate application is used for the separate child health program, the application form and any supporting verification must be transmitted to the appropriate Medicaid office for processing without further action by the applicant to initiate a Medicaid application. One commenter recommended that if an applicant is required to take any additional steps in order to apply for Medicaid, that the Medicaid agency inform the family of the steps it must take.

Response: As discussed above, under § 457.350(f)(3), States that use a separate application must provide an applicant screened potentially eligible for Medicaid with a Medicaid application; offer assistance in completing the application, including providing information about any additional information or documentation needed to complete the Medicaid application process; and send information and all relevant documentation obtained through the screening process to the appropriate Medicaid office or to Medicaid staff, to begin the Medicaid application process. An application for Medicaid would then be processed in accordance with Medicaid rules and regulations. Documentation (or photocopies) must be forwarded to the Medicaid agency along with other information wherever feasible. The family cannot be required to repeat information or provide documentation more than once. However, a separate child health application is not an application for Medicaid unless the State allows it to be used as such. Some States do use the separate child health program application as the Medicaid application when a child is screened as potentially eligible for Medicaid. This practice relieves the family and the State of the need to complete and review another application form.

As part of meeting their obligations under section 2102(b)(3)(B) of the Act, States must adopt reasonable procedures to ensure that a Medicaid application for children screened potentially eligible for Medicaid is completed and processed (provided that the family has not indicated that it does not wish to apply for Medicaid for the child). The obligations of the Medicaid agency in meeting this requirement are set forth in § 431.636 and discussed further in subpart M of this preamble, ''Expanded coverage of children under Medicaid and Medicaid coordination.''

Comment: A number of commenters suggested that the procedures in the regulations for facilitating Medicaid enrollment should specifically require that application assistance include bilingual workers, translators and language appropriate material or that the requirements of title VI and the ADA should be explained in the preamble. One commenter recommended that this include examples of how States and contracted entities can comply with these requirements.

Response: As required by § 457.130, the State plan must include an assurance that the State will comply with all applicable civil rights requirements. In addition, § 457.110 requires that States provide to potential applicants, applicants and enrollees information about the program that is linguistically appropriate and easily understood. Such materials and services, as well as compliance with the ADA, are required and important if

States are to effectively reach and enroll all groups of eligible children. We elected not to explain in detail all applicable civil rights requirements identified under § 457.130. However, interested parties can obtain additional information on these requirements by contacting the U.S. Health and Human Services' Office for Civil Rights.

9. Application for and Enrollment in a Separate Child Health Program § 457.340 (Proposed § 457.361)

Because we believe that the provisions of this section are closely related to those contained in proposed 457.340, in this final rule, we have incorporated the provisions of these two sections in the final regulation at § 457.340. However, we will respond to comments to proposed § 457.361 here.

In this section, we proposed to require that States afford individuals a reasonable opportunity to complete the application process and offer assistance in understanding and completing applications and in obtaining any required documentation. Furthermore, we proposed to require that States inform applicants, in writing and orally if appropriate, about the eligibility requirements and their rights and responsibilities under the program.

We noted in the preamble to the proposed rule that, although not specifically addressed in statute, a State may choose to provide a period of presumptive eligibility during which services are provided, although actual eligibility has not been established.

We proposed that the State must send each applicant a written notice of the decision on the child health application and that the State agency must establish time standards, not to exceed forty-five calendar days, for determining eligibility and inform the applicant of those standards. In applying the time standards, the State must count each calendar day from the day of application to the day the agency mails written notice of its decision to the applicant. We also proposed that the State agency must determine eligibility within the State-established standards except in unusual circumstances and that the State must specify in the State plan the method for determining the effective date of eligibility for a separate child health program.

In addition to the changes made in response to the comments discussed below, we have modified the language in § 457.361(c) (§ 457.340(d) in this final regulation) to clarify that States must notify families whenever a decision affecting a child's eligibility is made—whether the decision involves denial, termination or suspension of eligibility. In the case of a termination or suspension of eligibility, the State must provide sufficient notice, in accordance with § 457.1180, to enable the child's parent or caretaker to take any appropriate actions that may be required to allow coverage of the child to continue without interruption. This clarification has been added in response to comments in order to ensure that children do not experience an unnecessary break in coverage because they have reached the end of an enrollment period.

Comment: Several commenters stated that HCFA should require States to notify the public of the priority standards, if any, for enrollment; inform individuals of their status on any waiting list; and maintain sufficient records to document that favoritism or discrimination does not occur in selecting individuals for enrollment.

Response: As discussed in the preamble to § 457.305, above, if a State plans to institute a waiting list or otherwise limit enrollment, it must include in its State plan a description of how the waiting list will be administered, including criteria for how priority on the list will be determined. In addition, § 457.110 requires States to inform applicants about their status on a waiting list.

Comment: We received several comments on the proposed requirement that a State determine eligibility under a separate child health program within 45 days. One commenter stated that the date of the application should not be the beginning of the 45 day period but rather the date that the application is received in the separate child health program eligibility office as there could be a delay for mailed-in applications. Another commented that the 45-day requirement does not take into account delays in obtaining necessary verifications from third parties such as employers or insurers. They suggested adding ''or other party with information needed to verify the application [delays * * *]'' or just requiring States to determine eligibility in a timely manner. A third supported establishing a 45-day time limit and prohibiting the use of time standards as a waiting period, but recommended that the regulations provide more specificity regarding when notice of rights and responsibilities must be given and a notice of decision provided. Another commenter felt that the 45-day requirement should be removed, that mirroring Medicaid is burdensome and costly, and allowing mail-in and drop-off applications may mean it will take longer to reach people to get all the necessary information.

Response: We have not changed the requirement in § 457.340(c) (proposed § 457.361(d)) that States must determine eligibility for a separate child health program within 45 calendar days (or less if the State has established a shorter period) from the date the application is filed. We have, however, clarified § 457.340(c)(2) (§ 457.361(d) in proposed rule) to require that States determine eligibility and issue a notice of decision promptly, but in any event not to exceed the time standards established by the State. This is consistent with the requirement that child health assistance be provided in an efficient manner, and that the 45-day period—or other time period specified by the State—may not be used as a waiting period. States have flexibility in deciding when an application is considered filed.

We agree that States should not be held responsible for delays caused by third parties beyond the State's control and have accommodated that concern in § 457.340(c)(2). We also have revised § 457.340(b) to specify that the notice of rights and responsibilities must be provided at the time of application. This ensures that families have the information they may need to proceed with the application process and successfully enroll their child.

Comment: We received two comments objecting to the requirement in § 457.340(a) that States assist families in obtaining documentation. They commented that States are not in a position to do this and that the requirement has the potential for enormous administrative burden.

Response: We will not be removing the phrase from the regulation, but will offer clarification related to this provision as we think the commenter may have misinterpreted the proposed rule. We expect that, in offering application assistance, the State or contractor for the separate child health program will provide assistance to applicants in understanding what documentation is needed to complete their applications and, to the extent possible, will assist applicants in determining where they might obtain the needed information. For example, if the State's application process requires verification of income and the applicant does not understand how they can prove their income, we would expect the State or the individual providing application assistance to be able to inform the family of the type of documentation (*e.g.,* pay stubs or W–2 forms) needed and where the applicant might be able to obtain that information (*e.g.,* from their employer). We do not expect a State to literally perform the

task of obtaining the documentation for the applicant, unless it so chooses or the document is readily available to it, and agree with the commenters that such a requirement would be administratively burdensome. Most States have produced application materials and program brochures and operate telephone help lines that provide the type of assistance required by the regulation.

10. Eligibility and Income Verification (§ 457.360)

In this final regulation, we have moved two provisions of proposed § 457.970, concerning eligibility and income verification, to new § 457.360. In proposed § 457.970, we proposed to require that States have in place procedures designed to ensure the integrity of the eligibility determination process, and to abide by verification and documentation requirements applicable to separate child health programs under other Federal laws and regulations.

We proposed that States have flexibility to determine these documentation and verification requirements. In the preamble, we encouraged States to adopt procedures that ensure accountability while permitting self-declaration to minimize barriers in the application and enrollment process.

We also noted at § 457.970(c) that States with separate child health programs may choose to use the Medicaid income and eligibility verification system (IEVS) for income and resources, although they are not required to do so.

Finally, in § 457.970(d) we proposed to allow States to terminate the eligibility of an enrollee for ''good cause'' (in addition to terminating eligibility because the enrollee no longer meets the eligibility requirements)—*e.g.,* providing false information affecting eligibility. Under the proposed regulations, the State would have to give such enrollees written notice setting forth the reasons for termination and providing a reasonable opportunity to appeal, consistent with the requirements of proposed § 457.985.

Note that, in this final regulation, we have eliminated any specific reference to income verification systems, as income requirements are but one of a number of requirements for eligibility under a separate child health program.

Comment: One commenter expressed support for the flexibility HCFA gives States for verifying eligibility and income. Another recommended requiring that States' eligibility and income verification processes be designed to minimize barriers to and facilitate enrollment, and that the regulations explicitly provide that States may use self-declaration of income and assets. A third suggested that HCFA should include a description of the opportunity that States have to use innovative quality control projects to ensure that allowing families to self-declare income does not increase the rate of erroneous enrollment.

Response: We appreciate the support for the flexibility afforded to States and encourage States to adopt eligibility and income verification procedures that do not create barriers to enrollment. At the same time, States must have effective methods to ensure that SCHIP funds are spent on coverage for eligible children. We note that States can use their discretion in establishing reasonable verification mechanisms and have included this in the regulation text at § 457.360(b). We also encourage the creation of innovative projects to promote program integrity.

As stated in the preamble to the proposed rule, we also encourage States to develop eligibility verification systems using self-declaration or affirmation, and have decided to include this in the regulation text at § 457.360(b), to eliminate any question about the rule. States may use the existing IEVS system to verify income, as long as the information was provided voluntarily. While States may ask for voluntary disclosure of Social Security numbers, disclosure of such information cannot be made a condition of eligibility. States may use existing IEVS systems to verify income, as long as the information was provided voluntarily. We note that the integrity of a system which relies on self-declaration can be ensured through a variety of techniques. For example, a State could conduct a random post-eligibility check, requiring some applicants to provide documentation, or it could run computer matches of information provided by applicants against information available to the State through other sources.

Finally, we have deleted proposed § 457.970(a)(2) (requiring compliance with the verification and documentation requirements applicable to separate child health programs under other Federal laws and regulations) because it does not provide meaningful guidance to States on what they can and cannot do in designing their verification systems. If the system proposed violates other Federal laws or regulations, we will work with the State to bring its system into compliance.

Comment: One commenter noted his concern that the regulation authorizes States to terminate coverage of children for misconduct of a parent/caretaker and suggested that HCFA revise the definition of ''good cause'' to be more limiting. This commenter also noted his concern that the reference in proposed paragraph (d) to termination for good cause is troubling. The example of good cause as reporting false information on the application form does not seem to be good cause for a child losing benefits if the false statement does not affect the child's eligibility. The commenter stated that this kind of standard is highly subjective and susceptible to abuse given the large amount of discretion States already have in administering their plans.

Response: We agree with the commenter's concern and have deleted the good cause provisions from the regulation text accordingly. Children should not lose eligibility, as long as they meet the eligibility standards under the approved State plan and consistent with title XXI requirements. Further discussion of these issues can be found in Subpart K.

11. Review of Adverse Decisions (§ 457.365)

Finally, we proposed in the NPRM to require that States provide enrollees in separate child health programs with an opportunity to file grievances and appeals for denial, suspension, or termination of eligibility in accordance with § 457.985. In an effort to consolidate all provisions relating to review processes in new subpart K, we have removed proposed § 457.365. Comments on proposed § 457.365, are addressed in full in Subpart K—Applicant and Enrollee Protections.

D. Subpart D—Coverage and Benefits: General Provisions

1. Basis, Scope, and Applicability (§ 457.401)

As proposed, this subpart interprets and implements section 2102(a)(7) of the Act, which requires that States make assurances relating to certain types of care, including assuring quality and appropriateness of care and access to covered services; section 2103 of the Act, which outlines coverage requirements for children's health benefits; section 2109 of the Act, which describes the relation of the SCHIP program to other laws; section 2110(a), which describes child health assistance; and certain provisions of section 2110(c)(6) of the Act, which contains definitions applicable to this subpart. The requirements of this subpart apply to child health assistance provided under a separate child health program and do not apply to Medicaid expansion programs even when funding is based

on the enhanced Federal medical assistance percentage. We received no comments on this section and have retained the language in this final rule.

2. Child Health Assistance and Other Definitions (§ 457.402)

Proposed § 457.402 set forth the definition of child health assistance as specified in section 2110(a) of the Act. We did not propose to include any additional services in the definition of child health assistance or attempt to further define the services set forth in the Act in order to give States flexibility to provide these services as intended under the statute. Accordingly, we proposed that the term ''child health assistance'' means payment for part or all of the cost of health benefits coverage provided to targeted low-income children through any method described in § 457.410 for any of the following services as specified in the statute:

- Inpatient hospital services.
- Outpatient hospital services.
- Physician services and surgical services.
- Clinic services (including health center services) and other ambulatory health care services.
- Prescription drugs and biologicals and the administration of such drugs and biologicals, only if such drugs and biologicals are not furnished for the purpose of causing, or assisting in causing, the death, suicide, euthanasia, or mercy killing of a person.
- Over-the-counter medications.
- Laboratory and radiological services.
- Prenatal care and prepregnancy family planning services and supplies.
- Inpatient mental health services, other than inpatient substance abuse treatment services and residential substance abuse treatment services, but including services furnished in a State-operated mental hospital and including residential or other 24-hour therapeutically planned structured services.
- Outpatient mental health services, other than outpatient substance abuse treatment services, but including services furnished in a State-operated mental hospital and including community-based services.
- Durable medical equipment and other medically related or remedial devices (such as prosthetic devices, implants, eyeglasses, hearing aids, dental devices and adaptive devices).
- Disposable medical supplies.
- Home and community-based health care services and related supportive services (such as home health nursing services, personal care, assistance with activities of daily living, chore services, day care services, respite care services, training for family members and minor modification to the home.)
- Nursing care services (such as nurse practitioner services, nurse midwife services, advanced practice nurse services, private duty nursing, pediatric nurse services and respiratory care services) in a home, school, or other setting.
- Abortion only if necessary to save the life of the mother or if the pregnancy is the result of rape or incest.
- Dental services.
- Inpatient substance abuse treatment services and residential substance abuse treatment services.
- Outpatient substance abuse treatment services.
- Case management services.
- Care coordination services.
- Physical therapy, occupational therapy, and services for individuals with speech, hearing and language disorders.
- Hospice care.
- Any other medical, diagnostic, screening, preventive, restorative, remedial, therapeutic, or rehabilitative services (whether in a facility, home, school, or other setting) if recognized by State law and only if the service is prescribed by or furnished by a physician or other licensed or registered practitioner within the scope of practice as defined by State law; performed under the general supervision or at the direction of a physician; or furnished by a health care facility that is operated by a State or local government or is licensed under State law and operating within the scope of the license.
- Premiums for private health care insurance coverage.
- Medical transportation.
- Enabling services (such as transportation, translation, and outreach services) only if designed to increase the accessibility of primary and preventive health care services for eligible low-income individuals.
- Any other health care services or items specified by the Secretary and not excluded under this subchapter.

We proposed to define the terms ''emergency medical condition,'' ''emergency services, and ''post-stabilization services'' to give full meaning to the statutory requirement at section 2102(a)(7)(B) of the Act that States assure access to emergency services consistent with the President's directive to Federal agencies to address the Consumer Bill of Rights and Responsibilities, which includes the right to access to emergency services. We proposed to define the term ''emergency medical condition'' as a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in—

- Serious jeopardy to the health of the individual or, in the case of a pregnant woman, the health of a woman or her unborn child;
- Serious impairment of bodily function; or
- Serious dysfunction of any bodily organ or part.

We proposed to define the term ''emergency services'' as covered inpatient or outpatient services that are furnished by any provider qualified to furnish emergency services without requirement for prior authorization and needed to evaluate or stabilize an emergency medical condition. Because these terms are used throughout the regulation, we have moved the definitions of ''emergency services'' and ''emergency medical condition'' to § 457.10, the overall definitions section. The comments and responses related to these definitions are addressed in § 457.10.

We proposed to define ''post-stabilization services'' to mean covered medically necessary non-emergency services furnished to an enrollee after he or she is stabilized related to the emergency medical condition.

We proposed to define ''health benefits coverage'' as an arrangement under which enrolled individuals are protected from some or all liability for the cost of specified health care services.

Comment: A commenter agreed that our definition of ''child health assistance'' is appropriate and considered the specific identification of advanced practice nursing services at § 457.402(a)(14) to be crucial to ensuring that children in fact receive the care to which they are entitled by statute.

Response: We appreciate the commenter's support for our definition. The proposed regulation set forth the definition of child health assistance as specified in section 2110(a) of the Act. The provision of advanced practice nursing services is specifically identified in that section as a coverable service.

Comment: One commenter questioned why well-baby care, well-child care and immunizations are not explicitly included in the list of definitions. These benefits are the cornerstone of pediatric care and the commenter indicated that it is important that they are explicitly included wherever appropriate.

Response: Section 2102(a)(7) of the Act provides the authority for requiring that well-baby and well-child care and immunizations be included under every State plan. Well-baby and well-child care and immunizations were not specified in the statutory definition of ''child health assistance'' at section 2110 of the Act, although they clearly fall within this definition of ''child health assistance.'' Additionally, well-baby and well-child care are not separate categories of services, but can include services that are in any or all of the separately defined categories of services. However, because these terms are used throughout the regulation we have included them in the definitions at § 457.10. These services are also discussed at §§ 457.410 and 457.520.

Comment: One commenter was concerned about the definition of post-stabilization services and the language in the preamble stating that HCFA would expect States and their contractors to treat post-stabilization services in the same manner as required for the Medicare and Medicaid programs, while recognizing that not all such services would be necessarily covered by the State for purposes of SCHIP.

While the commenter did not object to permitting States to apply to separate child health programs an interpretation of post-stabilization services that is the same as that under Medicaid and Medicare, they believed that HCFA should give States flexibility to treat the coverage of post-stabilization services differently depending upon the structure of the State program. A State that designs its separate child health program to mirror its Medicaid program would want to retain the same interpretation for both programs. However, a State that models its program after commercial coverage would want to adopt an interpretation that is applicable to commercial coverage that is offered by MCEs. Such flexibility would be particularly important if the State decides to provide coverage to SCHIP eligibles by purchasing coverage from employer group health plans to cover children. In those cases, the emergency services requirement should parallel those applicable to the employer's group health insurance coverage. The commenter recommended that the proposed regulation be revised to reflect this needed flexibility.

To the extent that States adopt or HCFA requires use of the interpretation of the post-stabilization services requirements applicable under the Medicaid and Medicare programs, the commenter reiterated its comments on the Medicaid managed care notice of proposed rulemaking and the interim final Medicare+Choice regulation. The issue of concern to this commenter was whether the requirement that Managed Care Entities (MCEs) respond to requests for approval of post-stabilization services within one hour is reasonable.

The commenter expressed considerable concern about requirements for post-stabilization care for MCEs, particularly the requirement that MCEs respond to requests for approval of post-stabilization care within one hour. The commenter suggested conditions to moderate the effect of this requirement.

Response: We agree with the commenter that States should have the flexibility to treat coverage of post-stabilization services differently depending on the health benefits coverage elected by the State. The preamble to the proposed rule may have been misleading by appearing to require the provision of post-stabilization services under a separate child health program, therefore, we have removed the references to post-stabilization services, covered or otherwise, from the final rule. We hope that this will minimize confusion.

Comment: Several commenters on proposed § 457.995 had other concerns regarding the provision of post-stabilization services for individuals in managed care. These commenters expressed concern that managed care organizations should be allowed to control their own networks. A payment network needs the flexibility to require a patient to be transferred to an appropriate facility within its network after the emergency has been stabilized. According to these commenters, this regulation takes the control of non-emergency services away from the network and gives it to a non-network provider and could defeat the concept of managed care. The commenters believed that when emergency care is provided outside of the MCE network, it is usual and customary for the patient to be transferred to an appropriate facility within their MCE network for required post-stabilization services.

Response: Proposed § 457.995(d), the provision in the overview of beneficiary rights referencing post-stabilization services, has been removed from the regulations text along with the rest of § 457.995 for the sake of clarity and consistency.

Comment: One commenter noted that the preamble to the proposed rule indicates that HCFA considered defining transportation to include coverage for transportation to more than primary and preventive health care as stated in the law. However, the commenter noted that HCFA decided to leave the option of establishing the definition to the States. The commenter regarded transportation as including urgent and emergent care and that transfer/transport to a hospital or health facility for urgent and emergent care should be included in a child's health benefit package.

Response: Under the list of services in section 2110(a) of the Act and § 457.402 of this final regulation, transportation is mentioned in two different items: (26) medical transportation and (27) enabling services (such as transportation, * * *). While coverage for transportation services is not required, almost every State already provides coverage for emergency transportation under its State plan. Therefore, we do not see lack of coverage of this service as a problem and will not further define transportation services.

Comment: We received several comments on proposed § 457.402(a)(26), redesignated as paragraph (27), which provides for enabling services (such as transportation, translation, and outreach services) only if designed to increase the accessibility of primary and preventive health care services for eligible low-income individuals. One commenter indicated that States should be required to fund community health centers to provide outreach activities and enabling services such as translation and transportation (rather than, or in addition to, outreach costs that are reimbursed under administrative accounts).

Several other commenters indicated that the phrase ''outreach services * * * only if designed to increase the accessibility of primary and preventive health care services for eligible low-income individuals'' is ambiguous and requested clarification. They noted that this phrase could be read to permit a State to pay primary health providers such as health centers to conduct outreach activities to find eligible children as part of their overall child health assistance services (rather than, or in addition to, outreach costs that are reimbursed under administrative accounts). The commenter noted that this is important because the SCHIP statute caps States' overall administrative costs and thus has been viewed as providing insufficient funds to support the types of outreach efforts that experts say are necessary to find eligible children. To the extent that the phrase ''outreach * * * to eligible low-income individuals'' is interpreted as the identification of eligible children, then this represents an important option

for States and health centers. States could build outreach funds into their payments to SCHIP primary care providers, along with funding for other forms of enabling services, such as translation and transportation costs.

In the context of payment to primary health care providers, one commenter also indicated that States could build funds for outreach and enabling services into their payments to SCHIP primary care providers. The commenter indicated that community clinics and health centers in its State are encountering difficulties and confusion when being audited for purposes of receiving cost-based reimbursement from the State.

Response: In developing their State plans, States determine their own providers. We cannot require that community health centers be funded to provide outreach and enabling activities. The language of proposed § 457.402(a)(26) was taken directly from the language at section 2110(a)(27) of the Act. Enabling services, including outreach to assist children's access to primary and preventive care, are one of the types of services States may choose to provide as part of the ''child health assistance'' that meets the requirements of section 2103 of the Act. We note that under the terms of section 2110(a) and 2110(a)(27), these services must be delivered to ''targeted low-income children'' who are ''eligible'' for ''child health assistance'' under the State plan. Therefore, when enabling services are provided as part of the health benefits coverage for children who are found eligible and enrolled, these services would not be subject to the 10 percent cap on administrative expenditures under 2105(c) of the Act. However, outreach initiatives to potentially eligible children are subject to the 10 percent cap in accordance with section 2105(a)(2)(C) of the Act. We do not understand the commenter's specific concerns regarding difficulties in receiving cost-based reimbursement in the State's community clinics and health centers so we are unable to respond to this comment. (We note that, in this final rule, we have listed physician services and surgical services (proposed § 457.402(a)(3)) separately as paragraphs (3) and (4), respectively. As a result, the services listed at paragraphs (a)(4) through (a)(27) have been redesignated as paragraphs (5) through (28). Enabling services are now listed at paragraph (27).)

Comment: One commenter noted its belief that the preamble should encourage States, in selecting among benefits to cover, to consider the needs of different age groups, their varying health status and patterns of morbidity and mortality, the impact of developmental states on their needs and their patterns of utilization. They observe, for example, that coverage of over-the-counter medications may be of particular benefit to adolescents. Also, eating disorders are more common among adolescents than younger children, and family planning services should include a choice among all contraceptive methods and options.

Response: We concur with the commenter and encourage States to consider the populations they are serving and the needs of different age groups when designing their benefit package States need only cover medically necessary and appropriate services, but the statute at section 2102(a)(7) and the regulations at § 457.495, specifically require States to specify the methods they will use to assure appropriate care.

Comment: Two commenters noted that the language on services in the proposed rule was set out identically to the language in the statute. The commenters were concerned that the definition of both inpatient and outpatient mental health services excludes substance abuse treatment services, which are listed separately in the statute and the regulation. One commenter was concerned that this separation means only that payment may be made for these services, not that payment shall be made for these services and believes that States should be encouraged to consider their inclusion for comprehensive treatment for adolescents with co-occurring mental and substance abuse disorders.

Similarly, another commenter is concerned that the separation of outpatient substance abuse treatment services may allow the provision of outpatient mental health services but not the provision of outpatient substance abuse services, but would include services furnished in a State-operated mental hospital and community-based services. The commenters indicated that substance abuse impacts a significant number of children in their States and rather than removing this important benefit, they recommended that the regulations need to encourage and even highlight the importance of offering this benefit.

The commenter noted that while the listings for mental health inpatient and outpatient services in the regulations specifically exclude substance abuse services, these services are listed separately from inpatient and outpatient mental health services. The commenter called attention to this because of the high incidence of co-occurring disorders among adolescents with presenting symptoms of one or the other. Even though these services lack the 75 percent actuarial measure required when mental health services (and/or prescription drugs, vision and hearing services) are included, States should consider their inclusion for comprehensive treatment of adolescents with co-occurring mental and substance abuse disorders.

Response: We appreciate the commenter's view about the importance of respite care services. As we have indicated previously, the proposed rule at § 457.402 mirrors the language of section 2110(a). Therefore, inpatient mental health services and inpatient substance abuse treatment services, as well as outpatient mental health services, and outpatient substance abuse treatment services are listed separately in the regulation as they were in the statute. States choose to cover services from the list of services under the definition of ''child health assistance'' when they select a health benefits coverage option under § 457.410. The statute supports mandating that only three types of services, well-baby and well-child services, immunizations, and emergency services, be included in all SCHIP plans regardless of the type of health benefits coverage chosen. HCFA encourages States to provide inpatient and outpatient substance abuse services. A State may choose to provide inpatient mental health and substance abuse services; however the statute provides flexibility for the States in determining the scope of covered benefits.

We do, however, call the commenter's attention to the requirement in § 457.120 of the regulations for ongoing public input in the development and implementation of SCHIP plans. Comments and concerns about benefits and coverage should be directed to and taken under consideration by the State SCHIP agency. We encourage States to consider the populations they are serving and the needs of different age groups when designing their benefit packages.

Comment: One commenter particularly noted the inclusion in § 457.402 of ''respite care services and training for family members,'' which are especially relevant to families with children with severe and persistent mental illness or brain disorders. The commenter stated that it would appreciate attention being called to these services' eligibility for coverage and relevance in plans that offer supplemental mental health services, in addition to other services, ''*i.e.,* respite care, advanced practice nurse services,

and pediatric nurse services * * * in a home, school or other setting.''

Response: As we have indicated previously, States that implement separate child health programs are given broad flexibility to design their benefit packages. We encourage commenters to work with their States to assure that valuable health care services are made available to children to the extent possible in each State.

Comment: One commenter recommended § 457.402 be deleted because the statute provides States with flexibility in the design of the SCHIP benefit package and this section implies that coverage for certain services should be available under SCHIP when it is not required by statute and may not be included in the state-designed benefit package.

Response: Section 2110 of the Act allows for payment for part or all of the cost of health benefits coverage (as defined at § 457.10) for any services listed in section 2110(a) of the Act as implemented in § 457.402. These provisions do not indicate that States must provide all of these services; rather, they list the array of services for which payment may be made. We disagree with the commenter and have not deleted this section from the proposed rule.

3. Health Benefits Coverage Options (§ 457.410)

Under the authority of section 2103 of the Act, at proposed § 457.410, we listed the four options a State has for obtaining health benefits coverage for eligible children. Specifically, we proposed that States may choose to provide benchmark coverage, benchmark-equivalent coverage, existing comprehensive State-based coverage, or Secretary-approved coverage. These four options are described at §§ 457.420 through 457.450.

Based on the authority of section 2102(a)(7) of the Act, we also proposed at § 457.410(b) to require that a State must obtain coverage for well-baby and well-child care, immunizations in accordance with the recommendations of the Advisory Committee on Immunization Practices (ACIP), and emergency services. We noted that the State must cover these services even if coverage for these services is not generally included in the health benefits coverage option selected by the State.

We proposed to define well-baby and well-child care for purposes of cost sharing at proposed § 457.520(b), but we proposed to allow States to define well-baby and well-child care for coverage purposes. We encouraged States, however, to adopt the benefits and periodicity schedules recommended by a medical or professional organization involved in child health care when defining well-baby and well-child care coverage.

Comment: Two commenters supported the requirement that States use the ACIP schedule for immunizations under their separate child health programs. However, many commenters disagreed with the proposal that States be required to follow the immunization schedule of the ACIP, particularly because they are not allowed to participate in the VFC program. It was suggested that States should be able to adopt their own immunization periodicity schedules. One commenter suggested that we rewrite this section to require ''immunizations as medically necessary'' rather than require that immunizations be provided according to the ACIP schedule. Several commenters suggested that a State that utilizes existing commercial health plans may not use any particular standard immunization schedule or may follow other professional standards. One commenter mentioned that its State uses another standard, the recommended childhood immunization schedule jointly adopted by the American Academy of Pediatrics (AAP), the ACIP, and the American Academy of Family Physicians (AAFP).

Response: Section 2102(a)(7)(A) requires that a State child health plan include a description of a State's methods to assure the quality and appropriateness of care, ''particularly with respect to * * * immunizations provided under the plan.'' In order to ensure that all SCHIP children are appropriately immunized, States should use a uniform, nationally recognized schedule of immunizations. The ACIP schedule referred to in the proposed rule is a harmonized schedule approved by the ACIP, the AAP, and the AAFP. It is referred to as the ''Childhood Immunization Schedule of the United States.'' The AAP and AAFP no longer develop and maintain separate immunization schedules but rather use the harmonized ACIP schedule. This ACIP schedule is the same as the standard referenced by one of the commenters as the schedule relied on by its State. States should use the ACIP schedule because it reflects the current standards of these pediatric speciality providers who are the recognized authorities in childhood immunizations.

Comment: Several commenters expressed their belief that requiring SCHIP programs to use the ACIP immunization schedule is overly prescriptive and has no basis in the statute. According to one commenter, the only statutory limit on States' discretion is found in section 2102(a)(7)(A), which indicates that the State plan must include a description of the methods used to assure the quality and appropriateness of care, particularly with respect to immunizations. The commenter cited Executive Order 13132 on federalism, and asserted that, consistent with that authority, States should be permitted to select their own immunization standards unless HCFA can demonstrate both a need for a federal standard and that it has considered alternatives that would preserve the States' prerogatives.

Response: As described in the response to the previous comment, section 2102(a)(7)(A) of the Act provided authority to require immunizations in accordance with the recommendations of ACIP. Therefore, the requirement to use the ACIP schedule is not a violation of E.O. 13132. The ACIP schedule is a national standard developed and approved by three national medical organizations involved in child health care services, the ACIP, the AAP and the AAFP. These organizations use the harmonized ACIP immunization schedule and no longer use separate immunization schedules. Requiring coverage for appropriate immunizations at appropriate times, as the ACIP schedule recommends, does not place undue burden on States given the importance of childhood immunizations. In fact, it releases States from the burden of having to develop or choose their own individual schedules and establish the adequacy of those schedules with respect to title XXI statutory requirements. Given the unique nature of infectious diseases, and the mobility of the population across State lines, it is necessary to require a uniform approach to immunizing children across all States.

Comment: One commenter believed the 90-day requirement explained in the preamble to the proposed rule for States to adhere to any changes in the ACIP recommendations is inappropriate. The current policy is that States have 90 days from the publication of the revised ACIP schedule in the Morbidity and Mortality Weekly Report to implement those changes in their programs. The commenter believed that this requirement fails to recognize the realities of effectuating such a change in benefits. States should have until the end of the current contract period but in no case longer than one year to comply with any ACIP changes.

Response: It is essential for children to receive vaccines according to the most current ACIP recommendations in

order to maximize children's health, minimize morbidity and mortality, and reduce costs of treating preventable disease. In addition, good public health policy argues for consistent adoption of vaccine recommendations across all States in order to minimize the potential for transmission of communicable disease.

Comment: One commenter expressed its opinion on the importance of children in separate child health programs receiving all necessary immunizations and of vaccines being incorporated in all benefit packages. The commenter also suggested two ways that States may provide immunizations through their SCHIP programs without opening up the VFC program: (1) a State may add on payments for the provision of immunizations through participating MCEs; or (2) the State may declare that children enrolled under a separate child health program are State vaccine eligible. The State may then purchase the vaccines at the Federal contract price and distribute them to SCHIP providers as it currently does for Medicaid providers. The commenter stated that expenditures under either of these options would be matched by the Federal government at the SCHIP enhanced matching rate and would not count as administrative expenditures under the 10 percent cap. Additionally, the commenter believed that the State should require that plan contracts include provisions that require plans to provide and cover additional expenses for vaccines that are approved and recommended for all children during the life of the contract.

Response: We agree with the commenter that children in separate child health programs should receive all recommended immunizations, as should children in Medicaid expansion and combination programs. Also, regardless of the type of child health insurance program the State chooses, we agree with the suggestion that MCE contracts should provide that the MCEs furnish all vaccines, including new vaccines, recommended during the term of the contract.

However, regardless of whether the State chooses to include such a contract provision, States must furnish vaccines in accordance with the recommendations of the ACIP. States should furnish newly recommended vaccines to all eligible children within 90 days after the recommendation is published in Morbidity and Mortality Weekly Report. This report is available over the Internet at *www.cdc.gov/mmwr.*

We outlined ways that States could take advantage of the Federal discount contract price for vaccines in a letter dated June 25, 1999 to all State Health Officials. As stated in that letter, expenditures for vaccines will be matched by the Federal government at the enhanced SCHIP matching rate and will not count as expenditures subject to the 10 percent cap on administrative expenditures under section 2105(c)(2) of the Act, regardless of whether the State takes advantage of the Federal discount contracts.

Comment: Many commenters recommended that HCFA reconsider its position on the Vaccines For Children (VFC) program for various reasons. One commenter indicated that in light of national immunization goals not yet having been achieved, HCFA should not consider SCHIP enrolled children to be insured and therefore ineligible for free VFC vaccines. Several commenters expressed that States that have elected to implement separate child health programs are being unfairly penalized for not choosing to expand their Medicaid programs.

One commenter indicated that because the SCHIP statute states absolutely that the legislation creates no entitlement, and because the VFC program defines insurance as benefits to which an individual is entitled, it would appear to be clear that, despite their eligibility for SCHIP, children in separate child health programs are not entitled to insurance and thus should be considered VFC-eligible. One commenter also stated that having seen polio epidemics and iron lung machines, HCFA should be working to reduce barriers that prevent many children from getting vaccinated so that epidemic childhood diseases do not become more prevalent in the United States as they are in other countries. One commenter believed that the interpretation of section 316 of the Public Health Service Act, which is used to support the policy that separate child health programs are not eligible to participate in VFC, is overly strict and does not align with the intent of the Act to insure that children receive necessary immunizations.

Response: We agree with the commenter that the intent of the statute is that all children should receive necessary immunizations, and therefore require at § 457.410(b)(2) that all States with separate child health programs provide coverage for immunizations in accordance with the recommendations of the ACIP. We disagree with the commenters only as to whether the VFC program or SCHIP funds cover the cost of required immunizations. We disagree that the VFC program allows payment for immunizations provided to a child enrolled in a separate child health plan. As explained in a letter to State Health Officials of May 11, 1998, section 1928(b)(2) of the Act defines a ''Federally vaccine-eligible child'' or a child who is entitled to free Federal vaccines under the VFC program, as ''a Medicaid-eligible child, * * * a child who is not insured, * * * a child who is (1)administered a qualified pediatric vaccine by a Federally-qualified health center * * * or a rural health clinic * * * and (2) is not insured with respect to the vaccine, [or] a child who is an Indian * * * '' The law further defines the term ''insured'' as a child '' * * * enrolled under, and entitled to benefits under, a health insurance policy or plan, including a group health plan, a prepaid health plan, or an employee welfare benefit plan under the Employee Retirement Income Security Act of 1974 * * * '' The distinction between Medicaid coverage and other coverage is created by the VFC statute. Under the SCHIP statute, it is clear that children who are enrolled in a separate child health program must not be Medicaid-eligible, as explained in § 457.310(b)(2) of these regulations. They are enrolled under, and entitled to benefits under, a health insurance policy or plan within the definition in section 1928 (b)(2)(B)(ii), as explained above, and their insurance covers the cost of vaccines. Although there is no Federal entitlement to SCHIP coverage, a child who is enrolled in a SCHIP-funded plan is ''entitled'' to coverage under that plan just as a child enrolled under a group health plan is ''entitled'' to coverage under the group health plan. Unless they are Indians, children enrolled in SCHIP are not Federally vaccine-eligible under current law. Therefore, the Secretary cannot reconsider her decision on this matter without a change in the law that would define a child enrolled in a separate child health program as a Federally vaccine-eligible child.

Comment: One commenter indicated that it appears that the exclusion of SCHIP children from the VFC program would cause the SCHIP program to be less cost effective than the Medicaid program. The commenter asked if this policy means that States may use this provision as a cost offset in discussions of the revenue neutrality of the SCHIP program design. The Federal government, by design, assures that the SCHIP program will be more expensive in that it must pay for a service that is free under Medicaid.

Response: We do not understand the intent of this comment, as the concept of budget neutrality does not apply to the SCHIP program design. While immunizations are required to be

covered under a separate child health plan, States have discretion to determine what other services will be provided under their State plans, and the amount, scope, and duration of those services.

Comment: One commenter noted that it is crucial that any expansion of health care services in State plans include coverage for essential oral health care benefits. Historically, the number of dentists participating in State Medicaid programs is low. This low participation has prevented most poor children from developing good oral hygiene habits. SCHIP allows States to include oral health care services in their State plans and the commenter urged HCFA to consider this as an important component of increasing the overall health of America's rural children as the agency reviews State plans.

Response: We agree with the commenter that oral health is an integral part of the overall health of children and have engaged in a serious effort to promote oral health, as described earlier in a response to comments on this subpart. However, we do not have the statutory authority to require that States provide any specific services under their SCHIP plans other than those required under sections 2102(a)(7)(A) and 2103(c) of the Act. Although we do not have the authority to require the inclusion of these services, because of the importance of oral health services for children, we have included in the definition of well-baby and well-child care, for purposes of cost-sharing restrictions at § 457.520(b)(5), routine and preventive and diagnostic dental services. Accordingly, a separate child health plan may not impose copayments, deductibles, coinsurance or other cost-sharing for these services. Nonetheless, all but two States with separate child health programs have opted to provide coverage for some type of oral health services.

Comment: One commenter recommended that the regulation clarify that children enrolled under a Medicaid expansion program are entitled to all medically necessary services to the same extent as under the Medicaid EPSDT service and that the services for these children would not be considered a State option.

Response: The regulation indicates in § 457.401(c) that the information in this subpart does not apply to Medicaid expansion programs. Therefore, because this subpart addresses only provisions regarding separate children's health insurance programs, we have not added additional language to the regulation text to indicate that children enrolled under Medicaid expansion programs are eligible for Medicaid's EPSDT services. However, as we have made clear in the preamble to the proposed regulation and in other guidance, all Medicaid benefit rules, including rules requiring EPSDT services, apply fully to children enrolled in Medicaid expansion programs.

Comment: One commenter noted that the Medicaid program includes coverage for children with serious and severe mental illnesses. The commenter urged HCFA to collaborate with those States opting to develop separate child health programs to provide health coverage for the same level of treatment and service currently provided by Medicaid. Another commenter noted the importance of behavioral health as an integral part of a child's overall well being. According to this commenter, while rural families and children suffer mental disorders similar to those suffered by their urban counterparts, rural residents are less likely to receive treatment in part because of the extreme lack of behavioral health professionals in rural communities. The commenter strongly supported inclusion of coverage for mental health services in the State plans for the SCHIP program.

Response: We agree that mental health is an integral part of the overall health of a child and we urge States to consider providing these services. However, a requirement that States include any specific services in their State plans other than those required under 2102(a)(7)(A) and 2103(c) of the Act and specified under § 457.410(b) would be inconsistent with title XXI.

Comment: One commenter asked why the discussion of § 457.410(b) in the preamble to the proposed regulation about offering different health benefits coverage for children with special needs refers only to children with physical disabilities, and not mental disabilities. Such children may be encompassed within the category of special needs, but the additional listing only of physical disabilities gives the false impression that disability cannot be mental as well.

Response: We did not intend to exclude any type of illness, physical or mental, by using the example of children with physical disabilities in discussing the States' option to offer different health benefits coverage. The preamble noted that States can have more than one benefit package that meets the requirements of the subpart, including one designed for children with special needs or physical disabilities. We were simply giving one example of a population to which States may want to consider offering additional services or a special package of services and did not mean to offer the example as the only option. States should consider the needs of children with mental disabilities as they consider whether to adopt benefit packages designed specifically for children with special needs.

Comment: One commenter supported the preamble language to proposed § 457.410, which indicates that States can include in their comprehensive health benefits package ''supplemental services for children with special needs or physical disabilities'' and alternatively may offer multiple benefit packages. Such an approach permits States to expand services to children with special health care needs without regard to the 10 percent cap on Federally-matchable expenditures ''for other than the comprehensive services packages.'' The commenter supported this approach to increasing States' ability to help such children.

However, numerous commenters were concerned with this language in the preamble to proposed § 457.410. Several commenters expressed concern about the language in the proposed rule stating that if a State offers a supplemental package of limited services for children with special health care needs that is not part of the comprehensive coverage required by the regulation, then expenditures for those extra services would be counted against the 10 percent cap on administrative expenses under section 2105(c)(2) of the Act. They noted that a number of States have implemented SCHIP with supplemental benefits packages, or ''wrap-around packages'', for coverage of services for eligible children with special health care needs and that this is an important, appropriate and beneficial strategy for the provision of needed health care services for children. They indicated that requiring that expenditures for services for children with special health care needs count against the 10 percent cap would encourage States to limit the services that are offered to these children, which could affect their overall health and well being. The commenters argued very strongly that services for children with special health care needs that are provided through an additional limited benefits package should not be counted against the 10 percent cap, and that making them subject to the cap has the potential to discourage the development of creative benefit packages for children with special needs.

Two commenters questioned whether the Department intended to indicate that such initiatives are subject to the 10 percent administrative cap as section 2105(a)(2) makes no mention of special needs. The commenters recommended

that the preamble be modified by dropping the reference to special needs since this reference may be misconstrued when States are designing and implementing certain benefit packages for special needs children. The commenters indicated that the statute contemplates that there are permissible health initiatives which would be subject to the 10 percent cap and suggested that this section of the preamble be written to identify the types of initiatives subject to the limitation without calling into question those benefits packages for children not subject to the 10 percent cap.

One commenter cautioned States about the manner in which they define children with special health care needs. The commenter provided suggested language that States should be encouraged to use to define children with special health care needs.

One commenter believed that the explanation of required coverage in the preamble to the proposed rule forces States either to provide a comprehensive benefit package that is above and beyond the needs of the ''average'' child in order to ensure that the needs of special needs children are met, or to put administrative dollars at risk. By providing such a comprehensive benefit package, the capitated rate paid to health plans to pay for such services will significantly increase.

One commenter also noted that while the rules permit separate packages of services consistent with the ADA, the 10 percent cap is troubling and it is unclear what the potential impact will be or if this could penalize children and their families in unexpected ways.

Response: Unfortunately, the language in the preamble to the proposed rule about the application of the 10 percent administrative cap in connection with supplemental services for children with special needs caused much confusion to commenters. We will attempt to clarify below.

Under section 2105(a)(1), States may receive enhanced FMAP for expenditures for child health assistance for targeted low-income children provided in the form of health benefits coverage that meets the requirements of section 2103 of the Act. Under section 2105(a)(2) States may receive payment of a federal share of State expenditures for other items but expenditures for these other items are subject to the 10 percent administrative cap under section 2105(c)(2). A State has two options for providing more health benefits coverage to special needs children under which the expenditures for the coverage are not subject to the 10 percent cap on administrative expenditures. The first option would be for the State to have a separate eligibility group for the identified special needs children with a larger health benefits package than for other eligibility groups. The State would have to design the eligibility group without violating the statutory requirement under section 2102(b)(1)(a) of the Act that the eligibility standards ''not discriminate on the basis of diagnosis.'' The second option would be for the State to retain the general eligibility group that includes all children and include in the health benefits coverage package coverage for services needed by special needs children. The package could include limitations for coverage on these services (consistent with other benefits requirements) to ensure that they would be available primarily to special needs children. Under either option, the special needs coverage is part of an overall health benefits coverage package that is consistent with section 2103 of the Act and § 457.410 of the final regulation.

One key aspect of section 2105(a)(2) is that SCHIP funds can be used for health services initiatives for targeted low-income children as well as other low-income children. With respect to the suggestion that we include some examples of public health initiatives that would be subject to the 10 percent cap, we are including the following examples, some of which were proposed by one State: (1) access to mental health services for low-income children in the Juvenile Court System; (2) health care outreach and services for homeless children and adolescents; (3) mental health services for low-income children with special needs; (4) dental care for low-income children and their families; (5) health care services for migrant children; and (6) an immunization project for low-income children who are not enrolled in Medicaid or SCHIP. As we indicated, these are just a few examples for use of title XXI funds for public health initiatives as authorized by section 2105(a)(2) of the Act. States are free to develop and propose initiatives which are specific to the needs of their population.

Comment: One commenter noted that it was pleased that we have included a reference to Bright Futures in the proposed rule but encouraged that we use the term ''well-adolescent'' whenever we refer to ''well-child'' and the term ''age'' when offering examples of diverse populations.

Response: Under the definition of ''child'' set forth in section 2110(c)(1) of the Act, and implemented in § 457.10 of this final regulation, ''child'' is an ''individual under the age of 19.'' An adolescent clearly fits within this definition of child, and therefore we have not accepted the commenter's suggestion to use the term ''well-adolescent'' whenever we refer to well-child care. In addition, as we explained above, we did not intend to exclude any particular group or condition in describing a special population that States may want to consider offering additional services or a special package of services. Therefore, we have not added ''age'' to the example we used in the preamble.

Comment: One commenter indicated that there are various ways for separate child health programs to make health benefits coverage available to enrolled children. States may use direct, fee-for-service coverage or can operate as primary care case managers. Separate child health programs can also buy benchmark or benchmark-equivalent coverage provided through an MCE. The commenter went on to say that what is listed as a class of covered benefits in the State plan may not be precisely what is covered if the State chooses to offer coverage solely through a benchmark or benchmark-equivalent package that is purchased from a participating insurer or MCE. Furthermore, the insurer or MCE may apply limits to coverage that would not apply if the coverage were obtained directly through the State-based plan. Finally, the proposed rules on coverage do not require any particular standard for the measurement of medical necessity for children, either by the State or by benchmark insurers.

According to the commenter, because the benchmark plans may differ from the State comprehensive package and no specific medical necessity standard is required for separate child health programs, the issue of disclosure of coverage and coverage limitations becomes important. Both providers and families will need to have clear, understandable materials and information regarding what is and is not covered, as well as the limitations that apply to covered benefits. The commenter cautioned that benchmark plans may not be appropriately designed for children; for example, the plan may provide coverage for speech therapy after a stroke but no coverage for speech therapy to address developmental delays. There is nothing in the proposed rule that requires benchmark plans to be designed to meet the specific health needs of children.

Response: In order for a State plan to be approved, the State must indicate what type of health benefits coverage it is electing to provide. The State must make available to enrollees the full

coverage package defined in its State plan, and may not permit contractors to restrict that coverage. While neither the State nor a contractor is required to furnish medically unnecessary services, they cannot alter the basic coverage package from that specified in the State plan.

Because SCHIP is targeted for children under the age of 19, States must ensure that the health benefits coverage it elects to provide is appropriate for the population being served. The statute addresses the issue of appropriateness of coverage through the coverage requirements at section 2103 of the Act, which sets forth the required scope of health insurance coverage under a separate child health program. In addition, based on the authority of section 2102(a)(7) of the Act, we have required coverage for well-baby and well-child care, immunizations and emergency services. Finally, if a State elects to use benchmark-equivalent coverage, it must cover specific services listed at section 2103(c)(1) of the Act and be actuarially equivalent for additional services covered under one of the benchmark benefit packages. While we have not defined medical necessity for purposes of separate child health programs, we believe that the requirements of the statute and final regulations ensure the appropriateness of coverage for children in separate child health programs.

With respect to the commenter's concerns regarding the availability of understandable materials, we refer the commenter to the requirements at § 457.110(b) and § 457.525 which discuss the requirements for making certain information available and for information on the public schedule for cost sharing.

Comment: Several commenters agreed with HCFA's suggestion in the preamble to proposed § 457.410 that SCHIP programs use the AAP guidelines and/or Bright Futures periodicity schedules. However, they did not agree with HCFA's reasoning for not requiring States to adopt this definition of well-baby and well-child for benefit coverage. One commenter indicated that Medicaid guarantees children coverage of medically necessary services through EPSDT, while separate child health programs do not provide the same guarantee. It is therefore more critical and appropriate for HCFA to place specific requirements on the provision of services because there is no underlying entitlement, and HCFA should establish an appropriate floor. Another commenter indicated that because Medicaid uses the EPSDT standard for its schedule of periodicity, the schedule should be included for SCHIP coverage to be consistent and allow parity. Rather than merely recommending periodicity schedules, HCFA should require that an endorsed professional standard be adopted by SCHIP programs. Allowing States to devise their own schedules could leave children in different States with widely different coverage under SCHIP.

Response: For a number of reasons, we are not requiring States to use for coverage and other purposes the definition of well-baby and well-child care that is required for purposes of cost sharing. Specifically, HCFA wanted to assure States the flexibility accorded them under the statute in developing their SCHIP benefit packages, including their well-baby and well-child care packages. In addition, there are several expert groups that have developed professional standards for the delivery of well-baby and well-child care. These standards include those developed by the AAP, AAPD and the Bright Futures standards. HCFA has not endorsed any particular professional standard for well-baby and well-child care for Medicaid and we did not feel we should impose a more stringent standard on SCHIP plans. We have included a definition of well-baby and well-child care for purposes of cost sharing because Congress established basic rules for cost sharing that must be applied on a consistent basis across States.

The commenter is correct that under the Medicaid program, EPSDT services are mandatory for most Medicaid eligible children under the age of 21. However, the SCHIP statute did not require this comprehensive service package for children in separate child health programs but rather gave States the flexibility to design their own benefit packages within certain parameters.

With respect to the use of a specific periodicity schedule, the commenter is incorrect that EPSDT services require any specific periodicity schedule. HCFA cannot, by law, require States to use any particular periodicity schedule for the delivery of EPSDT services under Medicaid. The EPSDT statute at section 1905(r) specifies that each State must develop its own periodicity schedule for screening, vision, hearing and dental services after appropriate consultations with medical and dental organizations involved in child health care. In the proposed rule, we suggested that States use one of the professional standards already developed in determining their well-baby and well-child care benefit packages; however, we have declined to require the use of a specific schedule. There are several professional standards that are acceptable for States to adopt. In fact, many States have adopted one of those standards for use in their EPSDT programs also. This policy does present the possibility, as the commenter suggests, that children may be treated differently in different States. However, this is allowable under title XXI.

Comment: One commenter believed that States should be able to retain discretion to define well-baby and well-child care more broadly than § 457.520 and that HCFA should require States to follow the AAP and Bright Futures periodicity schedules in both Medicaid and SCHIP programs. In particular, many States have not yet adopted a periodicity schedule providing for annual health assessments for adolescents, even though there is consensus among the professional community that adolescents should receive annual assessments.

Response: If a State chooses to define well-baby and well-child care more broadly than defined in § 457.520 for cost sharing purposes in order to limit cost sharing for a broader range of services, the State is free to do so. It is true that some States have not adopted periodicity schedules to allow for annual assessment of adolescents under their Medicaid program. While both programs allow for that flexibility in adopting periodicity schedules, HCFA encourages States to ensure that their periodicity schedules reflect current professional standards.

Comment: One commenter recommended that the AMA's Guidelines for Adolescent Preventive Services (GAPS) be added to the list of appropriate standards for States to consider.

Response: We agree that GAPS is an appropriate standard for States to use in defining well-child care periodicity schedules for adolescents and recommend that States consider this standard as well.

Comment: One commenter reiterated that the preamble language indicates that well-baby and well-child care includes health care for adolescents and is subject to the cost-sharing prohibitions, but is ambiguous as to whether a State has to provide coverage for these services or merely apply the cost-sharing prohibitions to those services that they cover. The commenter believed that States should be required to provide such coverage. The commenter also urged HCFA to add language to the preamble encouraging States to consider the special problems that affect adolescents (for example, eating disorders) when defining special needs.

Response: We appreciate the commenter's concern about adolescents. States are required to provide coverage for well-baby and well-child care services under any separate child health plan but may specifically define those services as they choose. We note that we have revised § 457.410(b)(1) to provide that the State must obtain well-baby and well-child care services as defined by the coverage for the State. Cost sharing is not allowed for any services covered under a separate child health program that are included in the definition of well-baby and well-child care at § 457.520. We have not included language encouraging States to consider special problems that affect adolescents when defining special needs. However, we urge States to consider the special needs of the population being served by the separate child health plan.

Comment: One commenter recommended § 475.410(b) be deleted because the statute provides States with the flexibility to adopt a benchmark plan or to develop an actuarially equivalent benefit package.

Response: We have not adopted this suggestion. The commenter correctly notes that the SCHIP statute provides States with flexibility to adopt benchmark health benefits coverage or actuarially equivalent benefit-equivalent health benefits coverage when designing their programs. However, in accordance with section 2102(a)(7), § 457.410(b) ensures that enrollees in separate child health programs receive coverage for certain basic services.

4. Benchmark Health Benefits Coverage (§ 457.420)

Section 2103(b) of the Act sets forth the benchmark health benefits coverage from which a State may choose in accordance with section 2103(a)(1) of the Act. We proposed to implement these statutory provisions at § 457.420. We proposed to define benchmark health benefits coverage as health benefits coverage that is substantially equal to the health benefits coverage in one of the following benefit packages:

- The Federal Employee Health Benefits Program (FEHBP) Blue Cross/Blue Shield Standard Option Service Benefit Plan with Preferred Provider arrangements;
- A health benefits plan that the State offers and makes generally available to its own employees; or
- A plan offered by a Health Maintenance Organization (HMO) that has the largest insured commercial, non-Medicaid enrollment of any such plan in the State.

We discussed each option for benchmark health benefits coverage in detail in the preamble of the proposed rule. We noted that when a State chooses to increase, decrease, or substitute coverage available under its approved State plan, a State must submit a State plan amendment for approval if the change in benefits is intended to conform the separate State benefit package to the benchmark coverage. But if the change in benefits causes the State offered benefits to differ from the benchmark coverage, then the benefits must be reclassified as benchmark equivalent or one of the other benefit package options.

We also noted that section 2103(a)(1) of the Act provides that benchmark coverage must be ''equivalent'' to the benefits coverage in a reference benchmark benefit package. We stated that we would interpret this language to mean that coverage must be ''substantially equal'' to benchmark coverage. That is, benchmark coverage offered under a separate child health plan should differ from benchmark coverage available in the State only to the extent that the State must add coverage to the benchmark coverage, such as coverage for immunizations, to meet the requirements of title XXI.

Comment: Numerous commenters had requested clarification of when a State plan amendment is required if a benchmark plan changes. These commenters interpreted the language at § 457.20 of the proposed rule to mean that if the benchmark plan the State is using changes, we would not require a State plan amendment; whereas if the State chooses to change the coverage under its State plan to conform to the benchmark plan's changes, a plan amendment would be required. The commenters asked why changes to a State plan that simply parallel changes in a benchmark plan require an amendment given that benchmark plans are supposed to be the standard of adequacy in terms of SCHIP benefits.

Several commenters believed the preamble should be clarified to indicate that an amendment is only required when the SCHIP benefits package is altered.

Response: The approved State plan must accurately reflect the health benefits package being offered. A State must submit a State plan amendment to reflect any change in the health benefits coverage regardless of whether the change is made to conform to changes made in the benchmark plan to which the State's health benefits coverage is supposed to be equivalent, or whether the change is made to select a different health benefits coverage option. See subpart A for further discussion of when a State must submit a State plan amendment.

Comment: One commenter felt that States should not be allowed to amend their State plans to make them less comprehensive in terms of coverage or the benefits they provide. According to this commenter, State plans should only be amended to improve coverage, not to diminish it. A basic package of benefits should be required. In other words, certain benefits should be Federal entitlements. States then have the flexibility to improve that benefit package or to offer only what is Federally required.

Response: States are responsible for determining the health benefits coverage under a separate child health program subject to the standards set by title XXI and implemented in this final regulation. States have the option of choosing from the types of coverage specified in § 457.410 of the proposed rule and in accordance with section 2103 of the Act. States may amend their State plans to decrease the coverage provided as long as all of the requirements of §§ 457.410–457.490 are met, depending on the type of coverage approved in the State plan. The only services required to be covered under every separate child health program are well-baby and well-child care, immunizations according the ACIP schedule, and emergency services as defined in § 457.10.

Comment: One commenter was concerned that a State that is using the benchmark benefit package need not submit an amendment when the benchmark changes and believed this means that if the plan includes mental health services that are subsequently dropped, the State need not file a State plan amendment.

Response: If a State has elected to provide benchmark health benefits coverage that is substantially equal to coverage under a certain benefit plan, and that plan drops coverage for mental health services, the State has two options. First, the State may continue to provide coverage for mental health services as described in its approved State plan, even though the benchmark plan has discontinued this coverage. No amendment is necessary in this case. Alternatively, if the State wants to discontinue providing mental health services under its State plan, it must submit a State plan amendment to reflect the dropped coverage.

Comment: One commenter supported the preamble language on benchmark coverage being able to differ from coverage under a benchmark plan only as necessary to meet other requirements of title XXI.

Response: We appreciate the support. The commenter is correct that benchmark health benefits coverage under § 457.420 may only differ from coverage under the benchmark plan as necessary to meet title XXI requirements. For example, as noted earlier, a State may need to add coverage for immunizations in order to comply with the requirement that they be covered under every separate child health plan.

Comment: One commenter stated that the preamble indicates in discussing § 457.420(c) that ''in calculating commercial enrollment, neither Medicaid nor public agency enrollees will be counted.'' The commenter suggested that all public agency enrollees be counted as commercial enrollees when they are enrolled in a plan offered by a private sector HMO. If it is appropriate to count Federal employees as commercial enrollees, it should be just as appropriate to count any other public employees who are enrolled in the plan. Another commenter recommended that § 457.420(c) be modified to be consistent with the preamble to exclude public agency enrollees. The proposed regulation only excludes Medicaid enrollees.

Response: We agree with the comments noting that the preamble and regulation text were not consistent with respect to the calculation of commercial enrollment. We also recognize, as noted by one of the commenters, that the preamble statement that Federal employees are considered commercial enrollees, but public agency enrollees are not, merits further consideration.

After further consideration, we have decided to retain the regulatory language as proposed, that is, the health insurance coverage plan that is offered through an HMO and has the largest insured commercial, non-Medicaid enrollment in the State. Public agency employees, as well as Federal employees, may be considered enrollees for purposes of calculating commercial enrollment.

5. Benchmark-Equivalent Health Benefits Coverage (§ 457.430)

Section 2103(a)(2) of the Act provides that a State may opt to provide a benefits package with an aggregate actuarial value that is at least equal to the value of one of the benchmark benefit packages. In accordance with the statute, we proposed at § 457.430 that the benchmark-equivalent coverage must have an aggregate actuarial value, determined in accordance with proposed § 457.431, that is at least actuarially equivalent to coverage under one of the benchmark packages outlined in § 457.420.

In § 457.430 we set forth the proposed coverage requirements for States selecting the benchmark-equivalent coverage option. Under the authority of section 2103(c)(1), we proposed that a benchmark equivalent plan must include coverage for inpatient and outpatient hospital services, physicians' surgical and medical services, laboratory and x-ray services, well-baby and well-child care, including age-appropriate immunizations provided in accordance with the recommendations of ACIP.

Under the authority of section 2110(a) of the Act as implemented at proposed § 457.402, a State may provide coverage for a wide range of services. Under the authority of section 2103(a)(2)(C), we proposed that if the State provides coverage for prescription drugs, mental health services, vision services, or hearing services, the coverage for these services must have an actuarial value that is equal to at least 75 percent of the actuarial value of the coverage of that category of service in the benchmark benefit package. In addition, we proposed that if the benchmark plan does not cover one of the above additional categories of services, then the benchmark-equivalent coverage package may, but is not required to, include coverage for that category of service. A State may provide services listed in § 457.402 other than the services listed in § 457.430(b) without meeting the 75 percent actuarial value test.

Comment: Two commenters believed § 457.430 is ambiguous, confusing and potentially troublesome and allows for a court to read some distinction into the redundant provisions at 457.410(b)(1) and (2) and 457.430(b)(4) about well-baby and well-child care and immunizations applying only to benchmark-equivalent coverage. To avoid such a result, the commenter suggested that HCFA strike § 457.430(b)(4) and revise subsection (b) to read as follows: ''(b) Required services. Benchmark equivalent health benefits coverage must include, in addition to the services described in § 457.410(b), coverage for the following categories of service.''

Response: We have accepted the commenter's suggestion to revise proposed § 457.430. We have also revised § 457.410((b)(2) of the regulation text to add the phrase ''age appropriate'' to immunizations in order to make it consistent with proposed § 457.430(b)(4).

Comment: One commenter is concerned because mental health services do not fall within the scope of required services under SCHIP. The commenter is particularly concerned that children in a State that initially use a Medicaid-expansion program and then move to a separate child health program will lose the EPSDT safety net for mental health services.

Response: While children receiving SCHIP services under a Medicaid-expansion program are required to be provided the full complement of EPSDT services, there is no such requirement under a separate child health program. It is true that some children with coverage for mental health services under a Medicaid expansion could lose that coverage if the State decided to switch to a separate child health program. Those children, however, would be in no worse position than if the State had originally elected a separate child health program. We have no basis to limit State flexibility by mandating benefits beyond those specifically required by the statute, however, we encourage States electing to shift from a Medicaid expansion program to a separate child health program or combination program to retain a comprehensive benefits package that is similar to the Medicaid expansion benefit package to help ensure that children do not experience a significant disruption in care.

Comment: One commenter believed HCFA should promulgate minimum benefits standards for benchmark-equivalent coverage. They noted that HCFA indicated that it has chosen not to propose minimum standards for basic sets of services because a greatly reduced benefits schedule would be unlikely to meet actuarial value requirements. However, the commenter argues that because SCHIP plans may involve much lower cost-sharing requirements than commercial plans, a SCHIP benefits package can offer far fewer services than a benchmark commercial plan and still pass actuarial muster. Accordingly, the commenter respectfully urged the Secretary to revisit this decision and promulgate minimum benefits standards for benchmark-equivalent coverage.

Response: We have considered the issue raised by the commenter but have declined to revise the regulation to set minimum standards at this time. The actuarial value requirements should ensure that the benefits in an actuarial-equivalent benefit package that will not fall below levels intended by title XXI. In fact, experience has shown that States that have chosen to provide benchmark-equivalent health benefits coverage provide coverage that looks very similar

to coverage under other health benefits coverage options.

Comment: One commenter recommended deleting § 457.430(c)(2) because benchmark-equivalent coverage should not be required to include coverage for specific services just because they are covered in the benchmark package. According to this commenter, the intent of equivalent packages is to allow a State the flexibility to design coverage that meets the needs of children in the state.

Response: The language in § 457.430(c)(2) mirrors section 2103(a)(2)(C) of the Act. Therefore, we have not adopted the commenter's suggestion to delete this material.

6. Actuarial Report for Benchmark-Equivalent Coverage (§ 457.431)

In accordance with section 2103(c)(4) of the Act, at § 457.431 we proposed to require a State, as a condition of approval of benchmark-equivalent coverage, to provide an actuarial report, with an actuarial opinion that the benchmark-equivalent coverage meets the actuarial requirements of § 457.430. We also proposed that the actuarial report must specify the benchmark coverage used for comparison.

The actuarial opinion must meet all the provisions of the statute. We proposed that the report must explicitly state the following information:

- The actuary issuing the opinion is a member of the American Academy of Actuaries (and meets Academy standards for issuing such an opinion).
- The actuary used generally accepted actuarial principles and methodologies of the American Academy of Actuaries, standard utilization and price factors, and a standardized population representative of privately insured children of the age of those expected to be covered under the State plan.
- The same principles and factors were used in analyzing both the proposed benchmark-equivalent coverage and the benchmark coverage, without taking into account differences in coverage based on the method of delivery or means of cost control or utilization used.
- The report should also state if the analysis took into account the State's ability to reduce benefits because of the increase in actuarial value due to limitations on cost sharing in SCHIP.

Finally, we proposed that the State must provide sufficient detail to explain the basis of the methodologies used to estimate the actuarial value or, if requested by HCFA, to replicate the State's result.

Comment: We received two comments on this section. One commenter supported the requirement for a set of comprehensive actuarial reports. The second commenter suggested that the requirement for proof of actuarial equivalence of the benefits will be too costly. The commenter noted that insurance industry and State regulatory departments have developed methods of comparing coverage that would be significantly more cost effective and equally as useful for the program as an actuarial study.

Response: We appreciate the support of the first commenter. In response to the suggestion of the second commenter, the actuarial report requirements contained in this section of the regulation text are basically drawn from the section 2103(c)(4) of the Act. Therefore, we have chosen not to alter the requirements in the regulation to allow an alternative approach to benchmark equivalent coverage. However, as discussed under § 457.450, we are willing to entertain other suggestions for Secretary-approved coverage. We will consider States' specific proposals for alternatives to actuarial analysis under the provisions of § 457.450.

7. Existing Comprehensive State-Based Coverage (§ 457.440)

In accordance with section 2103(d) of the Act, at § 457.440 we proposed that existing comprehensive State-based health benefits coverage must include coverage of a range of benefits, be administered or overseen by the State and receive funds from the State, be offered in the State of New York, Florida, or Pennsylvania, and have been offered as of August 5, 1997. In essence, Congress deemed the existing State-based health benefit packages of three States as meeting the requirements of section 2103 of the Act. We noted that these States still need to meet other requirements of title XXI, including requirements relating to cost sharing, such as copayments, deductibles and premiums, as specified in subpart E of this final rule.

We also proposed that the States (Florida, New York, and Pennsylvania) may modify their existing, comprehensive, State-based program under certain conditions. First, the program must continue to offer a range of benefits. Second, the modification must not reduce the actuarial value of the coverage available under the program below either the actuarial value of the coverage as of August 5, 1997 or the actuarial value of a benchmark benefit package. A State must submit an actuarial report when it amends its existing State-based coverage.

We did not receive any comments on this section. Therefore, we are implementing these provisions as set forth in the proposed rule except that we have added language to the regulation to clarify that a State must submit an actuarial report when it amends its existing State-based coverage.

8. Secretary-Approved Coverage (§ 457.450)

Section 2103(a)(4) of the Act defines Secretary-approved coverage as any other health benefits coverage that provides appropriate coverage for the population of targeted low-income children to be covered by the program. In proposed § 457.450 we set forth the option of providing health benefits coverage under the Secretary-approved health benefits coverage option.

We proposed that the following coverage be recognized as Secretary-approved coverage under a separate child health program:

- Coverage that is the same as the coverage provided under a State's Medicaid benefit package as described in the existing Medicaid State plan.
- Comprehensive coverage offered under a § 1115 waiver that either includes coverage for the full EPSDT benefit or that the State has extended to the entire Medicaid population in the State.
- Coverage that includes benchmark coverage, as specified in § 457.420, plus additional coverage. Under this option, the State must clearly demonstrate that it provides all the benchmark coverage, including all coverage required under title XXI, but may also provide additional services.
- Coverage, including coverage under a group health plan, purchased by the State that the State demonstrates to be substantially equal to coverage under one of the benchmark plans specified in § 457.420, through use of a benefit-by-benefit comparison of the coverage. Under this option, if coverage for just one benefit does not meet or exceed the coverage for that benefit under the benchmark, the State must provide an actuarial analysis as described in § 457.431 to determine actuarial equivalence.

While we listed these four options as permissible types of Secretarial-approved coverage, we solicited comments on other specific examples of coverage packages that States have developed, or might wish to develop, to meet the Title XXI requirements. We also proposed that no actuarial analysis is required for Secretary-approved

coverage if the State can show that the proposed benefit package meets or exceeds the benchmark coverage. While the four options we listed meet or exceed the benchmark package, it is possible that a State may develop a Secretary-approved coverage proposal that may require an actuarial analysis.

Comment: One commenter argued that ''Secretary-approved coverage'' should provide HCFA with greater flexibility to approve SCHIP State plans. The commenter points out that Secretary-approved coverage is not simply another name for benchmark coverage; title XXI provides for Secretary-approved coverage as a flexible way for HCFA to approve a State plan. The statute requires no actuarial analysis for this option but rather requires only that the coverage be deemed ''appropriate'' for the target population.

The commenter recommended that the regulations should simply indicate that States must demonstrate, to the Secretary's satisfaction, that their coverage meets the needs of their SCHIP populations. The manner in which States make this demonstration should be left flexible in accordance with the discretion accorded to States by title XXI.

Response: The list of four examples included in the regulation text at § 457.450 was not meant to be an exhaustive list of examples of Secretary-approved coverage. The regulations text states that Secretary-approved coverage ''may include'' one of these options. We solicited additional examples of types of coverage that might qualify under this option but we did not receive any specific examples. We remain open to reviewing other proposals for Secretary-approved coverage.

Comment: One commenter noted that a number of States are exploring buy-in programs where SCHIP funds will be used to subsidize coverage for the uninsured under group health plans. A significant issue for States is how to design programs that can meet HCFA's SCHIP benefit requirements. The preamble to the proposed rule states that if any benefit under an employer plan does not meet or exceed that of a benchmark plan provided under title XXI, based on a benefit-to-benefit comparison, the State must document that the two benefit packages are actuarially equivalent. However, providing such comparisons would likely be costly and burdensome to implement on an employer-by-employer basis. The commenter strongly encouraged HCFA to modify the preamble to provide for maximum State flexibility in the area of benefit certification under buy-in programs. HCFA could provide such flexibility by allowing States more flexibility to designate benefit packages that meet the benchmark standard or to use simple benefit checklists.

Response: We recognize the administrative burden involved in determining whether employer plans meet benefit requirements for separate child health programs, and we agree that documenting the actuarial equivalence of a plan or using benefit side-by-side comparisons may be costly and burdensome. Nonetheless, employer plans through which States wish to offer coverage under a separate child health program must meet requirements for either benchmark coverage, benchmark-equivalent coverage, or Secretary-approved coverage in order to comply with section 2103 of the Act. However, we are open to, and encourage States to propose other options under the ''Secretary-approved'' category.

Comment: Two commenters recommended that proposed § 457.450 should explicitly reference Medicaid benefits for children rather than permit States to furnish SCHIP children with Medicaid benefits for adults without any actuarial analysis showing comparability to standard commercial benefits. Specifically, paragraphs (a) and (b) should be consolidated and revised to read: ''(a) Coverage that is the same as the coverage for children provided under the Medicaid State plan.''

Response: While we have not adopted the exact language and consolidation recommended by the commenter, we have revised § 457.450(a) to specify that coverage should be the same as that offered to children under the Medicaid State plan.

Comment: One commenter believed the proposed rule should be amended to eliminate the use of a benefit-by-benefit comparison for determining whether coverage provided through premium assistance under a group health plan is approvable. This provision appears to require benefit-by-benefit comparison for demonstrating that group health plans meet or exceed coverage requirements. This is a more rigorous test than that required for benchmark equivalent coverage purchased directly by States. Premium assisted group health plan coverage should be held to no more than the requirements for benchmark equivalent coverage.

The commenter noted that their State experience has shown that children are more likely to be insured if their parents are insured and that parents prefer to cover their entire family under the same plan. HCFA's imposition of barriers to the use of SCHIP programs to support group health coverage is a misguided attempt to address substitution of coverage. States should be given as much flexibility as possible to test different approaches, including buy-in to employer sponsored plans, for increasing creditable coverage for uninsured children. HCFA should not add any restrictions to those already established by law in title XXI.

Response: We did not intend to impose additional restrictions on States wishing to utilize premium assistance programs in SCHIP. The benefit-by-benefit comparison was developed in response to States who wanted to provide premium assistance through employer sponsored insurance but were concerned about the cost of performing the actuarial analysis required by the statute for each participating employer plan. Therefore, we proposed that States may compare each benefit to the benefits in the benchmark plan as a way of providing States with a simplified and lower cost option to the actuarial analysis. However, given the statutory requirement for actuarial equivalence we still require that States perform an actuarial analysis if one benefit is lower than the level specified in the benchmark plan.

9. Prohibited Coverage (§ 457.470)

In accordance with section 2103(c)(5) of the Act, we proposed at § 457.470 that a State is not required to provide health benefits coverage under the plan for an item or service for which payment is prohibited under title XXI even if any benchmark package includes coverage for that item or service. We did not receive any comments on this section. Therefore, we are implementing these provisions as set forth in the proposed rule.

10. Limitations on Coverage: Abortions (§ 457.475)

This section implements sections 2105(c)(1) and (c)(7) of the Act, which set limitations on payment for abortion services under SCHIP. At § 457.475, we proposed that FFP is not available in expenditures for an abortion, or in expenditures for the purchase of health benefits coverage that includes coverage of abortion services, unless the abortion is necessary to save the life of the mother or the abortion is performed to terminate a pregnancy resulting from an act of rape or incest.

Additionally, we proposed that FFP is not available to a State in expenditures of any amount under its title XXI plan to assist in the purchase, in whole or in part, of health benefits coverage that includes coverage of abortions other

than to save the life of the mother or resulting from an act of rape or incest.

We also proposed that, if a State wishes to have managed care entities provide abortions in addition to those specified above, those abortions must be provided pursuant to a separate contract using non-Federal funds. A State may not set aside a portion of the capitated rate to be paid with State-only funds, or append riders, attachments, or addenda to existing contracts to separate the additional abortion services from the other services covered by the contract. The proposed regulation also specified that this requirement should not be construed as restricting the ability of any managed care provider to offer abortion coverage or the ability of a State or locality to contract separately with a managed care provider for additional abortion coverage using State or local funds.

Comment: One commenter recommended that abortions be covered under any circumstances.

Response: Federal financial participation is available in expenditures for abortions in an SCHIP program only as specifically authorized by Congress in the statute. Section 2105(c)(1) of the Act limits funding of abortions to funding for those abortions necessary to save the life of the mother or to terminate pregnancies resulting from rape or incest.

Comment: We received many comments on the requirement that States that wish to cover abortions other than those allowed under the statute use separate contracts with managed care organizations to ensure that no Federal SCHIP funds are used to pay for those additional abortions. The commenters believed that this requirement exceeds the statutory authority, will be burdensome for States and managed care entities, and may ultimately serve to dissuade States and managed care entities from offering abortion services. Several commenters also indicated that enforcement of the requirement is not feasible in an employer-sponsored insurance environment where the benefits package is predetermined by an employer and a commercial insurer, rather than by the State. They recommended that employer-sponsored programs be exempt from the separate contract requirement.

Response: Section 2105(c)(7) of the Act specifies that ''payment shall not be made to a State under this section for any amount expended under the State plan to pay for any abortion or to assist in the purchase, in whole or in part, of health benefit coverage that included coverage of abortion.'' Congressional authorities have made clear that this section of the statute requires separate contracts where managed care organizations will be providing abortions in addition to those specified in the law. Thus, contrary to the opinion of the commenters, this prohibition can not be satisfied by carving out or allocating a portion of the capitated rate to be paid for with State-only funds.

11. Preexisting Condition Exclusions and Relation to Other Laws (§ 457.480)

In proposed § 457.480 we implemented the provisions of sections 2103(f), and 2109 of the Act under the authority of section 2110(c)(6) we implemented the provisions of sections 2103(f), 2109 and 2110(c)(6). At § 457.480(a), we proposed to implement section 2103(f) of the Act and provide that, subject to the exceptions in paragraph § 457.480(a)(2), a State child health plan may not permit the imposition of any preexisting condition exclusion for covered benefits under the plan. In § 457.480(a)(2), we proposed that if the State child health plan provides for benefits through payment for, or a contract with, a group health plan or group health insurance coverage, the plan may permit the imposition of a preexisting condition exclusion but only insofar as permitted under ERISA and HIPAA.

In proposed § 457.480(b), we implemented sections 2109 and 2103(f)(2) of the Act, which describe the relationship between title XXI and certain other provisions of law. Specifically, as set forth in proposed § 457.480(b), these provisions include section 514 of ERISA, HIPAA, the Mental Health Parity Act of 1996 (MHPA) (regarding parity in the application of annual and lifetime dollar limits to mental health benefits) and the Newborns and Mothers Health Protection Act of 1996 (NMHPA) (regarding requirements for minimum hospital stays for mothers and newborns). See regulations at 45 CFR 146.136 for a discussion of the MHPA and 45 CFR 146.130 and 148.170 for a discussion of the NMHPA.

Comment: One commenter agreed with the inclusion of language in § 457.480 requiring compliance with the Mental Health Parity Act. However, several commenters raised concerns because they interpreted the language at § 457.480(b)(3) and (4) to mean that States must comply with the MHPA and the NMHPA, regardless of whether or not the State's benchmark plan includes these components. The commenters believed this requirement negates the flexibility otherwise provided the State in choosing the option of using a separate child health plan. The commenters believed that this language should be removed from the final regulation and that States should decide if inclusion of these components in their separate child health programs is appropriate.

One commenter indicated that this requirement would require the offeror of the benchmark plan either to price a SCHIP product separately to the State, to incorporate the mental health parity costs and benefits, or to include these benefits at the same cost (an unlikely scenario). Either way, the commenter argued that the provision reduces the flexibility of using a benchmark plan and thus the proposed linkage of SCHIP to these laws is not appropriate and should be removed.

Response: We agree that the proposed regulation language was unclear and have revised the language to clarify this issue. The commenters appear to have interpreted the proposed rule to mean that States must provide coverage for mental health services and services for newborns and mothers regardless of whether a State's benchmark plan includes coverage for those services. We did not intend to impose such coverage requirements.

The requirements of the MHPA apply only to group health plans (or health insurance coverage offered by issuers in connection with a group health plan) that provide such medical/surgical benefits for newborns and mothers and mental health benefits. Thus, the provisions of MHPA apply only to title XXI coverage provided through a group health plan and only if that plan offers mental health benefits. However, if a State uses a group health plan as a benchmark, then the State may be implicitly required to comply with the MHPA even if that law is not directly applicable. Similarly, the NMHPA applies directly only to group health plans and health insurance issuers (in the group and individual markets) providing benefits for hospital lengths of stay in connection with child birth. We did not intend to impose additional coverage requirements on States or to reduce the State's flexibility in defining its service packages. We have thus revised the regulations to clarify that only group health plans through which States provide coverage under a State plan are subject to the requirements of the provisions described in §§ 457.480(b)(3) and (4).

Comment: One commenter raised the issue of HIPAA requirements and the pre-existing condition exclusions. The commenter noted that because SCHIP enrollees generally will not meet the requirements of ''eligible individuals'' under HIPAA, the level of protection

afforded by this proposed rule against pre-existing condition exclusion clauses in a SCHIP benchmark package offered by a private insurer is unclear. The proposed rule does state that SCHIP benefits are creditable coverage; however, the commenter stated that the prohibition against pre-existing condition exclusions is triggered only if creditable coverage was followed by COBRA coverage. The commenter noted that clarification of the pre-existing condition exclusion provisions will be important for health providers caring for children with disabilities.

One commenter also indicated that the regulations do not permit any ''preexisting conditions exclusions'' for a State plan in general. However, if a SCHIP plan provides coverage through a group health plan, the plan could impose preexisting conditions exclusions in accordance with what is allowable under HIPAA. While HIPAA does limit the extent of preexisting condition exclusions, States should be allowed to negotiate with health plans the elimination of all preexisting condition exclusions.

Another commenter encouraged the inclusion of a statement at § 457.480(a)(2) that while States may, in very limited circumstances, permit the imposition of a pre-existing condition exclusion consistent with applicable Federal law, States have the discretion to, and are encouraged to, negotiate group health plan coverage free of such exclusions.

Response: Section 457.480(a) of the regulation implements section 2103(f)(1) of the Act and provides that a State may not permit the imposition of a pre-existing condition exclusion, except in the case of a State that obtains health benefits coverage through payment for, or a contract with, a group health plan or group health insurance coverage, in which case the State may permit the imposition of such an exclusion to the extent permitted under HIPAA. The protection afforded to enrollees is clear; they either face no pre-existing condition exclusion or, if enrolled in a group health plan, they potentially face an exclusion that in no case can be longer than the 12 months permitted under HIPAA. The commenter correctly notes that enrollees in a separate child health program may not meet the definition of ''Federally eligible individual'' under HIPAA's individual market protections (although they may if their most recent coverage was SCHIP coverage through a group health plan and they then exhausted any COBRA or State continuation coverage offered to them). Presumably, the commenter was concerned about former enrollees wishing to purchase private, individual market coverage. Title XXI does not provide enrollees with an assurance of meeting the definition of Federally-eligible individuals under HIPAA. However, section 2110(c)(2) of the Act as implemented at § 457.410 provides that coverage meeting the requirements of § 457.10 provided to a targeted low-income child constitutes creditable health coverage. Therefore, coverage under a separate child health program will count towards the minimum 18 months of coverage required for someone to qualify as a Federally-eligible individual.

Comment: One commenter also urged States that do and do not have mental health parity statutes to include coverage for a full range of mental illness services in their State plans when they opt to develop separate child health programs.

Response: States are given flexibility in designing their benefit packages. While we encourage States to provide services for mental illness, there is no Federal requirement for a State to include this coverage under its separate child health program if it does not elect to do so.

Comment: One commenter believed the regulation should include a statement that pre-existing condition exclusions are contrary to the intent of SCHIP and unfair. Therefore, even under the limited circumstances where such exclusions are allowed, States must be required to demonstrate attempts to negotiate group health plan coverage free of such exclusions. According to this commenter, only after demonstrating that those efforts have been exhausted, should a State plan with these very limited exclusions be approved.

One commenter asserted that the HIPAA-allowable conditions for permitting a waiting period for services for a preexisting condition are adverse to the purposes of initiating coverage for children cut off from access to services precisely because they lack coverage. The commenter believed most, if not all, children should be assessed, diagnosed, and treated quickly in response to their health deficiencies. The commenter believed this is a matter for Congress to reconsider.

Response: The language in the proposed rule at § 457.480(a)(1) and (2) was included based on section 2103(f)(1) of the Act. Section 2103(f)(1)(B) clearly provides for the possibility that States providing benefits through group health plans may allow those plans to impose pre-existing condition exclusions to the extent permitted by HIPAA. One limited exception to this rule is permitted. Under § 2103(f)(1)(B) of Title XXI, if a State child health plan provides for benefits through payment for, or a contract with, a group health plan or group health insurance, the plan may permit the imposition of those preexisting conditions which are permitted under HIPAA. This permits the imposition of preexisting conditions consistent with the requirements of such plans when the State is providing premium assistance through SCHIP to subsidize child or family coverage under a group health plan or group health insurance pursuant to § 2105(c)(3) of the statute. Therefore, we are unable to revise this section as suggested by the commenter.

12. Delivery and Utilization Control Systems (§ 457.490)

In accordance with section 2102(a)(4) of the Act, at § 457.490 we proposed to require that State plans include a description of the type of child health assistance to be provided including the proposed methods of delivery and proposed utilization control systems. In describing the methods of delivery of the child health assistance using title XXI funds, the proposed regulation requires a State to address its choice of financing and the methods for assuring delivery of the insurance product to children including any variations. We also proposed that the State describe utilization control systems designed to ensure that children use only appropriate and medically necessary health care approved by the State or its subcontractor. We set forth examples of utilization control systems in the preamble to the proposed rule.

Comment: One commenter noted that in this section of the proposed rule, HCFA requests a description of utilization controls designed to ensure that children use only appropriate and medically necessary health care, but does not define ''medically necessary'' in any specific manner. The commenter suggested that this term be defined in the regulation and suggested language to be used in the regulation as a definition of medically necessary.

Response: As we have indicated in response to comments on § 457.420, HCFA will not define medical necessity for SCHIP. The determination of medical necessity criteria for separate child health programs is left up to each State to define.

Comment: One commenter noted that utilization controls that might be appropriate for the adult population may not be appropriate for the pediatric population. As States implement these controls, it is important that they are

appropriate for children. These controls should take into consideration children with special health care needs as well as the unique needs of children in general.

Response: The language in § 457.490(a) of the proposed rule very specifically says ''methods for assuring delivery of insurance products to the *children*.'' Section 457.490(b) provides for ''systems designed to ensure that *children* use only appropriate * * *'' (emphasis added). We believe this language, along with the language at proposed § 457.735 (now § 457.495) requiring States to assure appropriateness of care, very clearly requires that the utilization controls be appropriate for the pediatric population. If a State provides coverage for services for children with special health care needs, States would be expected to ensure appropriate utilization controls on these services also. We believe the language in paragraph § 457.490(a) requiring States to describe methods to assure delivery of services ''including any variations,'' is sufficient to address this commenter's concerns. ''Variations'' would include additional services delivered to special needs children.

Comment: We received two comments suggesting the addition of default enrollment language in the regulation. One commenter recommended that HCFA adopt language similar to the language in the Medicaid managed care proposed rule to address default enrollment under SCHIP for States that offer eligible children a choice of plans. The commenter suggested that HCFA require that States describe in their plans the policies and procedures that they will use to minimize rates of default enrollment and what efforts the State and its contractors will make to preserve traditional provider-patient relationships. The commenter also recommended that this section include an additional paragraph:

> Describe policies and procedures that minimize rates of default enrollment where beneficiaries have a choice of plans, and what efforts have been made by the State and its contractors to preserve existing provider/patient relationships. States must also describe opportunities for beneficiaries to disenroll both for cause or on a periodic basis without cause.

Response: Default enrollment, also referred to as auto assignment, is a practice utilized by several States in their enrollment processes. However, we believe that any information or requirements regarding managed care enrollment procedures, including default enrollment, should be addressed as part of the requirements of § 457.110(a), rather than in this section.

Comment: One commenter supported the language in this section and indicated that this sets out a helpful framework that encourages States to ensure that utilization controls limit costs without denying essential health care to children.

Response: We appreciate the commenter's support.

Comment: One commenter recommended that § 457.490(a) be modified to be applicable not only to the delivery of the insurance products but also to delivery of services covered by the product.

Response: We have adopted this suggestion and revised the regulation text accordingly.

Comment: Two commenters recommended that this section be modified to require State plans to identify methods the States will use to monitor and evaluate delivery and utilization control systems to ensure that children receive appropriate and medically necessary care.

Response: Proposed § 457.735 (now § 457.495) addresses State plan requirements for assuring quality and appropriateness of care provided under the plan. Please see our responses to comments in that section.

13. Grievances and Appeals (Proposed § 457.495)

At § 457.495, we proposed to require States to provide enrollees in a separate child health program with the right to file grievances or appeals for reduction or denial of services in accordance with proposed § 457.985. In an effort to consolidate all provisions related to review processes, we have removed proposed § 457.495 and incorporated those provisions into new subpart K, which contains provisions regarding grievances and appeals. We address comments on proposed § 457.495 in new subpart K.

14. State Plan Requirement: State Assurance of the Quality and Appropriateness of Care (§ 457.495)

Sections 2102(a)(7)(A) and (B) of the Act require the State plan to describe the strategy the State has adopted for assuring the quality and appropriateness of care, particularly with respect to providing well-baby care, well-child care and immunizations, and for ensuring access to covered services, including emergency services. We proposed to implement this provision at § 457.735(a), and provided further specifications therein consistent with this statutory requirement.

We also proposed to include additional, more specific assurances designed to ensure the quality and appropriateness of care for particularly vulnerable enrollees. In § 457.735(b), we proposed that States must provide assurances of appropriate and timely procedures to monitor and treat enrollees with complex and serious medical conditions, including access to specialists.

In this final rule, we are redesignating the provisions of proposed § 457.735 (which were previously located in subpart G, Strategic planning) as § 457.495. We believed that these provisions are more appropriately presented in the context of this subpart. We respond to all public comments on proposed § 457.735 below.

Comment: We received several comments indicating that this section of the proposed rule was unclear as to whether the requirement for State assurance of quality and appropriateness of care applies to SCHIP coverage provided through employer plans. Commenters indicated that the requirements of the proposed regulation seem tacitly to assume that the State will have a direct, contractual relationship with all SCHIP participating health plans, including employer-sponsored plans. A commenter further stated that any attempt to apply such requirements directly to employer-sponsored plans would mean that no employer plans will ever qualify for the State's premium assistance under SCHIP, as there is no incentive for an employer or plan to invest resources to comply with these requirements. Commenters indicated that employer-sponsored health coverage systems do not identify individuals who can be classified into such categories as ''enrollees with special or complex medical conditions,'' making it difficult to report on these subgroups.

Response: We understand the commenters' concerns and desire that data reporting requirements under SCHIP are able to work within the systems and regulatory structure for premium assistance programs. The provisions of this regulation section do apply to such coverage because the statute contains no exemptions from its reporting requirements for SCHIP coverage offered through premium assistance programs. However, the regulation does not require States to report encounter data in measuring their progress toward meeting performance goals. We encourage States to use a variety of methods to collect appropriate data. While requiring plans to report encounter data to the State is one means of gathering these data, it is by no means the only method. For example, States can rely on mail or telephone surveys of

participating families and surveys of participating providers, or can design a data collection methodology that works with the structure and offerings of their SCHIP programs, including those operating premium assistance programs.

Comment: We received comments recommending that we require specific reporting requirements for States offering premium assistance programs through group health plans.

Response: States that implement or design premium assistance programs for SCHIP have flexibility to explore different methods of working with employers, health plans and beneficiaries to obtain information on SCHIP coverage provided through group health plans. Because of the difficulty of obtaining data from employer plans with which the State may not have direct contractual relationships, we intend to continue to work with States exploring the implementation of premium assistance programs and will continue to consider a variety of State proposals regarding appropriate methods of obtaining information about the quality of care obtained through premium assistance programs.

Comment: We received comments that the regulation should allow States the flexibility to use strategies that employers already have in place, or to use alternative strategies, to ensure quality and appropriateness of care.

Response: First, it should be noted that, upon further reflection, we have determined that the provisions and intent of proposed § 457.735 would fit more appropriately within Subpart D, Benefits. The focus of this provision is to ensure that SCHIP enrollees have adequate access to health care services as needed. Therefore, we have moved the comments and responses on this provision to Subpart D, § 457.495.

We agree that, pursuant to the provisions of title XXI, States should have the flexibility to use innovative strategies to ensure quality and appropriateness of care. Section 457.495(a) provides that States must provide HCFA with a description of the methods that a State uses for assuring the quality and appropriateness of care provided under the plan. We did not specify a particular method States must use to monitor appropriateness and quality of care. We anticipate that States will use a variety of methods, including those most suitable for the type of program or programs a particular State is implementing.

Comment: Several commenters recommended that we establish specific, unified, quality and access standards with respect to those areas set forth in § 457.495 and identify the methodologies for monitoring those standards in the regulations. Several commenters recommended that we require States to describe methods they will use to ensure that children have access to pediatricians and other health care providers with expertise in meeting the health care needs of children. The commenters felt that physicians who are appropriately educated in the unique physical and developmental issues surrounding the care of infants, children, young adults and adolescents should provide children's care. As the SCHIP program is specifically designed to serve children, commenters noted that it is critical that access to appropriate providers of care be required. One commenter recommended the annual application of a standardized survey of children's mental, physical, and social health.

Response: Section 457.495 requires that a State describe the specific elements of its quality assurance strategies. These may include the use of any of the following methods: quality of care standards; performance measurement, information and reporting strategies, licensing standards, credentialing/recredentialing processes, periodic reviews and external reviews. We are not requiring that States meet specific, unified standards regarding access to and quality of care. However, the regulation at § 457.495 does requires States to assure the quality and appropriateness of care provided under the State plan. As part of the State's assurances, each State agency would be expected to assure that all covered services are available and accessible to program enrollees. This means that all covered services would be available within reasonable time frames and in a manner that ensures continuity of care, adequate primary and specialized services, and access to providers appropriate to the population being served under the SCHIP plan. We believe this assurance is sufficient to address the concerns of the commenters.

Comment: One commenter recommended that quality of care standards reflect professional judgment and local standards of care as distinguished from standards of care developed by third-party payers or fiscal intermediaries.

Response: We encourage States, as they create methods of assuring and evaluating quality of care provided to SCHIP participants, to take into consideration sources of quality of care standards and to make a determination about whether to incorporate standards endorsed or used by local providers, national provider associations, national health research institutes, or health insurance or managed care organizations into their State plan.

Comment: Several commenters supported the requirement in § 457.735(a) that States describe methods of assuring the quality and appropriateness of care under SCHIP, particularly with regard to well-baby and well-child care, immunizations, and access to specialty care. One commenter suggested that HCFA use the phrase ''access to specialty services'' rather than the phrase ''access to specialists'' in § 457.735(b).

Response: We considered the commenters' suggestion and concluded that modifying the term ''access to specialists'' with the clarification of ''access to specialists experienced in treating the enrolled's medical condition'' would provide broader assurances that the children identified in § 457.495(c) would have access to the appropriate specialty services. Therefore, we have revised § 457.495(c) accordingly.

Comment: We received several comments applauding the inclusion of well-adolescent care with well-child care in the quality assurance requirements at § 457.495. Commenters suggested including the word ''adolescent'' in the definition of well-baby and well-child services and using the term in connection with well-child care throughout the regulation. The commenters indicated that they believe we should focus on the unique health needs of adolescents, which make up approximately 39 percent of SCHIP eligible youth, because their health needs differ from those of younger children. The commenters also urged HCFA to list specifically in the regulation medical sources that have guidelines for infants, children and adolescents. In these commenters' view, these sources should include the American Academy of Pediatrics' ''Guidelines for Health Supervision of Infants, Children and Adolescents,'' the American Medical Association's ''Guidelines for Adolescent Preventive Services,'' and the American College of Obstetricians and Gynecologists' ''Primary and Preventive Health Care for Female Adolescents.''

Response: We appreciate the commenters' support of our emphasis on assuring the quality and appropriateness of care for children and our specific reference to certain types of adolescent care. While understand the view that this emphasis is important at § 457.495, because of our concern for assuring quality and appropriateness of care, we have not adopted the commenters suggestion with respect to using this terminology throughout the

rest of the final rule. The definition of child for purposes of SCHIP at § 457.10 and section 2110(c)(1) of the Act indicates that a ''child'' is an ''individual under the age of 19.'' Adolescents within this age range are clearly included in this definition and therefore we have not included the term in other references to well-baby and well-child care. Because we are not requiring that States adopt specific standards of care, we are not including the commenters' list of sources in the regulation text. We are including the commenters' listing here in the preamble so that States may consider these sources as recommendations in developing their own standards.

Comment: One commenter noted that accreditation is a method widely used by commercial purchasers to assure the quality of care provided by health plans. The commenter noted that accreditation, a comprehensive assessment of the quality of a health plan, is particularly useful in assessing the effectiveness and timeliness of procedures used to monitor and treat enrollees with serious medical conditions. The commenter urged HCFA to acknowledge that a State using HEDIS (Health Plan Employer Data and Information Set) measures would meet the State plan requirements set forth in this section. The commenter noted that HEDIS includes measures that specifically address the elements of care within SCHIP including:

—Childhood and adolescent immunizations;
—Use of appropriate medications for people with asthma;
—Children's access to primary case managers (PCPs);
—Annual dental visits;
—Well child visits in the first 15 months, third, fourth, fifth, and sixth years of life;
—Adolescent well visits;
—Ambulatory care;
—Inpatient utilization;
—Ratings of personal doctor, nurse, specialist;
—Rating of health care;
—Rating of health plan;
—Getting needed care and getting care quickly;
—How well doctors communicate;
—Courteous and helpful staff; and
—Customer service and claims processing.

Response: States have flexibility in determining the State-specific performance measures they will use in determining quality and access to care. In making these determinations, States have the ability to utilize those data collection tools and analysis methodologies that are most suited to the circumstances of their SCHIP program. HEDIS is one of several tools we recommended in the proposed regulation that States consider as they design ways of measuring appropriateness and quality of care in SCHIP, but there may be other tools States may wish to consider. Specifically, in the preamble to the proposed rule, we recommended that States refer to several tools including the Consumer Assessments of Health Plans Study (CAHPS), the U.S. Preventive Services Task Force Guidelines, Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents, and the Office of Disease Prevention and Health Promotion's Health People 2000 and Healthy People 2010.

Comment: One commenter cautioned HCFA that while HEDIS is a widely accepted and adopted collection system, it has limitations in its usefulness for monitoring performance under SCHIP. The commenter urged HCFA to work with NCQA to understand these limitations and the explore ways to address them. Additionally, the commenter encouraged HCFA to include the American Academy of Pediatrics Guide for Health Supervision III to the list of standards, benchmarks, and guidelines states should look to for performance measures.

Response: We agree that the suggested performance measure guidelines mentioned in the preamble to the proposed rule all have certain limitations that the States should take into consideration as they develop strategies for measuring performance goals related to their strategic objectives. Additionally, we encourage States to consider the American Academy of Pediatrics Guide for Health Supervision III in developing their performance measures.

Comment: Commenters recommended that we require States to include procedures to monitor the extent to which the program has sufficient network capacity, including providers and specialists who serve the particular needs of the adolescent enrollees, both male and female, and provides services such as women's health services, family planning and transitional services. According to these commenters, the monitoring should include measures relevant to the care of adolescents, (annual well-adolescent visits, adolescent immunization rates, etc.) and immigrants, and access to services without unreasonable delay.

Response: We have not adopted the commenters' suggestions. Section 457.495 requires States to include in the State plan a description of the methods that a State uses for assuring the quality and appropriateness of care and for ensuring access to covered services provided under an SCHIP plan. It is therefore, not appropriate to include a list of specific types of services, specialists, or groups; and risk unintentionally excluding an area that also needs attention. However, we did include language regarding access to specialists in general in order to emphasize the need for such access. We have also required States to provide a decision regarding the authorization of health services within 14 days of the service being requested. A possible extension to this 14 day period may be granted in the event that the enrollee requests an extension or the physician or the health plan determines that additional information is required. All such decisions must be made in accordance with the medical needs of the patient. The language of section 457.495 as finalized, allows us to address the concerns of the commenters while allowing States the flexibility the SCHIP statute provides them.

Comment: One commenter indicated that it was difficult to determine the applicability of the requirement to assure appropriate and timely procedures to monitor and treat enrollees with complex and serious medical conditions for fee-for-service programs. The commenter believed that the quality of care monitoring requirement in § 457.495(a) is sufficient to protect enrollees and that the requirement at § 457.495(b) regarding complex and serious medical conditions should be eliminated.

Response: We disagree with the commenter. Because of the importance of ensuring that children with chronic, serious or complex medical conditions receive continuous and appropriate care, with the ability to access specialists as often as needed, particular attention is necessary in specifying the requirement at § 457.495. We understand that it is more difficult for States to implement this requirement in the fee-for-service sector than it would be in a managed care environment. However, in order to assure quality care to participants with chronic, serious or complex medical conditions, it is essential that States provide specific assurances that they have established appropriate procedures to monitor and treat these participants whether they are enrolled through fee-for-service programs or through MCEs. Therefore, we have retained the requirement at § 457.495(b), as revised.

Comment: One commenter urged HCFA to require the States to describe

procedures for providing case management to those with complex and serious medical conditions. The commenter believed that quality of care for those with complex medical conditions is greatly enhanced by case management. The commenter also urged HCFA to require States' to include appropriate peer review by pediatricians and appropriate pediatric specialists in their quality assurance mechanism.

Response: While States may want to establish procedures for providing case management to enrollees with chronic, complex or serious medical conditions to enhance quality and access to care for those participants, we have not required all States to use that particular method to assure quality and appropriateness of care. We note that case management is one service that States may, but are not required to, provide under § 457.402. However, other methods to assure quality and appropriate care are also acceptable and may be just as effective, depending upon the design of the State's SCHIP.

Comment: One commenter suggested that we revise § 457.495(b) as follows: ''States must assure appropriate and timely procedures to monitor and treat enrollees with complex, serious or chronic medical conditions (including symptoms) including access to appropriate pediatric, adolescent and other specialists and specialty care centers and must assure that children with complex, serious or chronic medical conditions receive no lower quality of care than received by children with special health care needs served by the State's programs under title V of the Social Security Act.''

Response: We will modify the phrase ''complex and serious'', to add the term ''chronic'', as suggested by the commenter. In addition, to provide further flexibility, we are changing the word ''and'' to ''or''; and the phrase will be written as, ''chronic, complex or serious''. We believe this phrase encompasses the symptoms of these enrollees, making further specification unnecessary. We have also revised the requirement for access to specialists within that provision to read, ''access to specialists experienced in treating the specific medical condition* * *'' We believe the addition of these terms in § 457.495(b) assures that SCHIP programs will adequately serve the health needs of enrollees with chronic, complex or serious medical conditions, by assuring that children with these conditions will have access to care from specialists most adequately suited to meet the child's needs. Since States have the flexibility to establish their own standards for assuring appropriate treatment and quality of care, we do not agree with the commenter's suggestion that we should specify the inclusion of specialty care centers or particular standards of care.

Comment: One commenter mentioned several times throughout its comments that access to dental services is a problem under Medicaid and that HCFA should take action to correct this problem.

Response: While Medicaid coverage of dental services is not the subject of this regulation, we would like to bring to the attention of the commenter the HCFA/HRSA Oral Health Initiative (OHI) which is an ongoing effort to improve access to high quality oral health services for vulnerable populations, particularly children enrolled in Medicaid and SCHIP. HCFA teamed with HRSA almost two years ago and initiated the OHI in a effort to bring together Federal staff, State Medicaid agencies and national, State and local level dental organizations to recognize and address this issue. Both HCFA and HRSA recognize that resolving barriers to oral health access in Medicaid and SCHIP must begin with the understanding that Medicaid and SCHIP are programs that rely upon Federal-State partnerships: the Federal government provides broad guidelines under which States implement individual programs. Both HCFA and HRSA believe that solutions to oral health disparity in Medicaid and SCHIP will most likely be found at the local and State levels. Both agencies seek to provide resources, guidance and technical assistance necessary to enable States and localities to better address their local oral health concerns.

Some activities that have been undertaken by the OHI include: co-sponsoring a national leadership conference that brought together for the first time the State Medicaid and State Dental Directors with the leadership of the dental profession; collaborating with the private sector (that is, the American Dental Association convened a second national leadership conference for stakeholders to continue the progress and dialogue achieved in the first meeting and also to include State legislators in the process); supporting State dental summits/workshops to provide the opportunity for State level players to meet with each other on a face-to-face basis to address oral health problems specific to their States and develop State-specific strategies and implementation plans; promoting best practices by providing State dental officials the opportunity to share common dental concerns and potential best practices by initiating and supporting a privately managed electronic list serve which connects, for the first time, Medicaid program officials in each State with each other, and with State health officials and the Federal OHI team. Discussion of further activities undertaken by HCFA and the OHI to improve the oral health of this vulnerable population is contained in the Department responses to the April 27, 1999 report of the General Accounting Office (GAO), ''Oral Health: Dental Disease is a Chronic Problem Among Low-Income Populations.'' This report is available from the GAO web site at *www.gao.gov.*

Finally, in an effort to focus attention on the oral health issues and to build an oral health infrastructure, HCFA has appointed a full-time Chief Dental Officer to serve as a focal point for oral health issues and has identified staff in each HCFA Regional Office to serve as Medicaid dental coordinators.

Comment: Several commenters suggested that the regulation include language to specifically require access to various types of providers, such as, pediatric and adolescent specialists, and obstetricians/gynecologists. In addition, one commenter suggested that State plans should be required to assure that female adolescents have direct access to women's health specialists and that pregnant adolescents be permitted to continue seeing their treating provider through pregnancy and the post-partum period in instances where the contracting plan or provider has left the SCHIP program.

Response: We have not adopted the commenters' suggestions. Section 457.495 requires that the State plan include assurances of the quality and appropriateness of care and services provided under a State plan including treatment of chronic, serious or complex medical conditions and access to specialists. This requirement addresses the concerns of the commenters while allowing States the flexibility to establish the means by which they will assure access to appropriate care that the SCHIP program provides them. This regulation requires States to ensure access to providers appropriate to the population being served under the State plan.

Comment: Two commenters recommended that we revise the regulation to provide that a State and its participating contractors must provide services as expeditiously as the enrollee's health condition requires. The commenter also suggested time frames of approval of a request for services within seven calendar days after receipt of the request for services, with a possible extension of fourteen days. The

commenters also recommended an expedited time frame if the physician indicates, or the State/contractor determines that following ordinary time frames could seriously jeopardize the enrollee's life or health or ability to regain maximum function, to be no later than 72 hours after receipt of the request for services, with a possible extension of up to 14 additional calendar days. Another commenter suggested requiring a response within seven days to an initial request for service or within 72 hours for an expedited procedure.

Response: We recognize the commenters' concerns and have addressed these issues in new subpart K, Applicant and Enrollee Protections, at § 457.1160.

E. Subpart E—State Plan Requirements: Enrollee Financial Responsibilities

1. Basis, Scope, and Applicability (§ 457.500)

A State that implements a separate child health program may impose cost-sharing charges on enrollees. A State that chooses to impose cost-sharing charges on enrollees must meet the requirements described in section 2103(e) of the Act. In proposed § 457.500, we set forth section 2103(e) of the Act as the statutory basis for this subpart, containing cost-sharing provisions. As proposed, this subpart consists of provisions relating to the imposition under a separate child health program of cost-sharing charges including enrollment fees, premiums, deductibles, coinsurance, copayments, and similar cost-sharing charges. We proposed that these provisions apply to all separate child health programs regardless of the type of coverage (benchmark, benchmark equivalent, Secretary-approved or existing comprehensive State-based coverage) provided through the program.

We noted in the preamble that these requirements apply when a State with a separate child health program purchases family coverage for the targeted low-income child under the waiver authority of section 2105(c)(3) of the Act and proposed § 457.1010 and when a State provides premium assistance for coverage under a group health plan as defined in § 457.10. We proposed that this subpart does not apply to Medicaid expansion programs. In this final rule, we revised the statutory basis at § 457.500(a) to include section 2101(a) of the Act, which describes that the purpose of title XXI is to provide funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner.

Comment: A number of commenters noted that the numerous protections written into the Medicaid statute were not written into the SCHIP statute because Congress clearly recognized that these populations are different and intended that they be treated differently. The commenters noted that cost-sharing gives working families a sense of pride in sharing the cost of medical services, just like their friends, neighbors, and relatives who have employer-based insurance. They also indicated that asking families to track their own cost-sharing expenditures contributes to the development of self-sufficiency. Some commenters noted that establishing low levels of cost-sharing will encourage substitution of coverage.

Response: We have implemented §§ 457.500 through 457.570 of the final regulation under the authority of section 2103(e) of the Act. Congress included cost-sharing protections for children covered under SCHIP through separate child health programs, in recognition of the important role that affordability plays in determining whether a child has access to health care insurance and essential health care services for their families. High cost-sharing charges could result in low-income families choosing to remain uninsured, dropping insurance coverage, or avoiding utilization of necessary health care services. Increased cost sharing may also encourage enrollees to access health care only during times when care is most expensive (that is, during emergency or critical health care situations). We have retained States' ability to rely on a methodology for tracking cost sharing that places some of the responsibility on the enrollee. As noted in the preamble to the proposed rule, we do, however, encourage the use of more formal tracking mechanisms that ease any tracking or administrative burden on enrollees and providers, such as a swipe card. While we recognize that low levels of cost sharing may encourage substitution, States must meet the requirements in subpart H, Substitution of Coverage, that are intended to limit the occurrence of substitution.

Comment: One commenter suggested that HCFA revise this section to apply the SCHIP copayment rules to Medicaid expansion programs, not just separate child health plans. The commenter believed that this revision would effectuate Congressional intent, which was to allow States flexibility in implementing SCHIP plans.

Response: Section 2103(e)(4) of the Act provides that the cost-sharing requirements and limitations established pursuant to section 2103(e) do not affect the rules relating to the use of enrollment fees, premiums, deductions, cost sharing, and similar charges in a Medicaid expansion program under section 2101(a)(2). Therefore, Congress has made it clear that these cost-sharing provisions were intended to apply to separate child health assistance programs only. The title XIX cost-sharing rules apply to Medicaid expansion programs, and these rules generally prohibit cost sharing for children. Therefore, the reference to Medicaid expansion programs in § 457.500(c) has been removed.

Comment: One commenter recommended that we include language in the preamble advising States that they must ensure that cost-sharing requirements are administratively workable and not unduly burdensome for managed care entities.

Response: We agree with the commenter. States should strive to impose cost-sharing charges in a manner that eases administrative burden on managed care entities and their participating providers and thereby promotes provider participation in SCHIP. We believe the cost-sharing provisions in §§ 457.500 through 457.570 of this final rule provide States with flexibility to use a variety of strategies to implement these requirements while at the same time providing enrollees with important protections.

2. General State Plan Requirements (§ 457.505)

Section 2103(e)(1)(A) of the Act specifies that a State plan must include a description of the amount (if any) of premiums, deductibles, coinsurance, and other cost sharing imposed. Section 2103(e)(1)(A) also specifies that any such charges be imposed pursuant to a public schedule. In accordance with the statute, at § 457.505, we proposed that the State plan must include a description of the amount of premiums, deductibles, coinsurance, copayments, and other cost sharing imposed. We further proposed that the State plan include a description of the methods, including the public schedule, the State uses to inform enrollees, applicants, providers, and the general public of the cost-sharing charges, the cumulative cost-sharing maximum, and any changes to these amounts.

We also proposed that States that purchase family coverage or offer premium assistance programs must describe how they ensure that enrollees are not charged for copayments,

coinsurance, deductibles, or similar fees for well-baby and well-child care services and that they do not charge American Indian/Alaska Native (AI/AN) children cost sharing. We also proposed that a procedure that primarily relies on a refund given by the State to implement the requirements of this subpart is not an acceptable procedure. We proposed that in States that purchase family coverage or establish premium assistance programs, the State also must describe in its State plan the procedures used to ensure that enrollees are not charged cost sharing over the cumulative cost-sharing maximums proposed in § 457.560. We emphasized that this process must not primarily rely on a refund for cost sharing paid in excess of the cumulative cost-sharing maximum. In § 457.505, we have added a paragraph (c) that will require States to include in the State plan a description of the disenrollment protections required under § 457.570. We have also added paragraph (e) in this section to reduce redundancy and more clearly identify the State plan requirements when a State uses a premium assistance program.

Comment: Several commenters did not agree with the statement in the preamble that suggested that providers could bill the State directly, so that enrollees are not inappropriately charged for certain services. They noted that many health plans are not willing to make the administrative changes necessary to bill the State agency instead of the enrollee and, in light of the difficulties, proposed that a refund component be a valid option.

Response: We disagree. States should establish adequate procedures to ensure the requirements for cost-sharing charges are met and to educate both the provider and the enrollee regarding cost-sharing obligations. Having providers bill the State directly is one option States may use as part of these procedures. We also note that we have not prohibited the use of refunds in all circumstances, but we do require that a State not use a refund as the primary method for assuring compliance with cost-sharing prohibitions and cumulative cost-sharing maximums. Other examples of tracking procedures include informing enrollees that they are approaching the cumulative cost-sharing maximum right before the cap is reached, or sending monthly letters to providers to inform them of which enrollees do not need to pay copayment amounts as of a certain date. We have revised proposed section § 457.505(d) to clarify that when States provide premium assistance for group health plans, cost-sharing charges are not permitted for well-baby and well-child care services; cost sharing is not permitted for AI/AN children; and enrollees must not be charged cost sharing that exceeds the cumulative cost-sharing maximum. These provisions must be described in the State plan. Finally, the provision specifying that ''a procedure that primarily relies on a refund given by the State for overpayment by an enrollee is not an acceptable procedure for purposes of this subpart'' has been moved to § 457.505(e) for clarity.

Comment: One commenter suggested that we define the word ''primarily'' as used in § 457.560 for a variety of situations. For example, they indicated that a State may not be able to ascertain at the time of eligibility determination whether an applicant is an AI/AN due to the lack of verification of AI/AN status on the part of the applicant and/or the lack of cooperation in verification on the part of the tribe. In this situation, the State may not waive cost-sharing charges for the individual and, in their view, the only way a State could comply with the requirement that the AI/AN population be excluded from cost sharing would be to use a procedure of refunds for overpayments, once AI/AN status was verified.

Response: We realize that there may be unforeseen circumstances when an enrollee has paid cost sharing that either should not have ever been charged or is in excess of the cost-sharing limits. In these cases, refunds will be necessary. However, refunds should not be the State's only or ongoing method to ensure that cost sharing does not exceed the regulatory limits. The State should inform each enrollee of the precise amount of the cumulative cost-sharing maximum based on the enrollee's individual family income at the time of enrollment and/or reenrollment or, in the case of a set out-of-pocket cap, inform the enrollee of cost sharing as required under § 457.525. Rather than rely on a refund mechanism, the State should educate the enrollee regarding the cumulative cost-sharing maximum and when not to pay cost sharing for the applicable time period. In the case of the AI/AN population, States should provide accessible information to the population about the State requirements for demonstrating AI/AN status and, as in other instances, seek to minimize the use of refunds as a method for compliance with the cost-sharing requirements of Subpart E.

3. Premiums, Enrollment Fees, or Similar Fees: State Plan Requirements (§ 457.510)

Section 2103(e)(1)(A) of the Act requires that the State plan include a description of the amount of premiums, deductibles, coinsurance and other cost sharing imposed pursuant to a public schedule. At § 457.510 we proposed that when a State imposes premiums, enrollment fees, or similar fees on SCHIP enrollees, the State plan must describe the amount of the premium, enrollment fee, or similar fee, the time period for which the charge is imposed, and the group or groups that are subject to these cost-sharing charges. We also proposed that the State plan include a description of the consequences for an enrollee who does not pay a required charge. We noted in the preamble that the State should indicate enrollee groups that are exempt from any disenrollment policy.

In addition, proposed § 457.510 set forth the requirement that the State plan include a description of the methodology used to ensure that total cost-sharing liability for a family does not exceed the cumulative cost-sharing maximum specified in proposed § 457.560, pursuant to section 2103(e)(3)(B) of the Act. We noted in the preamble to the proposed rule that the State's methodology should include a refund for an enrollee who accidentally pays more than his or her cumulative cost-sharing maximum. We proposed that a methodology that primarily relies on a refund by the State for cost-sharing payments made over the cumulative cost-sharing maximum will not be an acceptable methodology.

We discussed the findings of the George Washington University study on the types of methods States and private insurance companies use to track cost-sharing amounts against an enrollee's out-of-pocket expenditure cap. We described several examples of methods States could use to ensure that enrollees do not exceed the cumulative cost-sharing maximum. We solicited comments on tracking mechanisms States can use that do not place the burden of tracking cost-sharing charges on the enrollee.

Comment: Two commenters specifically urged HCFA to encourage States to adopt cost-sharing provisions for premiums, enrollment fees, and similar fees, as opposed to cost-sharing charges related to the provision of services (copayments, coinsurance, deductibles, or similar cost-sharing charges). The commenter asserted that applying cost sharing to premiums

instead of services would avoid the tracking burden altogether.

Response: We agree that it would be easier to track cost sharing if the State only imposed premiums or enrollment fees and that this would relieve States from the burden of tracking cost sharing associated with services. However, the statute provides States with flexibility to design cost sharing that meets their policy goals. While some States may wish to design cost sharing in a way that avoids or minimizes the need for tracking, others may favor the use of copayments to discourage over-utilization. We therefore encourage States to consider the ease of tracking along with many other factors in devising their cost-sharing systems, but do not prescribe or recommend a specific cost-sharing design.

Comment: One commenter recommended that HCFA revise paragraph (d) of this section to require that State plans include a description of the disenrollment protections established pursuant to § 457.570, in addition to the consequences for an enrollee who does not pay a charge. The commenter noted that § 457.570 requires disenrollment protections; however, nothing in the regulation currently requires States to describe these processes in the State SCHIP plan.

Response: We agree with this comment. We intended to require States to include disenrollment protections in their State plans, as stated in the preamble to the proposed regulation. Therefore, we have revised § 457.510(d) and § 457.515(d) to include the State plan requirement that States provide a description of their disenrollment protections as required under § 457.570.

Comment: Several commenters indicated that HCFA should require, rather than recommend, that States develop tracking mechanisms that do not rely on the beneficiary demonstrating to the State that he or she has met the cumulative cost-sharing maximum. The commenters did not believe that the finding of the George Washington study (that States were not charging high enough cost-sharing to make it likely that families reached their cap) was good cause for a weaker standard. The commenters noted that States are currently experiencing very good budget climates that are likely to weaken at some point, perhaps causing States to raise their cost-sharing requirements. They also observed that expansion to higher income eligibility groups may cause States to increase cost sharing under SCHIP. Moreover, the commenters believed that all States could develop the capability to track enrollees' cumulative cost sharing if required, since some States do so currently. And the commenters urged that the requirement be imposed on States and contracting plans rather than individual providers, since such a responsibility could deter provider participation in SCHIP.

Response: As part of the study conducted by George Washington University, States were invited to a meeting to discuss tracking of cost sharing under SCHIP. During this discussion, HCFA noted that some States were capable of using sophisticated tracking mechanisms like swipe cards to track their cost sharing. These States typically have a large concentration of managed care entities with participating providers who already have in place hardware that aids in tracking cost sharing for the SCHIP population. However, States with providers located in rural areas, and with providers who are not part of managed care networks, have indicated that it is administratively expensive to require States to put in place a sophisticated swipe card mechanism that would track cost sharing. Therefore, we have decided to continue to encourage States to use a tracking mechanism that does not rely on the enrollee, but will not require such a tracking mechanism due to implementation challenges and resource limitations in different States.

States must distribute, as part of the information furnished consistent with §§ 457.110 and 457.525 and general outreach activities, materials that inform the enrollee regarding his or her cost-sharing obligations, and assist the family in keeping track of the charges paid. At a minimum, States are required to include the schedule of cost-sharing charges, and the dollar amount of the enrollee's family's cumulative cost-sharing maximum. We also recommend that States educate the enrollee's family regarding tracking cost sharing against the cumulative cost-sharing cap.

Comment: Several commenters disagreed with our provision at § 457.510(e) that ''a methodology that primarily relies on a refund given by the State for overpayment (of cost sharing) by an enrollee is not an acceptable methodology.'' These commenters indicated that the use of a refund process can be the most cost effective and simple approach to ensuring that cost sharing does not exceed limits, or that individuals exempt from cost sharing are not required to pay when it is not appropriate. The commenters believe States should be given the flexibility to develop their own process as long as the process guarantees that families will not have to pay cost-sharing charges for which they are not responsible. The commenters suggested that we consider that States are limited to a 10 percent cap on administrative costs, and that overly prescriptive measures added to administrative costs can take away from other important administrative functions, such as outreach and eligibility determinations. Several commenters also questioned how these provisions apply to a State that administers SCHIP through employer-sponsored health insurance plans.

Response: As stated in an earlier response, we recognize that there are situations in which the use of a refund methodology may be necessary. However, we believe States generally must be proactive and provide specific procedures for enrollees and their families to follow so that they are not overcharged cost sharing. A State methodology that merely reimburses or refunds enrollees for any cost sharing in excess of the cumulative cost-sharing maximum without including steps to help enrollees avoid overpayment will require the enrollees to outlay cash to obtain access to services that they should have been able to access without the burden of cost sharing. We view such a refund policy to be contrary to the limits on cost sharing set forth in section 2103(e) of the Act.

Comment: One commenter suggested that we revise this section to require that, in describing the methodology used to ensure that total cost-sharing liability for an enrollee's family does not exceed the cumulative cost-sharing maximum, the State plan must describe how the State calculates total income for each family, and how the State will prevent charges over the cumulative cost-sharing maximum. The commenter noted that the preamble stated that the description of the methodology must explain these areas. The commenter asked that this language be incorporated into the regulation.

Response: We agree with the general point that the commenter was making, that States should be required to disclose the principles used to calculate cumulative cost sharing maximums, but we believe such disclosure is equally important on an individual level as on a statewide level. Thus, we are adding paragraph (d) to 457.560, to require that the States provide the enrollee's family the precise dollar amount of the cumulative cost-sharing maximum at the time of enrollment and at the time of re-enrollment. However, we have not revised § 457.510 because it already requires the State plan to describe the methodology for ensuring that cost sharing for a family does not exceed

cumulative maximums, and this must include the information described above. If the description submitted in a proposed State plan or amendment does not include a full explanation of how income is calculated for purposes of the cumulative cost sharing maximum and other relevant details, HCFA requests this information in reviewing the submission.

Comment: One commenter stated that, if a family must pay more than the customary rate for child care due to the special needs of the child, there should be a mechanism for that additional cost to be considered when determining financial status. Children with chronic conditions should be defined to include children with mental health and substance abuse conditions. Another commenter agreed with the finding of the George Washington study that children with chronic conditions or special needs often have expenses for related, non-covered services, which can create a tremendous financial burden for the family. The commenter recommended that the statute be changed to eliminate the cost-sharing provision for eligible children with chronic illness or other special needs. In this commenter's view, at a minimum, all related expenses should be counted toward the cumulative cost-sharing cap for these children. The commenter also agreed with the George Washington study's recommendation that States assign a case manager to children with chronic needs to assure that cost sharing does not exceed the cumulative cost-sharing maximum for these children.

Response: Title XXI does not include any special provision regarding cost sharing for children with special needs or chronic conditions and we appreciate the commenter's recognition that this issue is driven by the statute. States may consider the additional costs, including the costs associated with child care and case management, borne by families of children with special needs or chronic conditions when imposing cost sharing on this population, but HCFA does not have statutory authority to require that States take these costs into account. In addition, States may, at their option, exempt families of children with special needs or chronic conditions group from cost sharing, because the added costs of care can significantly reduce their disposable income. However, we have not specifically required States to exempt these children, and have therefore not included the commenter's recommendation in the regulation text.

Comment: Several commenters opposed our suggestion in the preamble that States count non-covered services towards the cumulative cost-sharing maximum.

Response: We do not require States to count the costs of non-covered services towards the cumulative cost-sharing maximum. However, we encourage States to consider the additional costs of uncovered services particularly for families with special needs children, when imposing cost sharing. States may pursue this policy option by counting non-covered services toward the cumulative cost-sharing maximum or by implementing other State policies to limit the burden on such families.

4. Co-Payments, Coinsurance, Deductibles, or Similar Cost-Sharing Charges: State Plan Requirements (§ 457.515)

Section 2103(e)(1)(A) of the Act requires that the State plan include a description of the amount of premiums, deductibles, coinsurance and other cost sharing imposed. We proposed that the State plan describe the following elements regarding copayments, coinsurance, deductibles or similar charges: the service for which the charge may be imposed; the amount of the charge; the group or groups of enrollees to whom the charge applies; and the consequences for an enrollee who does not pay a charge. We proposed that the State plan describe the methodology used to ensure that total cost-sharing liability for an enrollee's family does not exceed the cumulative cost-sharing maximums. This description must explain how the State calculates total income for each family, and how the State will prevent charges over the cumulative cost-sharing maximums.

Finally, we proposed, in accordance with the prudent layperson standard in the Consumer Bill of Rights and Responsibilities, that States must provide assurances that enrollees will not be held liable for costs for emergency services above and beyond the copayment amount that is specified in the State plan. Specifically, we proposed that the State plan must include an assurance that enrollees will not be held liable for additional costs, beyond the copayment amounts specified in the State plan, that are associated with emergency services provided at a facility that is not a participating provider in the enrollee's managed care network. In addition, we require that the State will not charge different copayment amounts for emergency services, based upon the location (in network or out of network) of the facility at which those services were provided. We indicated that we welcomed public comments on our proposed policy. In this final rule, we have added a provision to § 457.515(d) that States must describe in the State plan the disenrollment protections adopted by the State pursuant to § 457.570.

Comment: One commenter suggested that §§ 457.510(d) and 457.515(d), which require that the State plan describe the consequences for an enrollee who does not pay a charge, be revised to also require State plans to describe the consequences for a provider who does not receive a payment from an enrollee. The commenter indicated that providers should have information on the State's policy regarding unpaid copayments. The commenter questioned if providers may deny services to, or pursue collection from, enrollees who refuse to pay cost sharing. The commenter also asked if States will increase payments to providers when enrollees do not pay.

Response: Unlike under the Medicaid program, we do not have the statutory authority to prevent providers under separate child health programs from denying services to enrollees who do not pay their cost-sharing charges. Nor do we have clear authority to preclude providers or the State from billing the enrollee for unpaid cost-sharing charges. State plans should, consistent with fairness and equity, ensure that the provider or State gives the enrollee a reasonable opportunity to pay cost sharing before pursuing collection. Providers should refer the enrollee back to the State if he or she is demonstrating a pattern of non-payment, so that the State can review the financial situation of the enrollee. For example, the State should inquire whether the enrollee's income has dropped to a Medicaid eligibility level, or to a level of SCHIP qualification that does not require cost sharing or requires it at a lower level. We also suggest that States maintain open communication with providers regarding any financial losses for the provider resulting from non-payment of cost sharing. However, we note that the State's policy in this area is a matter of State discretion under this regulation.

Comment: One commenter urged HCFA to add a provision making clear that an enrollee may not be denied emergency services based on the inability to make a copayment, regardless of whether the provider is inside or outside of the enrollee's managed care network. The commenter also recommended that we include in the preamble a discussion of the obligations of emergency services providers under the Emergency Medical Treatment and Active Labor Act (EMTALA).

Another commenter suggested that as a general rule for all SCHIP services, including emergency services, cost-sharing limits should apply only to services delivered through network participating providers. If there is to be an exception to this rule for emergency services, then cost-sharing limits should only apply to out-of-network emergency service providers that are not within a reasonable distance of network participating providers.

Response: While this is not an appropriate vehicle to discuss EMTALA responsibilities at length, when those responsibilities are triggered, a hospital cannot turn away a patient solely because of inability to pay. In addition, § 457.410 requires States to provide coverage of emergency services; § 457.495 requires States to ensure that SCHIP enrollees have access to covered services, including emergency services; and § 457.515 specifies that enrollees cannot be held liable for cost sharing for emergency services provided outside of the managed care network.

If an enrollee goes outside of a managed care network to receive non-emergency services that are not authorized by the health plan, then the enrollee may be responsible for the full cost of the services provided. However, because of the nature of emergency services and the importance of ensuring that enrollees receive such services without delay or impediment, such a situation is not reasonable. Thus, as we discuss further below, we have retained the regulation text at § 457.515(f) providing that enrollee financial responsibility for emergency services must be equal whether the enrollee obtains the services from a network provider or out-of-network.

Comment: Several commenters supported the proposed requirement that beneficiary cost sharing for emergency services can not vary based on whether the provider is participating in a managed care network or not. One commenter specifically asserted that the use of differential copayments would be contrary to the spirit of the ''prudent layperson'' standard for emergency services. Another commenter recommended retaining or lowering the proposed maximum limit for copayments on emergency services, rather than raising the limit to levels parallel to those permitted in the Medicare+Choice programs, in light of the inability of many low-income families to access this amount at the time of an emergency.

Response: In keeping with the prudent layperson standard of assuring immediate access to emergency services, we have retained the prohibition against differential copays based upon location (in-network or out-of-network) under § 457.515(f). These services are required to address an emergency and can be time sensitive, and higher copayment levels for out of network providers might result in an unacceptable delay to determine whether the provider participates in the enrollee's managed care network. Furthermore, differential copayment levels might affect the ability of enrollees to access the closest and most accessible provider.

We have neither raised nor lowered the proposed permissible copayment levels for emergency services, because we believe the overall cost-sharing limitations are sufficient to protect enrollee families. We have not adopted the Medicare+Choice policy that would have permitted a $5.00 copayment for emergency medical services. The cost sharing provisions at § 457.555 will apply to emergency medical services.

Comment: We received a comment on our statement in the preamble that we considered adopting the Medicare+Choice policy regarding emergency services obtained outside of the provider network. The commenter noted that limitations on emergency room cost sharing at Medicare+Choice levels, whether in network or out of network, could be administratively burdensome to group health plans and participating providers, and might dissuade such entities and practitioners from contracting with SCHIP.

Response: As noted above, we have not adopted the Medicare+Choice policy described in the preamble to the proposed rule. We do note, however, that premium assistance programs are subject to the same cost-sharing requirements and protections as other types of SCHIP programs. Such protections are required by statute and recognize the unique financial constraints of the SCHIP population. In situations where employer plans charge more than is permissible under these rules, the State will need to develop a mechanism to prevent enrollees from paying excess charges.

5. Cost Sharing for Well-Baby and Well-Child Care (§ 457.520)

Under section 2103(e)(2) of the Act, the State plan may not impose copayments, deductibles, coinsurance or other cost sharing with respect to well-baby and well-child care services in either the managed care or the fee-for-service delivery setting. At proposed § 457.520, we set forth services that constitute well-baby and well-child care for purposes of this cost-sharing prohibition. We proposed to define these well-baby and well-child services consistent with the definition of well-baby and well-child care used by the *American Academy of Pediatrics* (AAP) and incorporated in the Federal Employees Health Benefits Program (FEHBP) Blue Cross and Blue Shield benchmark plan.

We also proposed to apply the prohibition on cost sharing to services that fit the definition of routine preventive dental services used by the *American Academy of Pediatric Dentistry* (AAPD) when a State opts to cover these services under its program.

We proposed at § 457.520 that the following services are considered well-baby and well-child care services for the purposes of the prohibition of cost sharing under section 2103(e)(2):

- All healthy newborn inpatient physician visits, including routine screening (whether provided on an inpatient or on an outpatient basis).
- Routine physical examinations.
- Laboratory tests relating to their visits.
- Immunizations, and related office visits as recommended in the AAP's ''Guidelines for Health Supervision III'' (June 1997), and described in ''*Bright Futures:* Guidelines for Health Supervision of Infants, Children, and Adolescents'' (Green M., (ed.). 1994).
- When covered under the State plan (at the State's option) routine preventive and diagnostic dental services (for example, oral examinations, prophylaxis and topical fluoride applications, sealants, and x-rays) as described by the AAPD's current Reference Manual (Pediatric Dentistry, Special Issue, 1997–1998, vol 19:7, page 71–2).

Comment: One commenter noted that the language of this section is ambiguous in stating that the ''State plan may not impose copayments, deductibles, coinsurance or other cost sharing with respect to well-baby/well child care services as defined by the State.'' HCFA should clarify that no preventive service as defined by the Guidelines for Health Supervision III (including the appended Recommendations for Preventive Pediatric Health Care) and Bright Futures is subject to cost sharing, as was intended by the underlying statute.

Response: We agree with the commenter and have revised § 457.520(a) to be clearer that a State may not impose cost sharing on services that would ordinarily be considered well-baby and well-child care. As described in subpart D, Benefits, States may define well-baby and well-child services for coverage purposes. While this may provide States flexibility in determining the appropriate scope of

benefits, such flexibility is not appropriate with respect to cost sharing which might deter appropriate utilization of covered services. Thus, we are specifying in § 457.520(a) that cost sharing may not be imposed on any covered services that are also within the scope of AAP well-baby and well-child care recommendations.

Comment: One commenter noted that there are differences between the discussion of this provision in the preamble (64 FR 60913) and in the regulations text (64 FR 60955). The commenter believed the provision as set forth in the regulations text is more clear.

Response: In this final rule, we are adopting the provisions regarding well-baby and well-child care as set forth in the regulations text at § 457.520, except that we have amended these provisions to clarify the scope of services to which the prohibition on cost sharing applies.

Comment: A number of commenters expressed concern that adolescent health care services are not specifically listed as well-baby and well-child care services exempt from cost sharing. Although the preamble notes that well-child care includes health care for adolescents, the commenters urged HCFA to make specific mention of this fact in the regulation. One commenter recommended that HCFA define adolescent health care services using the schedules from the American Medical Association's ''Guidelines for Adolescent Preventive Services,'' and the American College of Obstetricians and Gynecologists, ''Primary and Preventive Health Care for Female Adolescents'' as well as those of the American Academy of Pediatrics. Another commenter noted that there is no reason why a physical exam for a toddler should be exempt from cost-sharing requirements while an exam and related services for an adolescent are not.

Response: It is not necessary to add the term adolescent to the regulation because the term ''child'' as defined by the statute and regulation refers to enrollees under the age of 19 the cost-sharing rules set forth in this regulation apply to all children under age 19. Therefore, States cannot impose cost sharing on any well-child care services provided to an adolescent under the age of 19. In addition, the standard recommended by the AAP for routine physical exams specifically includes treatment of adolescents.

Comment: One commenter disagreed with the use of a specific immunization schedule because it may be difficult for States using employer-sponsored insurance to implement this requirement. The commenter recommended that we revise the regulation to state ''Immunizations and related office visits *as medically necessary.*''

Response: We are not accepting the commenter's suggestion because immunizations recommended by the Advisory Commission on Immunization Practices (ACIP) are generally accepted as being medically necessary. The State is responsible for assuring that an enrollee does not pay cost sharing for any immunizations recommended by ACIP.

Comment: One commenter recommended that the immunization schedule include updates.

Response: As proposed, § 457.520(b)(4) prohibits cost sharing for immunizations and related office visits as recommended by ACIP. We are retaining this language in the final regulation at § 457.520(b)(4) which also indicates that updates to these guidelines must be reflected in States cost-sharing policies.

Comment: One commenter urged that HCFA remove the term ''routine physical examinations'' from the list of well-baby and well-child care services. The inclusion of this term is confusing in this commenter's view because almost every office visit for children entails a ''physical examination'' as part of the evaluation and management component of the office visit. As an alternative, the commenter recommended using the language for well-baby and well-child care services as listed in § 457.10. Other commenters recommended that routine exams be specifically tied to professionally established periodicity schedules.

Response: We agree that our intent may have been unclear. We have revised § 457.520(b)(2) to provide that the well-baby and well-child routine physical exams, as recommended by the AAP's ''Guidelines for Health Supervision III'', and described in ''Bright Futures: Guidelines for Health Supervision of Infants, Children and Adolescents'', (which would include updates to either set of guidelines) may not be subject to cost sharing.

Comment: Several commenters stated that lab tests should not be exempt from cost sharing, especially given that lab tests are expensive and not always preventive. Since lab services are provided by a separate entity, outside of the office of the physician providing the well-baby and well-child care service, States should be given flexibility in determining whether to exempt lab services from cost sharing, particularly in managed care settings. One commenter requested that HCFA clarify the intention of the provisions excluding lab services from cost sharing. The commenter questioned if the exemption is limited to laboratory tests that are associated with the well-baby and well-child visit.

Response: We have revised the regulation text at § 457.520(b)(3) to indicate that States are required to exempt from cost sharing only those lab tests associated with the well-baby/well-child routine physical exams described in § 457.520(b)(2). We believe the exemption from cost sharing for these lab tests is consistent with the statutory intent that there is no cost sharing imposed on enrollees for well-baby and well-child care services. All other lab tests that are not routine and not part of a well-baby or well-child visit may be subject to cost-sharing charges consistent with the other cost-sharing provisions of this subpart.

Comment: Several commenters indicated their view that States should have the flexibility to determine how best to improve access to dental services. In their view, the prohibition of cost-sharing for dental services may discourage States from offering dental services under SCHIP because it is an optional benefit. One commenter recommended prohibiting States from imposing copayments, deductibles, coinsurance or other cost sharing for all covered dental services. This commenter indicated that the Medicaid program has clearly demonstrated that imposing costly, difficult, and risk shifting management procedures on providers severely limits participation in such programs and therefore severely restricts access to essential oral health care for this high risk, high need population. The commenter stated that, for example, if a child arrives in a dental office without the appropriate cost-sharing funds, the practitioner must either defer the needed service, enter into costly billing procedures, or waive the money due and such waivers previously have, on some occasions, been interpreted as insurance fraud. The commenter indicated that our policy may discourage practitioners from participating in the SCHIP program and result in problems of access to care for the children with the greatest need.

Response: The majority of separate child health programs offer dental benefits and do not impose cost sharing on preventive dental services. If States were to impose cost sharing on preventive benefits, due to their limited incomes, enrollees would only access services when needed and when services are most expensive. Almost all States have elected to provide at least some dental coverage in their State

plans without cost sharing for preventive services. The cost-sharing exemption policy has not caused States to discontinue coverage of dental services thus far. In addition, we note that the cost-sharing exemption on well-baby and well-child care services is based upon section 2103(e)(2)of the Act, which provides that the State plan may not impose cost sharing on benefits for these preventive services. We have interpreted this statutory provision to support the cost-sharing exemption for routine preventive and diagnostic dental services.

6. Public Schedule (§ 457.525)

Section 2103(e)(1)(A) of the Act requires that the State provide a public schedule of all cost-sharing charges. We proposed that the public schedule contain at least the current SCHIP cost-sharing charges, the beneficiary groups upon whom cost sharing will be imposed (for example, cost sharing imposed only on children in families with income above 150 percent of the FPL), the cumulative cost-sharing maximums, and the consequences for an enrollee who fails to pay a cost-sharing charge. We also proposed that the State must make the public schedule available to enrollees at the time of enrollment and when the State revises the cost-sharing charges and/or cumulative cost-sharing maximum, applicants at the time of application, SCHIP participating providers and the general public. To ensure that providers impose appropriate cost-sharing charges at the time services are rendered, we proposed that the public schedule must be made available to all SCHIP participating providers. In this final rule, we have added § 457.525(a)(4) which indicates that the State must include in the public schedule, the mechanisms for making payments for required charges. We also added to § 457.525(a)(5) that the public schedule describe the disenrollment protections pursuant to § 457.570.

Comment: Several commenters recommended that States have the option to provide information in the public schedule that defines cumulative cost sharing as a percentage of income. The commenters requested that we clarify that States can defer responsibility for distributing the public schedule to all SCHIP providers to the managed care entities as part of their contractual obligations.

Response: States may define the cumulative cost-sharing maximum as a percentage of income in the public schedule and request that managed care entities distribute the public schedule to all SCHIP providers (although the State retains the responsibility that the entities involved make the schedule available to providers). However, we have modified the regulation at § 457.110(b)(2) to indicate that States must calculate the precise amount of the cumulative cost-sharing maximum (the dollar amount instead of a percentage of income) that applies to the individual enrollee's family at the time of enrollment (as well as at the time of re-enrollment) to maximize the usefulness of information provided to the family and to ensure uniform calculation of the amount, maximize the usefulness of the information, and make tracking easier.

Comment: One commenter urged HCFA to include language in the preamble that ''applicants'' and ''enrollees'' include adolescents (independent from other children in their family) and that information should be directed to them about any schedule of costs. The commenters noted that adolescents often seek care on their own, not only for services that they need on a confidential basis, but for other services as well. Unless they are aware of the charges they may encounter, and the services that do not require a copayment, they may be deterred from seeking care, in this commenter's view.

Response: Section 457.525(b) specifically requires States to provide a public schedule, which includes a description of the plan's current cost-sharing charges, to SCHIP enrollees at the time of application, enrollment, and when cost-sharing charges are revised. We have added a provision at § 457.525(b)(1) requiring that States provide SCHIP enrollees the public schedule at reenrollment after a redetermination of eligibility as well. This section also requires that cost-sharing charges be disclosed to SCHIP applicants at the time of application. SCHIP enrollees, by definition, are children under age 19. In most cases, this information will be given to family members due to the age of the child. However, we encourage States to provide information about cost sharing directly to adolescent applicants and enrolles when appropriate. We also encourage States to consider the range of applicants, enrollees and family members who might benefit from the provision of this information, including adolescents, and we encourage States to describe the plan's current cost-sharing charges in language that is easily understood and tailored to the needs of target populations, consistent with section 457.110.

Comment: One commenter suggested that the requirement to provide the public schedule to applicants may be overwhelming to both the program and the applicants. Enrollees are most interested in the information relating to the family's individual obligations.

Response: Section 2103(e)(1)(A) of the Act provides sufficient authority to require States to make a public schedule available, and to provide all interested parties with notice of cost-sharing obligation for the program. In addition, applicants should be given a chance to review the cost sharing structure prior to enrollment, so that the applicant will understand the potential costs of SCHIP and can make a reasoned choice as a health care consumer. This policy also aids in future tracking of the family's cost-sharing obligation.

Comment: One commenter recommended that HCFA require that the public schedule contain information about an enrollee's rights with respect to cost sharing, including the right to receive notice and make past due payments, as well as other protections established by the State in compliance with § 457.570.

Response: Section 457.525(a)(5) of this final rule requires that the public schedule include a description of the consequences for an enrollee who does not pay a cost-sharing charge. We are also revising this section to require States to discuss, as part of this description, the disenrollment protections it has established pursuant to § 457.570. Section 457.570 requires States to provide enrollees with an opportunity to pay past due cost sharing, as well as an opportunity to request a reassessment of their income, prior to disenrollment.

Comment: One commenter recommended that we require States to include detailed information about the cost-sharing schedule at each annual renewal and in the SCHIP application packet/pamphlet. Applications should also include information to notify participants of services that are subject to cost sharing.

Response: We have revised § 457.525(b)(1) to require that States also provide the public schedule at the time of a re-enrollment after a redetermination of eligibility. In addition, we note that § 457.525(a)(1) requires that the public schedule of cost-sharing requirements include information on current cost-sharing charges and the cumulative cost-sharing maximums. This information should specify the services or general category of services for which cost sharing is imposed and services that are exempt from cost sharing.

7. General Cost-Sharing Protection for Lower Income Children (§ 457.530)

At § 457.530, we proposed to implement section 2103(e)(1)(B) of the Act, which specifies that the State plan may only vary premiums, deductibles, coinsurance, and other cost-sharing charges based on the family income of targeted low-income children in a manner that does not favor children from families with higher income over children from families with lower income. We noted that this statutory provision and the implementing regulations apply to all cost sharing imposed on children regardless of family income.

Comment: One commenter requested that when considering the requirement that States not vary cost sharing based on the family income of the targeted low-income children in a manner that favors children from families with higher income over children from families with lower income, HCFA should consider the issue of disposable income. The commenter recommended that we should consider only the income the family receives above 100 percent of the FPL (disposable income). When applying a flat percentage assessment, the assessment will consume more of the lower-income family's disposable income than the disposable income of a higher-income family. The commenter cited the following example: A straight 3 percent assessment would consume 9 percent of the disposable income for a family at 150 percent of poverty but only 6.5 percent of the income for a family at 185 percent of poverty.

Response: We recognize that health care costs may consume a larger proportion of a lower income family's disposable income. Accordingly, at § 457.560(d), we provide for a lower cumulative cost-sharing maximum (2.5 percent) for cost sharing imposed on children in families at or below 150 percent of the FPL in part because of the higher proportionate consumption of disposable income at lower poverty levels. Also, in accordance with § 457.540(b), and section 2103(a)(1)(B) of the Act, copayments, coinsurance, deductibles and similar charges imposed on children whose family income is at or below 100 percent of the FPL may not be more than what is permitted under the Medicaid rules at § 447.52 of this part and the charges may not be greater for children in lower income families than for children in higher income families.

8. Cost-Sharing Protection to Ensure Enrollment of American Indians/Alaska Natives (§ 457.535)

Section 2102(b)(3)(D) of the Act requires the State plan to include a description of the procedures used to ensure the provision of child health assistance to targeted low-income children in the State who are Indians (as defined in section 4(c) of the Indian Health Care Improvement Act). To ensure the provision of health care to children from AI/AN families, we proposed that States must exclude AI/AN children from the imposition of premiums, deductibles, coinsurance, copayments or any other cost-sharing charges. For the purposes of this section, we proposed to use the definition of Indians referred to in section 2102(b)(3)(D) of the Act, which defines Alaska Natives and American Indians as Indians defined in section 4(c) of the Indian Health Care Improvement Act, 25 U.S.C. 1603(c). We also specified in the regulation that the State must only grant this exception to AI/AN members of Federally recognized tribes (as determined by the Bureau of Indian Affairs).

Comment: Several commenters requested that HCFA reconsider the AI/AN exemption. Many commenters noted that it is administratively burdensome (especially in States with small AI/AN populations) and expensive in light of the fact that a number of States have already negotiated contracts with health care entities that assume cost sharing for this population and application of the 10 percent limit on administrative expenditures. Many commenters recommended that we focus on technical assistance instead to assure that States are consulting with tribes. Some commenters were concerned that having no cost sharing for this group, but having it for other children in the program would single out AI/AN children in health care provider offices and facilities. Also, commenters believed our policy contradicts the statutory intent to prevent discrimination against children with lower family incomes. In their view, the elimination of cost sharing in these situations creates a different standard for a specific population group and may imply to both providers and families SCHIP enrollees that AI/AN children's parents cannot be relied upon to pay anything toward the costs of their health care. One commenter observed that if HCFA's reason for exemption is because AI/AN children are typically unable to pay cost sharing, then the exemption should apply to special needs children as well.

Response: Section 2102(b)(3)(D) of the Act requires that a State ensure the provision of child health assistance to targeted low-income children in the State who are Indians. In accordance with this statutory provision and to enhance access to child health assistance, we have specified that States may not impose cost sharing on this population. This exemption is consistent with section 2103(e)(1)(B) of the Act because this statutory provision prohibits States from imposing cost sharing based on the family income of targeted low-income children in a manner that favors children from families with higher income over children from families with lower income. The exemption from cost sharing for AI/AN children is not a variation of the cost sharing based on the family's income and is not a violation of section 2103(e)(1)(B). The cost-sharing exemption for AI/AN children is based upon the statutory requirement at section 2102(b)(3)(D), which requires particular attention to this population.

This cost-sharing exemption also reflects the unique Federal trust with and responsibility toward AI/ANs. The statute specifically singles out children who are AI/ANs and requires that States ensure that such children have access to care under SCHIP. The statute confirms that AI/AN children are a particularly vulnerable population, and that a requirement to pay cost sharing will act as a barrier to access to care for this population. Therefore, in order to operate a SCHIP program in compliance with section 2103(b)(3)(D), the only way to ensure access to AI/AN children is to exempt them from the cost-sharing requirements. In addition, absent this exemption for AI/AN children, these children may pursue services from the Indian Health Service (IHS) (where cost sharing is not required) without pursuing coverage under SCHIP or Medicaid. We disagree with the commenter's assertion that a similar exemption should be granted for children with special needs, there is no parallel statutory provision that requires States ensure access to this population. While the unique medical needs of this population are not insignificant, the AI/AN exemption is based on the Federal tribal relationship and responsibility for protection of this specific group. However, we do not believe there is sufficient rationale or authority for including special needs children under this exemption.

We further recognize that it may be administratively burdensome for some States to exempt this population if States are required to verify the status of

the enrollee as Indians. However, States may rely on the beneficiary to self-identify their membership in a Federally-recognized tribe and self-identification would substantially reduce the administrative burden and associated costs to the State. Also, this exemption will not single out AI/AN children at providers' offices and facilities if the State requires the enrollee to self-identify at the time of enrollment and the State provides inconspicuous identification for these children so that providers know not to charge them cost sharing at the time the enrollee receives services.

Comment: One commenter asked HCFA to clarify that cost-sharing charges are not imposed by Tribal clinics or community health centers.

Response: Under § 457.535, the AI/AN population is exempt from cost sharing. IHS facilities and tribal facilities operating with funding under P.L. 93–638 (''tribal 638 facilities'') do not charge cost sharing to the AI/AN population.

Comment: Several commenters recommended that the States' costs incurred due to the AI/AN exemption should be reimbursed with 100 percent Federal funds.

Response: A State will be able to claim match for increased costs resulting from the AI/AN exemption at the State's enhanced matching rate. However, we do not have authority under title XXI to provide 100 percent FMAP for these costs and would therefore need a legislative change to do so.

Comment: Several commenters recommended that AI/AN enrollees be permitted to self-certify their AI/AN status if HCFA does not concur with the commenter's request to remove the AI/AN cost-sharing exemption.

Response: We agree and take note that we have revised the policy set forth in the preamble to the proposed rule. States may allow self-identification for the purposes of the AI/AN cost-sharing exemption. Self-identification is consistent with our policies that encourage States to simplify the application and enrollment processes.

Comment: One commenter suggested that we apply the AI/AN cost-sharing exemption to all Indians based on the definition referred to in section 2102(b)(3)(D). The commenter requested that we remove the provision in the proposed regulation at § 457.535 that would narrow this definition to ''AI/AN members of *a Federally recognized tribe*.'' The commenter stated that this definition of AI/AN children is more restrictive than that in the Indian Health Care Improvement Act, has no basis in title XXI and it is also inconsistent with the definition of Indian set forth in the consultation provisions at § 457.125(a), which expressly request that States consult with ''Federal recognized tribes and other Indian tribes and organizations in the State * * *'' The commenter indicated the view that there is little point in consulting with non-Federally recognized tribes about enrollment in SCHIP if the children of those tribes are not excluded from the premiums and cost sharing.

Response: Because the Federal/tribal relationship is focused only on AI/ANs who are members of Federally recognized tribes, this final rule only requires States to exempt from cost sharing AI/ANs who are members of Federally recognized tribes. With regard to the consultation requirements at proposed § 457.125(a), we note that, although the cost-sharing exemption is required only for AI/ANs who are members of a Federally recognized tribe, individuals from other tribes may be eligible for child health assistance under SCHIP. There are numerous issues other than cost sharing that are involved in designing and operating a program, and we believe that States should be open to consultation with all interested parties, including non-federally recognized tribes. As such, we have removed the consultation requirement from § 457.125 and encourage the participation of these groups in the public involvement process established by the State in accordance with the new § 457.120(c). Finally, we have modified the definition of American Indian/Alaska Native at § 457.10 to be consistent with the Indian Health Care Improvement Act, yet also comport more closely with the definition used in the Indian Self Determination Act (ISDEAA).

Comment: One commenter suggested that HCFA allow time for States to comply with this new requirement and not delay approval of State plans or plan amendments for the time it will take to change State law to implement this change.

Response: In a letter dated October 6, 1999, HCFA informed SCHIP State health officials that we interpret the SCHIP statute to preclude cost sharing on AI/AN children. Since October 1999, we have required States submitting State plan amendments to alter cost sharing to comply with the exemption in order to gain approval for these amendments. States that have not submitted such amendments have been given ample notice of this policy. We will expect all States to comply with the requirements of § 457.565(b), which implements the exemption of AI/AN targeted low-income children from cost sharing and comply immediately with this requirement upon the effective date of this regulation.

Comment: One commenter suggested that States with small AI/AN Indian populations be waived from the cost sharing exemption so they can continue their programs as implemented.

Response: We realize there is some concern about the administrative difficulties related to exempting AI/AN children from cost sharing in States with small AI/AN populations. However, as noted above, we will permit AI/AN applicants to self-identify at the time of enrollment for the purposes of the cost-sharing exemption. This policy minimizes the administrative burden on States.

Comment: Two commenters asked HCFA to clarify that, in States with SCHIP or Medicaid expansions involving AI/AN adults or entire families, the cost-sharing exemption be applied to AI/AN adults as well.

Response: In States with separate child health programs or Medicaid expansions that provide coverage to AI/AN adults or entire AI/AN families, the cost-sharing exemption only applies to children. If a State has imposed a premium on the family, the State must reduce the premium proportionately so that it applies to adults only. They also must not deny children access to coverage if the adults in the family cannot make premium payments. We are not restricting cost sharing for AI/AN adults because section 2102(b)(3)(D) directly refers to children only.

9. Cost-Sharing Charges for Children in Families at or Below 150 Percent of the Federal Poverty Line (FPL) (§ 457.540)

Section 2103(e)(3) of the Act sets forth the limitations on premiums and other cost-sharing charges for children in families with incomes at or below 150 percent of the FPL. Pursuant to section 2103(e)(3)(A)(I) of the Act, we proposed that in the case of a targeted low-income child whose family income is at or below 150 percent of the FPL, the State plan may not impose any enrollment fee, premium, or similar charge that exceeds the charges permitted under the Medicaid regulations at § 447.52, which implement section 1916(b)(1) the Act. Section 447.52 specifies the maximum monthly charges in the form of enrollment fees, premiums, and similar charges, for Medicaid eligible families.

Section 2103(e)(3)(A)(ii) provides that copayments, coinsurance or similar charges imposed on children in families with income at or below 150 percent of the FPL must be nominal, as determined consistent with regulations referred to in section 1916(a)(3) of the Act, with

such appropriate adjustment for inflation or other reasons as the Secretary determines to be reasonable. The Medicaid regulations that set forth these nominal amounts are found at § 447.54. For children whose family income is at or below 100 percent of the FPL, we proposed that any copayments, coinsurance, deductibles or similar charges be equal to or less than the amounts permitted under the Medicaid regulations at § 447.54. For children whose family income is at 101 percent to 150 percent of the FPL, we proposed adjusted nominal amounts for copayments, coinsurance, and deductibles to reflect the SCHIP enrollees ability to pay somewhat higher cost sharing. We proposed that the frequency of cost sharing meet the requirements set forth in proposed § 457.550.

We also proposed that the cost sharing imposed on children in families with incomes at or below 150 percent of the FPL be limited to a cumulative maximum consistent with proposed § 457.560. Specifically, we proposed that total cost sharing imposed on children in this population be limited to 2.5 percent of a family's income for a year (or 12 month eligibility period).

Comment: One commenter questioned if the cost-sharing limits at §§ 457.540, 457.545, 457.550, 457.555 and 457.560 apply to out-of-network cost-sharing charges. The commenter recommended that the limits only apply to services delivered through the network participating providers. If not, the commenter argued that States cannot effectively use managed care to control costs and will be unable to develop effective partnerships with employer-sponsored health insurance programs to provide SCHIP services.

Response: If an enrollee receives services outside of the network that were not approved or authorized by the managed care entity (MCE) to be received outside of the network, then the services are considered non-covered services and the enrollee may be responsible for related cost-sharing charges imposed (other than in the case of emergency services provided under § 457.555(d)) irrespective of the limits established under the above referenced sections. If, however, the services are authorized by the MCE and provided by an out-of-network provider, the cost-sharing limits of this subpart apply. A State must ensure enrollees access to services covered under the State plan, but a State has discretion over whether to use a fee-for-service or a managed care arrangement.

Comment: A couple of commenters observed that the premium limits as set forth in the Medicaid regulations at § 447.52 are unreasonably low, since these cost-sharing provisions and limits have not been updated since the 1970s. These commenters proposed that we use a percentage (of payment) to set these amounts instead of a flat dollar amount.

Response: Section 2103(e)(3)(A)(I) provides that States may not impose enrollment fees, premiums or similar charges that exceed the maximum monthly charges permitted, consistent with the standards established to carry out section 1916(b)(1) of the Act. Permitting States to charge higher premiums on families with incomes at this level of poverty would be inconsistent with the statute.

Comment: One commenter suggested that the rule and preamble explicitly address the cost sharing treatment of children in families below the Federal Poverty Level. They noted that, in States that have retained the resource test for children in Medicaid, significant numbers of children below poverty will be enrolled in separate child health programs due to excess assets. This commenter recommended that § 457.540 be revised to reflect the fact that some adolescents under 100 percent of the FPL may be receiving SCHIP services until they are fully phased into regular Medicaid and that protections must apply to these children as well.

Response: Section 457.540(b) of the proposed regulation addresses the need for lower cost-sharing limits for cost sharing imposed on all children below 100 percent of the FPL. This section limits cost sharing to the uninflated Medicaid cost-sharing limits permitted under § 447.54 of this chapter. Section 2103(e)(3)(A)(I) limits premiums, enrollment fees, or similar charges to the maximums permitted in accordance with section 1916(b)(1) of the Act. In addition, because the definition of ''child'' includes adolescents under the age of 19, there is no need to revise this section. We have retained this proposed provision in the final regulation. However, it should be noted that we have added paragraphs (d) and (e) to § 457.540. These requirements were originally part of § 457.550, which has been removed to improve the format of the regulation.

Comment: One commenter disagreed with the separate grouping, relative to cost sharing, for SCHIP enrollees under 100 percent of the FPL and the application of the Medicaid cost-sharing limits to this population. The commenter noted that the proposal is beyond the statute (the statute only refers to two tiers—above 150 percent of the FPL and at or below 150 percent of the FPL) and that the monetary difference between the SCHIP schedule applicable to 101 percent to 150 percent of the FPL and the Medicaid cost-sharing schedule is minimal. The commenter noted that the cost to States to create a program for this new income level is very significant. The commenter argued that the Medicaid cost-sharing requirements proposed for SCHIP enrollees under 100 percent FPL were developed two decades ago and have no connection to current health care costs or program changes. According to this commenter, creating this new tier of eligible SCHIP enrollees does not seem to comport with the flexibility provided States in the Congressional debate on SCHIP, or written in title XXI.

Response: Section 2103(e)(3)(A)(ii) of the Act specifies that the State plan may not impose ''a deductible, cost sharing, or similar charge that exceeds an amount that is nominal (as determined consistent with the regulations referred to in section 1916(a)(3) of the Act), with such appropriate adjustment for inflation or other reasons as the Secretary determines to be reasonable.'' The Secretary has the discretion to determine the increases to the Medicaid cost-sharing limitations that are reasonable and under this authority the Secretary has determined that it is not reasonable for States to impose cost sharing above the Medicaid limitations contained in § 447.54 for children with family incomes that are below the Federal poverty line. As noted in the comment above, children at this income level who are eligible for separate child health programs typically reside in States that have retained the resource test for children in Medicaid, and may be well below 100 percent of the FPL. In this case, even small increments in cost sharing may impact the ability to access services.

10. Cost Sharing for Children in Families Above 150 Percent of the FPL (§ 457.545)

Section 2103(e)(3)(B) mandates that the total annual aggregate cost sharing with respect to all targeted low-income children in a family with income above 150 percent of the FPL not exceed 5 percent of the family's income for the year involved. The proposed regulation provided that the plan may not impose total premiums, enrollment fees, copayments, coinsurance, deductibles, or similar cost-sharing charges in excess of 5 percent of a family's income for a year (or 12 month eligibility period). We have deleted this section because it repeats the requirements already stated in § 457.560(c). Please see the comments and responses at § 457.560(c) for further discussion.

11. Restriction on the Frequency of Cost-Sharing Charges on Targeted Low-Income Children in Families at or Below 150 Percent of the FPL (§ 457.550)

Section 2103(e)(3)(A)(ii) of the Act specifies that the State plan may not impose a deductible, cost sharing, or similar charge that exceeds an amount that is nominal as determined consistent with regulations referred to in section 1916(a)(3) of the Act, ''with such appropriate adjustments for inflation or other reasons as the Secretary determines to be reasonable''. We proposed to adopt the Medicaid rule at § 447.53(c) that does not permit the plan to impose more than one type of cost-sharing charge (deductible, copayment, or coinsurance) on a service. We also proposed that a State may not impose more than one cost-sharing charge for multiple services provided during a single office visit.

We also proposed to adopt the Medicaid rules at § 447.55 regarding standard copayments. Specifically, we proposed to provide that States can establish a standard copayment amount for low-income children from families with incomes from 101–150 percent FPL for any service. We proposed to expand upon the Medicaid rules and allow States to provide a standard copayment amount for any visit. Similar to the provisions at § 447.55 that allow a standard copayment to be based upon the average or typical payment of the service, our proposed provision would allow a State to impose a standard copayment per visit for non-institutional services based upon the average cost of a visit up to the copayment limits specified at proposed § 457.555(a), on these families.

Comment: A few commenters asked if States can still charge an enrollment fee. HCFA should clarify that States can charge both an enrollment fee for SCHIP and copayments for services, provided aggregate and individual dollar limits on cost sharing are observed.

Response: States can charge an enrollment fee for families at or below 150 percent FPL as long as the enrollment fee does not exceed the maximums specified in § 457.540(a) for children in families at or below 150 percent of the FPL and does not exceed the cumulative cost-sharing maximum in accordance with § 457.560(d) (2.5 percent of a family's income for a year or length of the child's eligibility period). For enrollment fees imposed on children in families with income above 150 percent of the FPL, enrollment fees and other cost sharing are limited to the cumulative cost-sharing maximum specified in § 457.560(c) (5 percent of the enrollee's family income for a year or the length of the child's period of eligibility). The restriction on imposition of one type of cost sharing in this section applies only to copayments, deductibles, and coinsurance or similar charges.

Comment: One commenter strongly supported the provision of the proposed rule that prohibits imposition of more than one copayment for multiple services provided during a single office visit. The commenter noted that this is a key issue for adolescents and that adolescents seek a variety of health care services on their own and seek to do so on a confidential basis (for example, diagnosis and treatment for a sexually transmitted disease). The commenter recommended that the preamble (or regulation) clarify whether there can be only one copayment required for a single office visit (for example, a $5.00 copayment for the visit) and whether the copayment must cover any associated lab tests, diagnostic procedures, and prescription drugs, or whether any additional copayments can be required. The commenter urged that HCFA make clear that only one copayment per visit may be required for all services associated with the single visit.

One commenter opposed the prohibition on imposing more than one cost-sharing charge for multiple services provided during a single office visit. In the commenter's view, cost sharing should relate to the provision of services rather than a visit. The commenter noted that CPT IV codes for physicians do not bundle multiple physicians or multiple services into a single visit. In this commenter's view, the proposed rule is also more restrictive than the current Medicaid provisions, which tie cost sharing to services, not to visits. The commenter argued that this added restraint on cost sharing is unnecessary because SCHIP enrollees are already protected from excessive charges by the overall cost-sharing caps and the limits on copayments.

Response: Section 457.550(b) (now § 457.540(e)) specifies that States cannot impose more than one copayment for multiple services furnished during one office visit. Thus, the copayment must cover any associated lab tests and diagnostic procedures. Only one copayment per visit may be required for all services delivered during the single visit. Lab tests performed at another site or prescription drugs obtained at a pharmacy may be subject to additional copayments. While the commenter notes that this is more restrictive than Medicaid, under Medicaid a provider cannot deny services to an enrollee if he or she cannot pay the associated copayment. SCHIP providers can deny services to enrollees under these circumstances. The per visit cost-sharing limit is intended to prevent access problems for SCHIP enrollees.

Comment: Several commenters requested that § 457.550(b) not apply to dental services or vision services because they are benefits that are defined by each individual service. In these commenters' view, limiting the frequency of cost sharing jeopardizes the State's ability to contract with many participating dental providers and limits the provision of needed dental services for SCHIP enrollees.

Response: The majority of State child health programs offer coverage for dental services and we believe this provision will not adversely affect State coverage of these services. In addition, provider participation is more likely to be influenced by States' payment rates than by cost sharing from enrollees. Once again, we believe it is important that the cost sharing on enrollees at or below 150 percent of the FPL be nominal in order to encourage enrollees to access vision and dental services before more expensive treatment is required.

Comment: One commenter indicated that § 447.550(b) should state that ''any copayment that the State imposes under a fee for service system may not exceed $5.00 per visit, regardless of the number of services furnished during one visit.'' Because the commenter assumes that the provider will seek the highest allowable copayment, for clarity, the rule should simply state that $5.00 is the maximum allowable per copayment visit. Section 457.550(b) is redesignated as § 457.540(e).

Response: We have modified the regulation to clarify that the provider can only collect up to the maximum amount allowed by the State based on the total cost of services delivered during the office visit. The provider cannot charge copayments in excess of what the State permits under the State plan.

Comment: One commenter pointed out an error in paragraph (c) of § 457.550, which refers to the maximum copayment amounts specified in paragraphs (b) and (c) of this section. The reference should be to § 457.555 (b) and (c).

Response: We agree with the commenter and have made these corrections to the final regulation text (§ 457.550(c) has been redesignated as § 457.555(e)). In addition, we have revised the reference to include subsection (a) as well.

12. Maximum allowable cost-sharing charges on targeted low-income children between 101 and 150 percent of the FPL (§ 457.555).

Section 2103(e)(3)(A)(ii) of the Act specifies that for children in families with incomes below 150 percent of the FPL, the State plan may not impose a deductible, cost sharing, or similar charge that exceeds an amount that is nominal as determined consistent with regulations referred to in section 1916(a)(3) of the Act, ''with such appropriate adjustment for inflation or other reasons as the Secretary determines to be reasonable''. We proposed provisions regarding maximum allowable cost-sharing charges on targeted low-income children at 101 to 150 percent of the FPL that mirror the provisions of §§ 447.53 and 447.54 but are adjusted to permit higher amounts.

Specifically, for noninstitutional services provided to targeted low-income children whose family income is from 101 to 150 percent we proposed the following service payment and copayment maximum amounts for charges imposed under a fee-for-service system:

Total cost of services provided during a visit	Maximum amount chargeable to enrollee
$15.00 or less	$1.00
$15.01 to $40	2.00
$40.01 to $80	3.00
$80.01 or more	5.00

We proposed to set a maximum per visit copayment amount of $5.00 for enrollees enrolled in managed care organizations. In addition, we proposed to set a maximum on deductibles of $3.00 per month per family for each period of SCHIP eligibility. We noted that, if a State imposes a deductible for a time period other than a month, the maximum deductible for that time period is the product of the number of months in the time period by $3.00. For example, the maximum deductible that a State may impose on a family for a three-month period is $9.00.

We also proposed, for the purpose of maximums on copayments and coinsurance, that the maximum copayment or coinsurance rate relates to the payment made to the provider, regardless of whether the payment source is the State or an entity under contract with the State.

With regard to institutional services provided to targeted low-income children whose family income is from 101 to 150 percent of the FPL, we proposed to use the standards set forth in the Medicaid regulations at § 447.54(c). Accordingly, we proposed to require that for targeted low-income children whose family income is at or below 150 percent of the FPL, the State plan must provide that the maximum deductible, coinsurance or copayment charge for each institutional admission does not exceed 50 percent of the payment made for the first day of care in the institution.

We proposed to allow States to impose a charge for non-emergency use of the emergency room up to twice the nominal charge for noninstitutional services provided to targeted low-income children whose family income is from 101 to 150 percent of the FPL. In § 457.555(d), we further proposed that States must assure that enrollees will not be held liable for additional costs, beyond the specified copayment amount, associated with emergency services provided at a facility that is not a participating provider in the enrollee's managed care network.

We realized that the regulation text as proposed regarding the limit on cost sharing related to emergency services was not clear. Therefore, we have added to § 457.555(a) that the cost-sharing maximums provided in this section apply to non-institutional services provided to treat an emergency medical condition as well. We also clarified in paragraph (c) that any cost sharing the State imposes for services provided by an institution to treat an emergency medical condition may not exceed $5.00. We also removed proposed paragraph (d), because this requirement is already included in § 457.515(f)

Comment: One commenter suggested that copayments and deductibles for families with incomes over 150 percent of the FPL be subject to the same limits that apply for families with incomes 101 to 150 percent of the FPL, noted in § 457.555 (a) and (b).

Response: The limitations proposed in § 457.555 (a) and (b) implement section 2103(e)(3)(A)(ii)of the Act. This section of the Act only applies to cost sharing imposed on targeted low-income children in families at or below 150 percent of the FPL. With respect to targeted low-income children in families above 150 percent of the FPL, the statute explicitly sets forth different cost-sharing provisions at 2103(e)(3)(B) and permits States to impose cost sharing that is only subject to the 5 percent cumulative cost-sharing maximum. Therefore, we do not have the statutory authority to apply these limits to cost sharing on children in families with incomes above 150 percent of the FPL.

Comment: One commenter encouraged HCFA to make the maximum allowable cost-sharing charges consistent with Medicaid. The commenter noted that a family with an income at or below 150 percent of the FPL enrolled in SCHIP has the same disposable income as a family with an income at or below 150 percent of the FPL in Medicaid, and therefore should not be expected to absorb a higher cost-sharing limit. Also, in this commenter's view, because the family may move from one program to another, there should be consistency in cost sharing.

Another commenter stated that the cost-sharing limits in this section should have been based on the Medicaid maximums increased by the actual inflation experienced since the promulgation of the original Medicaid regulations.

Response: Section 2103(e)(3)(ii) of the Act limits the copayments, deductibles, or similar charges imposed under SCHIP, for families with incomes at or below 150 percent of the FPL, to Medicaid cost-sharing amounts ''with such appropriate adjustments for inflation or other reasons as the Secretary determines to be reasonable.'' The cost-sharing amounts under Medicaid (found at 42 CFR 447.52) were originally established in regulation in 1976 and have never been adjusted for inflation. Therefore, using the discretion permitted under the statute, we inflated the schedule for SCHIP for cost sharing imposed on enrollees whose income is from 101 to 150 percent of the FPL. In doing so, we looked at both the general inflation rate and the level of need in the population at issue in reference to Medicaid recipients. Because children in families with incomes below the poverty line are more closely tied to the traditional Medicaid population, we have not inflated the Medicaid cost sharing limits found at § 447.52 for SCHIP enrollees with incomes at or below 100 percent of the FPL. We also note that under Medicaid, States cannot impose copayments, deductibles, and coinsurance on children under the age of 18. Therefore, children under the age of 18 who become eligible for the Medicaid program should not be subject to any copayments, deductibles or similar charges in accordance with § 447.53 of the Medicaid regulations. The SCHIP statute, however, clearly contemplates and permits the application of cost-sharing to SCHIP enrollees.

Comment: One commenter supported the higher cost sharing for non-emergency use of the emergency room. The commenter believes in promoting the concept of the medical home and

encouraging families to receive their children's care in that context.

Response: We appreciate the support of the commenter and also note that the policy, by only permitting twice the usual copayment amount for non-emergency use of the emergency room, protects the lower income populations served by SCHIP from having to pay excessive cost sharing if they find they can only access services at an emergency room. At the same time, it encourages enrollees to receive non-emergency services outside of an emergency room setting.

We realized that the proposed regulation text was not clear regarding the limit on cost sharing related to emergency services. Therefore, we added to section § 457.555(a) that the maximums provided in this section apply to non-institutional services provided to treat an emergency medical condition as well. We also clarified in paragraph (c) that any cost sharing the State imposes on services provided by an institution to treat an emergency medical condition may not exceed $5.00. Finally, we removed paragraph (d) from this section, because the requirement is already included in § 457.515(f).

Comment: Several commenters were concerned about the language in § 457.995(c)(2) which prohibits patients from being held responsible for any additional costs, beyond the copayment amount specified in the State plan, that are associated with emergency services provided by a facility that is not a participating provider in the enrollee's managed care network.

Response: With respect to the issue of additional costs for out-of-network emergency services, we believe that any costs associated with evaluating and stabilizing a patient in an out-of-network facility in a manner consistent with the cost-sharing restrictions in this regulation at § 457.555(d) must be worked out between the State and the managed care entity. Given the nature of the circumstances that may necessitate emergency services, enrollees may not be able to choose their place of care. Thus, the regulations do not allow additional cost sharing to be imposed on the beneficiary for emergency services including those provided out-of-network as described in § 457.515(f)(1) of this final regulation.

Comment: Two commenters asked that we clarify the interpretation of the phrase at § 457.555 (a)(3) and (b) ''directly or through a contract'', with regard to payment made by the State. This commenter interpreted the phrase to mean that when the State operates SCHIP through employer-sponsored health plans, States would be expected to determine the rates paid by those health plans to hospitals and other providers and apply the standards cited in this section to determine allowable cost-sharing limits. The commenter asserted that, if this is HCFA's expectation, these requirements will make it difficult for States to implement SCHIP programs utilizing employer-sponsored health insurance since the State is not the purchaser of health care services in these cases and does not have a legal basis for accessing confidential or proprietary information, such as rates paid by plans to participating providers. The commenter recommended that States that use employer-sponsored insurance be exempt from the requirements proposed of § 457.555 (a)(3) and (b) since these requirements are likely to dissuade many employers from participating in SCHIP.

Response: Any State that contracts with another entity to provide health insurance coverage under the SCHIP program is paying for services through a contract. If a State subsidizes SCHIP coverage other than through a contract, such as in a premium assistance program, the State is still responsible for ensuring that cost-sharing charges to enrollees in such plans comply with this regulation. We recognize that this might require some additional steps but it is important to provide these protections to all SCHIP enrollees uniformly. States, as part of any contract with a health insurer, should request the payment rate information to assure that cost sharing being imposed by the insurer does not exceed the amounts in this section. We are also revising § 457.555(b) to specify that copayments for institutional services cannot exceed 50 percent of the payment the State would have made under the Medicaid fee-for-service system for the service on the first day of institutional care. As previously discussed, employer-sponsored insurance is subject to the same cost-sharing limits as all separate child health programs. This rule applies to both managed care and premium assistance programs.

Comment: One commenter urged HCFA to include language in the preamble to underscore that the philosophy and structure of managed care delivery systems make unnecessary the use of cost sharing to control utilization. HCFA should encourage States to set lower maximum allowable cost-sharing amounts for institutional services.

Response: States have discretion under 2103(e) to impose cost sharing up to the limits established in the statute and in this regulation. We note that many studies have shown that cost sharing does impact utilization in managed care delivery systems. We also note that 50 percent of the cost of the first day of care in an institution may be expensive for families below 150 percent of the FPL. We encourage States to set reasonable limits that take into consideration the income level of these families.

Comment: One commenter supported limiting copayments per inpatient hospital admission, but noted that the current proposal is based on each institutional admission. In this commenter's view, this policy has the potential to promote early release and frequent readmissions that could be detrimental to a child's health. The commenter suggested that cost sharing for institutional admissions be based on a period of time or some other criteria in order to prevent potential inappropriate releases.

Response: Section 2103(e)(3)(A)(ii) limits the imposition of cost sharing to the nominal amounts consistent with regulations referred to in section 1916(a)(3) of the Act. Proposed § 457.555(b) mirrors § 447.54 of the Medicaid regulations regarding institutional services with some clarification for its application in the SCHIP context. We have not found data that supports a pattern of early discharge exists in the Medicaid program due to this provision. Therefore, we will adopt the regulation as proposed, consistent with section 2103(e)(3)(A)(ii) of the Act.

Comment: One commenter indicated that, with regard to institutional services, the proposed regulation states that the cost sharing cannot exceed 50 percent of the payment the State makes directly or through contract for the first day of care in that institution. The commenter stated that, in a managed care context, the State does not pay a per day amount to the managed care entity (MCE). The commenter requested that HCFA clarify how this institutional cost-sharing limitation is to be interpreted in the MCE setting.

Response: We have clarified § 457.555(b) to indicate that cost sharing may not exceed 50 percent of the payment the State would have made under the Medicaid fee-for-service system for the first day of care in that institution. We believe this remains consistent with the legislative intent to keep cost sharing at nominal levels in accordance with Medicaid.

Comment: One commenter observed that the imposition of copayments for emergency room visits that mirror copayments for other services, including

physician or clinic visits ($5.00 copayment) provides a negative incentive. States should have the ability to impose a differential copayment for emergency visits, even if it is minimally higher than that imposed for visits to a primary health care provider.

A commenter stated that, in order to control non-emergency utilization of the emergency room and to smooth the transition of families from SCHIP to commercial insurance coverage, States should be permitted flexibility in establishing the maximum copayment amount for such services and notes that, in some States, amounts up to $25.00 have been permissible. One commenter noted that without differential copayments for emergency room visits, the incentives are aligned to promote use of a primary care model over unimpeded access to emergency rooms.

Response: We have revised § 457.555(a) of the final regulation to specifically require that services provided to an enrollee for treatment of an emergency medical condition shall be limited to the cost schedule under (a) of that section with its maximum of $5.00. We also note that States are not required to charge the maximum amount permitted in § 457.555(a) for a physician service and may choose to impose a lower amount than $5.00 on physician services, providing the incentive for the beneficiary to access services at the physician level before using the emergency room. In addition, § 457.555(c) permits a maximum amount of $10.00 for nonemergency use of the emergency room, which may also create incentives to use the primary health care provider when appropriate.

For the targeted low-income child in a family with income above 150 percent of the FPL, States may impose a higher amount than $5.00 for emergency services provided in an emergency room as long as the family has not paid cost sharing that exceeds the cumulative cost-sharing maximum of 5 percent of the family's income for a year. The regulation only requires that States limit copayments for emergency services provided in the emergency room to the schedule in § 457.555(a) for those children in families with income from 101 to 150 percent of the FPL, and limit such copayments consistent with § 457.540(b) for those children in families with incomes below 100 percent of the FPL.

Comment: A commenter recommended that no arbitrary amount ($10.00) be used as the maximum copayment for non-emergency use of the emergency room. In this commenter's view, if such an amount is included in this section, it should be indexed for inflation.

Response: The maximum copayment amount is based on the statutory requirement that cost sharing for families at or below 150 percent of the FPL must be in accordance with the Medicaid rules. The amount of $10.00 in § 457.555(c) is consistent with § 447.54(b), which allows a waiver of the nominal amount in the Medicaid regulation for nonemergency services furnished in a hospital emergency room up to double the maximum copayment amounts. We have chosen a set limit for the SCHIP enrollees in families with income from 101 to 150 percent of the FPL in lieu of the complicated waiver requirement in Medicaid.

Comment: A commenter agreed that non-emergency use of emergency facilities should be limited. However, the commenter is concerned about doubling the noninstitutional copayment amount permitted when an enrollee uses an emergency room for non-emergency services. The commenter noted that, in many rural areas, access to non-emergency facilities may not be readily available, and argued that families should not be penalized (charged double) when alternative services are not available.

Response: Proposed § 457.735 (now § 457.495) of the regulation requires the State plan to include a description of the methods it uses for assuring the quality and appropriateness of care provided with respect to access to covered services. States must ensure that an adequate number of providers available so families do not need to seek routine treatment in an emergency room.

Comment: Several commenters asked that the regulation clarify that States should use the prudent layperson standard proposed at § 457.402(b) in the assurance that cost sharing for emergency services to managed care enrollees would not differ based on whether the provider was in the managed care network.

Response: We agree that the prudent layperson standard should be applied to this section. In the proposed rule, we defined emergency services at § 457.402(c), to include the evaluation or stabilization of an emergency medical condition. Because this definition is relevant to the entire regulation, we have moved the definitions of emergency services and emergency medical condition to § 457.10. Section 457.10 now defines emergency medical condition as a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in jeopardizing the individual's health (or in the case of pregnant women, the health of the woman or her unborn child), serious impairment of bodily function or serious dysfunction of any bodily organ or part.

Comment: One commenter suggested that HCFA issue additional guidance on what, if any, sanctions for non-payment of cost sharing can be exercised.

Response: States are allowed flexibility when proposing sanctions. HCFA will review the State sanctions as part of the State plan and consider proposed sanctions on a case-by-case basis. We will require that States, in accordance with § 457.570(b), provide an opportunity for the targeted low-income child's family to have its income reevaluated when the family cannot meet its cost-sharing obligations. The family income may have dropped to a point where the child qualifies for Medicaid, or where the child is in the category of SCHIP enrollees that is subject to lower (or no) cost sharing.

13. Cumulative Cost-Sharing Maximum (§ 457.560)

Section 2103(e)(3)(B) of the Act provides that any premiums, deductibles, cost sharing or similar charges imposed on targeted low-income children in families above 150 percent of the FPL may be imposed on a sliding scale related to income, except that the total annual aggregate cost sharing with respect to all targeted low-income children in a family may not exceed 5 percent of the family's income for the year involved. We refer to this cap on total cost sharing as the cumulative cost-sharing maximum.

We proposed two general rules regarding the cumulative cost-sharing maximums. First, a State may establish a lower cumulative cost-sharing maximum than those specified in § 457.560(c) and (d). Second, a State must count cost-sharing amounts that the family has a legal obligation to pay when computing whether a family has met the cumulative cost-sharing maximum. We proposed to define the term ''legal obligation'' in this context as liability to pay amounts a provider actually charges the family and any other amounts for which payment is required under applicable State law for covered services to eligible children, even if the family never pays those amounts.

We proposed that for children in families above 150 percent of the FPL, the plan may not impose premiums,

enrollment fees, copayments, coinsurance, deductibles, or similar cost-sharing charges that, in the aggregate exceed 5 percent of total family income for a year (or 12 month eligibility period).

We proposed that for targeted low-income children in families at or below 150 percent of the FPL, the plan may not impose premiums, deductibles, copayments, co-insurance, enrollment fees or similar cost-sharing charges that, in the aggregate, exceed 2.5 percent of total family income for the length of the child's eligibility period.

Comment: A number of commenters disagreed with the proposed definition of ''legal obligation'' for use in connection with counting cost-sharing amounts against the cumulative cost-sharing maximum. They noted that it is very difficult and time-consuming to track payments that have not occurred. One commenter suggested changing the definition of the term ''legal obligation'' to only those ''cost-sharing amounts, which families have actually paid.''

Response: States may rely on documentation based upon provider bills that indicate the enrollee's share rather than relying only on evidence of payments made by the enrollee. We have not adopted the commenters' suggestion because this could result in families being legally obligated to pay cost-sharing amounts in excess of the cumulative maximum.

Comment: One commenter asked if this provision means that for any and all out-of-network health services, (provider charges in excess of the amount paid by the health plan) must count toward the family's cumulative cost-sharing maximum. The commenter noted that no private health plans work this way, especially employer-sponsored plans. According to this commenter, a requirement to recognize out-of-network provider charges would greatly complicate this process by requiring States to verify that provider bills submitted by families as evidence of having reached the maximum were not in fact paid by the health plan in which the children are enrolled.

Response: If an enrollee has been authorized by his or her health plan to receive out-of-network services, then the associated charges must comply with these rules and be counted toward the cumulative cost-sharing maximum. In addition, an enrollee's costs incurred for emergency services (as defined at § 457.10) furnished at an out-of-network provider also count toward the cumulative cost-sharing maximum. The regulation does not require coverage of out-of-network services that are not authorized, except for emergency services. Therefore, States are not required to count costs of unauthorized services received out-of-network toward the cumulative cost-sharing maximum.

Comment: One commenter recommended that States be able to retain the flexibility to define the year for purposes of cost sharing as the insurance benefit year for group insurance rather than an individual family's eligibility period as proposed. In this commenter's view, the use of individual family eligibility periods would be an ''administrative nightmare.''

Response: States may apply the cumulative cost-sharing limits based on the insurance benefit's 12 month period for group insurance. In that case, for families that enroll during the benefit year, the State must calculate the cumulative cost-sharing maximum based on the income of the family only for the period of time the beneficiary is actually enrolled within that benefit year.

Comment: One commenter noted that these rules allow a State to count cost-sharing amounts that the family has a legal obligation to pay. The commenter indicated that as section 330 Public Health Service grantees, Federally qualified health care centers (FQHCs) are required to prepare a schedule of fees or payments for incomes at or below those set forth in the most recent FPL. They also noted that health centers are obligated to charge patients on a sliding scale basis if their income is between 100 and 200 percent of the FPL. Therefore, the commenter stated that, based on this proposed rule, health center patients will not receive cost-sharing credits for that portion of the copayments that the health center is expected to waive under a sliding fee schedule policy.

The commenter requested that HCFA provide an exception to consider SCHIP patients served in FQHCs as having paid the full highest possible copay cost of the copayment in calculating the cumulative cost-sharing maximum, whether or not they were charged this amount. In addition, the commenter indicated that SCHIP plans should be instructed that, if a FQHC normally charges its patients with incomes between 100 and 200 percent of the FPL on a sliding scale basis, it should not be required or expected to apply a cost-sharing charge to a SCHIP patient that would exceed its sliding scale discount. For example, if the health center charge for a service is $100.00, but it only charges $50.00 for those with incomes between 150 percent and 200 percent of the FPL, it should only charge 50 percent of the allowable copayment for patients covered under SCHIP, in this commenter's view.

Response: States are only obligated to count towards the cumulative cost-sharing maximum the amounts that a patient has a legal obligation to pay. Therefore, States may not count the amounts that the health center covers towards the maximum. The State is only obligated to count what the SCHIP patient is actually charged by the health center for purposes of the cumulative cost-sharing maximum. However, we do agree that the FQHC should not charge the enrollee more than is permissible under the FQHC's sliding scale, nor should it charge the enrollee more than is permissible under the SCHIP program.

Comment: Several commenters requested that we reconsider the 2.5 percent cumulative cost-sharing maximum. They raised specific concerns regarding the 2.5 percent cumulative cost-sharing maximum, including: The provision is not supported by the statute; it is very difficult to administer two caps (2.5 percent and 5 percent) and track against two caps; limits on copayments and deductibles are already found in § 457.555 and section 2103(e)(3)(A) of the Act; States have already implemented flat cumulative cost-sharing maximums that are administratively efficient and provide families with fluctuating incomes greater stability; HCFA's commissioned study by George Washington clearly demonstrates that it is rare that enrollees will reach the 5 percent cost-sharing maximum; and when a limit is set using a percentage, there is no need to make the percentage less.

One of the commenters also noted that the Medicaid maximum charges for premiums and other cost-sharing charges, which apply to families at or below 150 percent of the FPL, are minimal in amount and are not based upon income or family size. As a result, the addition of another level of cost sharing (2.5 percent) adds to an already complex cost-sharing structure, in this commenter's view. The commenter added that such requirements are virtually impossible to implement in a program that subsidizes employer sponsored insurance.

Response: We disagree with the commenters. A lower cost-sharing maximum on children is necessary in order for States to comply with the requirements at section 2103(e)(2)(B), which require that separate child health plans may only vary cost sharing based on the family income of targeted low-income children in a manner that does not favor children in families with

higher incomes over children in families with lower incomes. If the State does not want to administer two caps, it does have the option to place the 2.5 percent cap or a flat amount equal to 2.5 percent of the family's income on the entire enrollee population that is subject to cost sharing. This should have a minimal impact on the amount of cost sharing States will impose; particularly in light of the George Washington University study, as indicated by the commenter, which found that it is rare for families to reach the 5 percent cap at all. The State may also choose to impose premiums instead of copayments, coinsurance or deductibles, so that tracking of cost sharing is not necessary.

Comment: One commenter noted that the separate calculation requirement applied to each beneficiary's family to ensure that the five percent cost-sharing limitation is met is unwieldy and expensive. In this commenter's view, it is unlikely that opportunities for participation in premium assistance programs will be aggressively pursued. The commenter also asserted that our policy eliminates the opportunity for children in SCHIP to be enrolled in premium assistance programs.

Response: For targeted-low income children in families with income greater than 150 percent of the FPL, section 2103(e)(3)(B) requires States to ensure that cost sharing does not exceed 5 percent of a family's income. The statute does not exempt States from this cap if they provide child health assistance through an employer-sponsored insurance program. Therefore, we have not included any exceptions to the rules for States utilizing premium assistance programs.

Comment: One commenter stated that the regulation goes beyond legislative intent by requiring that copayments and deductibles be included in the computation of the maximum cost sharing for a family with income above 150 percent of the FPL. In support of this point, the commenter noted that section 2103(e)(3)(B) of the Social Security Act limits ''enrollment fees, premiums, or similar charges'' to five percent of the family's income. The commenter asserted that deductibles and copayments are not ''similar charges,'' because they are not prepayments for benefits coverage; rather, they are payments made to treating providers at the time of service delivery. By requiring States to include deductibles and copayments in the calculation of the maximum, HCFA has created major administrative problems, especially for the majority of states that are using HMOs or other insurers in this commenter's view. The commenter recommended that we limit the calculation of the maximum amount to ''enrollment fees, premiums and similar charges''. The State merely has to make sure it sets a premium below the maximum of 5 percent of family income.

Response: Section 2103(e)(3)(B) of the Act provides that ''any premiums, deductibles, cost sharing, or similar charges imposed under the State child health plan may be imposed on a sliding scale related to income, except that the total annual aggregate cost sharing with respect to all targeted low-income children in a family under this title may not exceed five percent of such family's income for the year involved.'' The statute's reference to ''deductibles, cost sharing, and similar fees'' clearly indicates that the charges to be counted towards the cumulative cost-sharing maximum are not to be limited to premiums and enrollment fees. However, States have the option to impose only premiums under their SCHIP plans.

Comment: One commenter noted an error in this section. Specifically, the commenter pointed out that the proposed regulation text states that total cost sharing imposed on families with incomes above 150 percent of the FPL not exceed the maximum permitted under § 457.555(c). It should be § 457.560(c).

Response: The commenter is correct that the reference should have been to § 457.560(c). In addition, in order to eliminate this confusion and redundancy in the final regulation text, we have eliminated section § 457.545 and reflected the policy at § 457.560(c).

14. Grievances and Appeals (§ 457.565)

We proposed that the State must provide enrollees in a separate child health plan the right to file grievances and appeals in accordance with proposed § 457.985 for disenrollment from the program due to failure to pay cost sharing. We address comments on proposed § 457.565 in subpart K, Enrollee Protections, which now contains the provisions relating to applicant and enrollee protections. We have deleted proposed § 457.565 in an effort to consolidate all provisions relating to the review process in the new subpart K.

15. Disenrollment Protections (§ 457.570)

Section 2101(a) of the Act provides that the purpose of title XXI is to provide funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner that is coordinated with other sources of health benefits coverage for children. Based upon this provision of the statute, we proposed in § 457.570 to require that States establish a process that gives enrollees reasonable notice of, and an opportunity to pay, past due cost-sharing amounts (premiums, copayments, coinsurance, deductibles and similar fees) prior to disenrollment. We requested comments on this requirement, including specific comments on the determination of an amount of time that would give enrollees reasonable notice and opportunity to pay cost-sharing amounts prior to disenrollment. We stated that we would request that States with approved plans submit this additional information after publication of the proposed rule and prior to the State's onsite review. We stated that we would also ask the State to include a description of its process in future amendments to its State plan.

Comment: One commenter noted that disenrollment occurs in the Hispanic population because the SCHIP process is extremely paper-intensive. In this commenter's view, one of the most common reasons for disenrollment from SCHIP is the termination of benefits due to the failure to provide premium payments in a timely manner. They stated that, Hispanics in eligible income brackets, in particular, tend to deal in a cash economy, making it difficult to pay SCHIP premiums in the preferred method of payment. In order to slow disenrollment the commenter stated that it is necessary to devise a plan to eliminate the barrier to payment, and effectively reduce the rate of disenrollment among Hispanics.

Response: The SCHIP statute specifically allows States to impose premiums on the SCHIP population within statutorily defined limits. However, we encourage States to be flexible in the methods of payment permitted for cost-sharing charges and to allow grace periods and to provide adequate notice when payments are not made. We have clarified in the final rule that the State plan must describe the disenrollment protections provided to enrollees. In addition, States might monitor disenrollments by reason for disenrollment and determine whether certain groups of enrollees are more likely than others to lose coverage due to failure to meet the cost-sharing requirements. In addition, we encourage States to work with advocates from the Hispanic community to devise culturally sensitive methods to inform consumers about cost sharing and

devise appropriate procedures for obtaining necessary premium payments.

Comment: One commenter noted that the appeals procedures should not be structured in such a way as to give a child's family an incentive to drop SCHIP coverage for a child until he or she needs health services. This practice undermines basic insurance principles and threatens the financial integrity of SCHIP programs because it would result in the pool of enrollees being significantly more sick and more costly than would otherwise be anticipated, in this commenter's view. They stated that the result of such a practice would be to unnecessarily increase the costs of providing coverage to enrollees, which in turn would potentially threaten the viability of the State's SCHIP. The commenter recommended that HCFA revise the regulation to require States to address this issue when they define the circumstances under which a member will be permitted to re-enroll following voluntary disenrollment or disenrollment for nonpayment of premiums or cost sharing.

Response: We are aware that there may be problems when an enrollee is disenrolled and permitted to re-enroll. Some States have adopted lock-out periods to promote the appropriate utilization of health insurance, although other States have discontinued their lock-out periods because they did not find any significant increase in sicker enrollees. States have the flexibility to design their programs based on their unique circumstances to assure that eligible enrollees maintain coverage.

Comment: Many commenters agreed that enrollees should be given an opportunity to pay past due cost sharing prior to disenrollment. Many commenters noted that there should not be any lock-out periods, that States should give families every opportunity to pay past due premiums and at a minimum, grant grace periods of 60 days for the non-payment of premiums. One commenter suggested that the preamble urge States to conduct a Medicaid screen if a child's family is unable to pay premiums due to financial hardship.

Response: We agree that, at the very least, a State should give enrollees a chance to pay past due cost sharing prior to disenrollment. While many commenters noted that lock-out periods should not apply, it is appropriate to allow States to implement a lock-out period so that individuals are not obtaining or maintaining SCHIP coverage only when they need services. We also agree with the comment encouraging States to perform a Medicaid eligibility screen for enrollees who are unable to pay cost-sharing charges due to financial hardship and have emphasized this elsewhere in comments to this final rule. We have added that the disenrollment process must afford enrollees the opportunity to show that their family income has declined prior to being disenrolled for nonpayment of cost-sharing charges. In the event that such a showing indicates that the enrollee may have become eligible for Medicaid or a lower level of cost sharing under separate child health plans, States should take action to either enroll the child in Medicaid or adjust the child's cost sharing category. We expect this new protection will afford enrollees the opportunity to enroll in Medicaid if they have become eligible.

Comment: A few commenters noted specific standards regarding disenrollment protections that HCFA should articulate in the final regulation. Specifically, the commenter recommended that HCFA clearly define what constitutes reasonable notice; clarify that only the State may disenroll a child or impose any other sanction due to an enrollees's failure to pay cost sharing; provide that disenrollment can only be effected after all reasonable steps have been undertaken to avoid disenrollment; require that families should be offered the opportunity to establish a repayment plan; and that families cannot be subjected to penalties or interest for past due payments.

Response: The regulation at § 457.570 regarding disenrollment protections provides enrollees with meaningful protections in connection with any disenrollment related to cost sharing while giving the States flexibility to establish processes consistent with the goals and structure of their programs. We do not accept the commenter's recommendation that HCFA be prescriptive in the regulation regarding disenrollment protections, because each State's SCHIP program is separate and distinct and should retain flexibility accordingly.

Comment: One commenter noted that States should be given the flexibility to decide how they will implement this standard. Specifically, this commenter believes it is administratively burdensome to track a specific grace period before a family is disenrolled from SCHIP.

Response: States are granted flexibility to establish disenrollment procedures under § 457.570 of the final rule. These procedures must be included as part of the State plan. However, the rule does require States to provide reasonable notice prior to disenrollment and provides for a period of time (grace period) for the enrollee's family to pay past due amounts. The rule also enables the State to evaluate the enrollee's financial situation prior to disenrollment to ensure he or she does not qualify for Medicaid.

Comment: One commenter complained that the proposed disenrollment protections were too burdensome because they do not permit disenrollment for nonpayment of premiums even after reminder notices have been sent. One commenter noted that implementing a grace period before disenrollment will result in duplicative coverage and wasted funding since research shows that the primary reason a family fails to pay its monthly premium is that the family has obtained other coverage.

Response: The regulation at § 457.570 regarding disenrollment protections gives the States flexibility to establish processes consistent with the goals and structures of their programs. A disenrollment process without any grace period could result in a system that would disenroll a family prematurely (without adequate notice) and interrupt the family's continuity of care. Therefore, we continue to require that States establish a process that gives enrollees reasonable notice of, and an opportunity to pay past due premiums, copayments, coinsurance, deductibles, or similar fees prior to disenrollment.

Comment: One commenter noted that there may be cases in which the individual responsible for paying a premium is not the custodial party or head of household for the children. In such cases, the commenter stated that notices of disenrollment for failure to pay a premium need to be provided to both the payer of the premiums and the SCHIP beneficiary. Also, if premiums are owed by an individual other than the head of household, and are not paid, the family receiving the SCHIP benefits should not be subject to penalties, and should be given an opportunity to assume responsibility for making future payments.

Response: We agree with the commenter and recommend that States review all viable financial options of an enrollee prior to disenrolling an enrollee due to a parent or caretaker's failure to pay cost sharing. We will also require that States include a disenrollment policy as part of its public schedule, so that all family members who are responsible for paying cost sharing on behalf of the enrollee are informed of the disenrollment process.

F. Subpart G—Strategic Planning, Reporting, and Evaluation

1. Basis, Scope, and Applicability (§ 457.700)

As proposed, this subpart sets forth the State plan requirements for strategic planning, monitoring, reporting, and evaluation under title XXI. Specifically, this subpart implements sections 2107(a), (b), and (d) of the Act, which relate to strategic planning, reports, and program budgets; and section 2108 of the Act, which sets forth provisions regarding annual reports and evaluations.

In the preamble to the proposed rule, we noted the importance of reporting and evaluating SCHIP data. We stated that these activities will provide the critical information necessary for meeting Federal reporting requirements, documenting program achievements, improving program function, and assessing program effectiveness in achieving policy goals. We also described that our information dissemination policy will include making State annual reports, State evaluations and a summary of State expenditures and statistical reports regularly available on the Internet.

Comment: Several commenters strongly supported the statement in the preamble to proposed § 457.700 indicating that we plan to make annual reports, State evaluations, and summaries of State reports regularly available for public access on the Internet. One commenter recommended that an annual, separate, consumer-friendly SCHIP State-by-State status report be available in written and electronic form to the public.

Response: We plan to continue the information dissemination policy that includes making annual reports, State evaluations, and a summary of State expenditures and statistical reports regularly available on the Internet, to the maximum extent possible. We have already produced two State-by-State reports on SCHIP enrollment and released a summary of the States' March 31, 2000 evaluations. We plan to produce and make available future informational reports based on State evaluations, enrollment data, and other sources. We encourage the public not only to access our web site to read the State annual reports and other State-specific information but also to access individual State web sites. In addition, we note that several national organizations, such as the National Governors' Association (NGA), the National Academy for State Health Policy (NASHP), the Children's Defense Fund, the National Conference of State Legislators (NCSL), the American Public Human Services Association (APHSA), the American Academy of Pediatrics (AAP), and other organizations representing State and local governmental entities periodically produce State-by-State SCHIP status or informational reports that are available to the public. We encourage the public to utilize these resources.

Comment: Several commenters stated that we should require States to collect information in a manner that does not discourage individuals from applying for SCHIP. Techniques suggested for achieving this goal include: explaining to participants the purpose of the information collected, assuring confidentiality of information collected, and disclosing that the failure to provide the requested information will not be used to deny eligibility.

Response: We agree with commenters on the importance of gathering evaluative information without creating barriers to participation in SCHIP; and we know this is a concern for States and other stakeholders who have worked to simplify and streamline the application process. We also recognize the flexibility given to States in creating and evaluating their uniquely designed SCHIP programs. We encourage States to be mindful of potential barriers created by collecting information and to create systems that do not prevent potential enrollees from applying for health insurance coverage under SCHIP.

In addition, as noted later in the responses to comments on §§ 457.740 and 457.750, in conjunction with the requirement that States collect and report information about the gender, race, ethnicity and primary language of SCHIP enrollees; we emphasize the importance of States ensuring through the application process that failure to provide information on one of these areas will not affect a child's eligibility for the program. In addition, States must request this information in a manner that is linguistically and culturally appropriate so as not to discourage enrollment in the program.

2. State Plan Requirements: Strategic Objectives and Performance Goals (§ 457.710)

In accordance with section 2107(a) of the Act and the Government Performance and Results Act of 1993 (GPRA), proposed § 457.710 encouraged program evaluation and accountability by requiring the States to include in their State plan descriptions of the strategic objectives, performance goals, and performance measures the State has established for providing child health assistance to targeted low-income children under the plan and for otherwise maximizing health benefits coverage for other low-income children and children generally in the State.

In accordance with section 2107(a)(2) of the Act, we proposed at § 457.710(b) that the State plan must identify specific strategic objectives related to increasing the extent of health coverage among targeted low-income children and other low-income children. We encouraged States to view the development of strategic objectives as a process that involves translating the basic overall aims of the State plan into a commitment to achieving specific performance goals or targets, recognizing that there will be variation among States in specific evaluation approaches and terminology. One of the strategic objectives established in the Act is the reduction in the number of low-income, uninsured children.

Under section 2107(a)(3) of the Act, States must identify one or more performance goals for each strategic objective. We proposed to implement this statutory provision at § 457.710(c). We noted in the preamble that detailed performance goals should facilitate the State's ability to assess the extent to which its strategic objectives are being achieved. In addition, we provided guidance on factors States should consider in drafting strategic objectives and performance goals, noting that they should consider not only the general population targeted for SCHIP enrollment, but special population subgroups of particular interest as well.

In accordance with section 2107(a)(4) of the Act, proposed § 457.710(d) provides that the State plan must describe how performance under the plan will be measured through objective, independently verifiable means and compared against performance goals. We set forth specific examples of acceptable performance measures in the preamble to the proposed rule.

Comment: We received several comments suggesting that we require States to report on a common core of widely-used, objective, standardized, and child-related performance measures and strategic objectives designated by the Secretary. Furthermore, commenters recommended that we require the results of these standard performance measures to be included in the States' annual reports. Some commenters feared that, absent a requirement to report a common set of measures, the information collected might be meaningless and could not be used to evaluate or compare the effectiveness of State plans.

Commenters recommended strategic objectives including: the need to reduce and/or eliminate racial and ethnic disparities in children's health insurance coverage; the need to reduce and/or eliminate barriers to health coverage for children with disabilities; the need to reduce stigma and barriers to access in Medicaid; the need to ensure that the goal of increasing coverage for uninsured children does not supplant or overshadow the importance of ensuring that the receipt of health benefits coverage results in the provision of quality health care and improves health outcomes. Commenters believed that HCFA should consult with the States in creating these national standards, and in doing so, build upon the efforts of other Federal agencies, such as the performance measures developed for State Maternal and Child Health Services Block Grants by the Health Resources and Services Administration.

Response: We agree there should be a common core of evidence-based, standardized, child-related performance measures and performance goals. These measures and goals can be used to evaluate the overall effect of the program in access, service delivery, processes of care and health outcomes with the intent of improving the quality of care, particularly in the areas of well-baby care, well-child care, well-adolescent care, and childhood and adolescent immunizations. Section 2701(b)(1) of the Act and proposed § 457.20 directs that State plans must include assurances that the State will collect data, maintain records, and provide reports to the Secretary at the times and in the format the Secretary may require. The development of common quality and performance measures and goals is essential to assessing the national impact of the SCHIP program and we have modified the regulation text at § 457.710(d)(3) to provide that the Secretary may prescribe a common core of national measures.

However, we also acknowledge the difficulties in achieving national consensus on specified measures. Therefore, HCFA will convene a workgroup to develop a set of core performance measures and performance goals incorporating appropriate quality assurance indicators, and the methodology for implementing common measures and goals for SCHIP in an appropriate and timely manner. As we undertake this effort, we will be guided by the objectives, goals and measurement methods States have developed, as described in their annual reports and evaluations.

The development of national performance indicators and goals does not diminish the importance of having States identify their own specific strategic objectives, and accompanying performance goals and measurements. While States may be required to adopt national performance measures and goals once they have been developed, we expect States to implement their own performance measures, performance goals and strategic objectives specific to the unique design and priorities of their own program. States, in accordance with section 2107(a)(4) of the Act, will continue to be required under § 457.710 to establish State-specific performance measures and to describe how performance under the plan will be measured through objective, independently verifiable means and compared against performance goals.

Comment: One commenter suggested that HCFA recommend to States the following outcome measures: out-of-home placements, the Children and Adolescent Functional Assessment Scale (CAFAS), days-in-school, school performance, and reduced involvement in the legal system.

Response: We agree with the commenter that measures from a variety of sources can be useful in evaluating the impact of SCHIP on the health and the behavior of participants and we would encourage States to take them into consideration as they develop their State-specific performance measures. Additionally, as we convene a workgroup to discuss the development of national core performance and quality assessment measures, we will consider the measures the commenter has suggested. We are mindful, however, that SCHIP's first goal is to expand coverage to uninsured children and that, while it is generally believed that coverage and better access to health care can lead to improvements in school attendance and school achievement, it is difficult to isolate the cause and effect of changes in social behavior that are influenced by a wide range of factors and circumstances.

Comment: We received one comment expressing concern that the willingness and ability of managed care entities (MCEs) to participate in SCHIP depended on whether the revenues adequately covered the MCEs' costs. The commenter noted that costs associated with collecting and validating data may be substantial, and thus may prevent MCEs' from participation in the program. The commenter expressed concern that the MCE might not have a large enough population of SCHIP participants to generate statistically valid data. Additionally, the commenter asserted that HCFA has failed to establish realistic goals for Quality Improvement System for Managed Care (QISMC)-related health plan activities and performance that take into consideration available resources and responsibilities for the delivery of quality care for beneficiaries.

Response: We recognize the concerns expressed by the commenter. However, we disagree that the requirements in the proposed regulation may impose an undue financial hardship upon MCEs. This regulation provides States with significant flexibility regarding the performance measurements they will use and the preamble to the proposed rule encouraged States to review measures, including those widely used by private-sector purchasers of MCE services. We suggested in the preamble of the NPRM that States may wish to consider adopting standardized methods and tools in quality assurance and improvement, such as those of the QISMC initiative, but we did not propose and are not requiring the use of QISMC-related measures. However, the burden on MCEs would be minimized to the extent a State chooses measures that the MCEs are already using in connection with other programs.

In any event, the regulation imposes obligations on States and does not directly govern actions of MCEs. While we require States to report data relating to their strategic objectives and specific performance goals, we are aware of the difficulty in compiling statistically valid data in small sample sizes and are mindful of States' interest in reducing burden for their MCEs. The regulation does not require that States collect encounter data. States have the option of choosing other methods of collecting data related to their strategic objectives, including, but not limited to, surveys of SCHIP participants and/or SCHIP health care providers and looking at encounter data, to the extent it is available.

Comment: One commenter urged HCFA to include the American College of Obstetricians and Gynecologists educational bulletin entitled ''Primary and Preventive Health Care for Female Adolescents'' in the list set forth in the preamble of examples of widely recognized measures and guidelines states should review in developing performance measures for SCHIP programs.

Response: We agree with the commenter that there may be several measures beyond those we specifically mentioned in the preamble to the proposed rule that States might find helpful in translating their strategic

objectives into performance measures and goals. We encourage States to consider this bulletin as well as others that provide widely-used performance measures for children's and adolescent's health and health care.

Comment: A couple of commenters indicated that while the Health Employer Data and Information Set (HEDIS) was designed to be reported at the health plan level, plan-reported numerators and denominators can be added together to yield aggregate State-level reports that could help measure performance in reaching State enrollment targets and in delivering high quality health care. The commenters indicated that HEDIS measures are objective, validated measures of health plan performance (on quality, access and availability, and the use of services) and, when audited using the HEDIS Compliance Audit, performance measures are independently verified. In addition, the commenters stated that national benchmarks exist for both the commercial and Medicaid populations which can be used to establish performance goals and to evaluate performance of a specific health plan or State SCHIP program. One commenter noted that the National Committee on Quality Assurance (NCQA) offered to work with HCFA and States on implementation strategies, including making HEDIS specifications broadly available.

Response: We agree that HEDIS may be a useful tool for States in measuring their performance and establishing goals. We appreciate NCQA's willingness to assist with SCHIP implementation and are working with them to develop HEDIS specifications for SCHIP. In States that are considering using HEDIS measures, we have recommended the following approach to reporting data and information on SCHIP programs: Where a State contracts with managed care entities (MCEs) for health benefits coverage for SCHIP enrollees, States should, where possible, identify individual SCHIP enrollees for its contracting MCEs as detailed below.

If the State has identified SCHIP enrollees to a contracting MCE, and the contracting MCE also contracts with the State Medicaid program, then the MCEs should, as directed by the State either: (1) report the required HEDIS measures separately for SCHIP enrollees; or (2) include SCHIP enrollees in their Medicaid product line reports.

If the State has identified SCHIP enrollees to a contracting MCO and the contracting MCE is a commercial MCE without a Medicaid product line, the MCE should exclude SCHIP enrollees from its commercial product line reports, because including SCHIP enrollees in HEDIS reports for commercially enrolled populations may affect commercial MCE-to-MCE comparisons. Under these circumstances, HEDIS performance measures for SCHIP enrollees will need to be reported separately. In addition, MCEs with small numbers of eligible SCHIP enrollees should follow the small numbers general guideline. These specifications will be included in the HEDIS guidelines for 2001.

Comment: In response to HCFA's solicitation for comments on additional measures that will assist in articulating the success of programs implemented under title XXI, several commenters recommended the following performance measures:

Access

—Percentage of Medicaid eligible enrolled in Medicaid;
—Percentage of SCHIP eligible enrolled in SCHIP;
—Percentage of children with a usual source of health care;
—Percentage of children with an unmet need for physician services and/or delayed care;
—Reduction of hospitalization for ambulatory sensitive conditions;
—Percentage of enrollees who are enrolled for a year or more;
—Percentage of children who are identified as having special health care needs;
—Percentage of employers offering health insurance coverage to employees and dependent children;
—Percentage of enrollees whose parents decline employer-sponsored dependent health insurance coverage;
—Percent of children whose eligibility switches between title XIX and title XXI who enroll in the appropriate program (or who maintain health insurance coverage);
—Percentage of pediatricians, family physicians, and dentists who participate in Medicaid and SCHIP;

Process

—Percentage of children and adolescents who have received immunizations according to the ACIP/American Academy of Pediatrics recommended immunization schedule;
—Percentage of children and adolescents who have received all of the well-child visits appropriate for their ages, based on the American Academy of Pediatrics Recommendations for Pediatric Health Care;
—Percentage of adolescents ages 12 though 18 who were counseled for symptoms or risk factors for STDs;
—Percentage of children ages four through 18 during the reporting year who received a dental examination during that year;
—Percentage of children ages three through six who received a vision screening examination during the reporting year;
—Percentage of children and adolescents with all of the well-child visits provided at one health care site during the reporting year;
—Percentage of children and adolescents, parents or caretakers with difficulty communicating with health care professionals because of a language problem or difficulty understanding health care professionals;
—Percentage of children and adolescents with asthma who regularly use a peak flow meter during the reporting year, regularly use a spacer with a metered dose inhaler, and/or who received influenza vaccine during the reporting year;
—Percentage of children with special health needs who received care during the reporting year;

Outcomes

—Rate of hospitalization for ambulatory sensitive conditions such as asthma, diabetes, epilepsy, dehydration, gastroenteritis, pneumonia; or urinary tract infection (UTI);
—Rate of hospitalization for injuries;
—Percentage of children and adolescents reporting days lost from school due to health problems;
—Percentage of children reporting risky health behaviors including injuries, tobacco use, alcohol/drug use, sexual behavior, poor dietary behavior, lack of physical activity;
—Percentage of adolescents reporting attempted suicides;
—Percentage of children reporting unmet medical needs;
—Percentage of children reporting unmet vision needs;
—Percentage of children reporting unmet dental needs; and
—Percentage of family income used for medical and dental care.

Response: Assessments of the impact of the title XXI program on children's health insurance coverage, access to care and use of health care services will occur on both the State level and national levels. On the State level, we would encourage States to consider the commenters' suggested performance measures as they identify those measures which are appropriate for each

of their strategic objectives as required under section 2107(a)(3) of the Act and § 457.410(b).

Nationally, as HCFA works to develop a common core of standardized child-related performance measures, performance levels and quality measures that can be used to evaluate access, service delivery, processes of care, health outcomes and quality in the overall SCHIP program, we will consider the performance measures recommended by the commenters.

3. State Plan Requirement: State Assurance Regarding Data Collection, Records, and Reports (§ 457.720)

Section 2107(b)(1) of the Act requires the State plan to provide an assurance that the State will collect the data, maintain the records, and furnish the reports to the Secretary, at the times and in the standardized format that the Secretary may require to enable the Secretary to monitor State program administration and compliance and to evaluate and compare the effectiveness of State plans under title XXI. We proposed to implement this statutory provision at § 457.720.

We did not receive any comments on this section and are therefore implementing the provision as proposed.

4. State Plan Requirement: State Annual Reports (§ 457.730)

Section 2107(b)(2) of the Act discusses the requirement that the State plan include a description of the State's strategy for the submission of annual reports and the State evaluation.

Accordingly, we proposed to implement this provision at § 457.730. We noted that, in order to facilitate report submission, a group of States worked with staff from the National Academy of State Health Policy (NASHP), with HCFA representation, to develop an optional model framework for the State evaluation due March 31, 2000 and for subsequent annual reports. We also noted that we would permit States to submit their FY 1999 annual report and their State evaluation on March 31, 2000, together as one comprehensive document. However, since the States evaluations/annual reports have all been submitted, this provision is unnecessary and has been deleted from the final rule. In addition, we have moved the discussion of the annual report requirements to comments and responses on § 457.750.

Comment: One commenter recommended that we require States to use a designated framework for submitting annual reports and evaluations. This commenter suggested that we include clinicians, child advocates and research groups to participate in the development of frameworks for future reports.

Response: While we do not believe it is necessary to require a designated framework for annual reports and evaluations, in order to facilitate report submission, a group of States worked with staff from NASHP and with representatives from HCFA to develop an optional model framework for the State evaluation due March 31, 2000. This framework was finalized and sent to every State and territory with an approved State plan. All States that have submitted their State evaluations have voluntarily used this framework as the basis for their evaluation, although several States supplemented their evaluations with additional data. We currently are in the process of analyzing and synthesizing the data submitted in these evaluations. We will continue to work with States and other interested parties to support these efforts to promote ease of reporting and to facilitate analysis and comparison of important data reported by States on their programs.

NASHP has subsequently developed a similar framework for the annual reports that States will be submitting in January 2001. As SCHIP development continues, we encourage continued participation in the evaluation process by interested researchers, health care providers and provider groups, advocates and advocacy groups, insurance providers, State and local government officials, and other interested parties and intend to keep the process as open and collaborative as possible.

5. State Expenditures and Statistical Reports (§ 457.740)

We proposed to require that the States collect required data beginning on the date of implementation of the approved State plan. We proposed that States must submit quarterly reports on the number of children under 19 years of age who are enrolled in separate child health programs, Medicaid expansion programs, and regular Medicaid programs (at regular FMAP) by age, income and service delivery categories. In the preamble, we noted that the Territories are excepted from the definition of ''State'' for the purposes of quarterly statistical reporting. We also proposed to require that thirty days after the end of the Federal fiscal year, the State must submit an unduplicated count for that Federal fiscal year of children who were ever enrolled in the separate child health program, the Medicaid expansion program and the Medicaid program as appropriate by age, service delivery, and income categories.

We proposed that the age categories that must be used to report the data are: under 1 year of age, 1 through 5 years of age, 6 through 12 years of age, and 13 through 18 years of age. We further proposed to require States to report enrollment by the service delivery categories of managed care, fee-for-service, and primary care case management.

We noted in the proposed regulation and explained in the preamble that States must report income by using State-defined countable income and State-defined family size to determine Federal poverty level (FPL) categories. We proposed that States that do not impose cost sharing and States that only impose cost sharing based on a fixed percentage of income (such as 2 percent) in their Medicaid expansion program or their separate child health program must report their SCHIP and Medicaid enrollment by using two categories: at or below 150 percent of the FPL and over 150 percent of FPL. States that impose cost sharing at defined income levels (for example, at 185 percent and over of FPL) in their Medicaid expansion programs and/or separate child health programs would be required to report their Medicaid and SCHIP enrollment by poverty level (that is, countable income and household size) categories that match their Medicaid expansion program and separate child health program cost-sharing categories. We proposed to require enrollment reporting by income for Medicaid as well as for SCHIP.

We proposed that required standardized reporting be limited to expenditure data and enrollment data as reported by age, poverty level, and service delivery category. We noted in the preamble to the NPRM that States should collect other relevant demographic data on enrollees such as gender, race, national origin, and primary language and that collecting such data will encourage the design of outreach and health care delivery initiatives that address disparities based on race and national origin.

We stated that we were working to develop an option for States to provide the needed SCHIP data through existing statistical reporting systems in the future.

Comment: One commenter suggested that we revise the regulations to specify that a State's failure to submit the statistical reporting forms would ordinarily be considered substantial non-compliance.

Response: Section 457.720 requires States to comply with data reporting

requirements. Section 2106(d)(2) of the statute and § 457.204(c) provide the Secretary with authority to enforce these and other requirements. We do not believe that it is necessary to specify more specific sanctions for non-reporting or delayed reporting within the rule.

We are working closely with States to develop and implement data tracking and reporting systems. SCHIP reporting may involve creating new systems or adjusting existing systems to collect data which can then be reported to DHHS and we recognize that the reporting changes required in this final rule may require further changes to these systems. We will work with the States to accommodate individual needs for technical assistance during the transition.

In the past, some States have had difficulty reporting data to us in a timely matter due to systems constraints. However, we anticipate that many of these difficulties will be resolved in the near future. We recently implemented a new, more easily accessible web-based data reporting system (the Statistical Enrollment Data System (SEDS)) that all States can access through the Internet, rather than through the main frame system. We have also revised the reporting instructions to clarify definitions in a way that will be more clear for States and provide for more standardized reporting among the States. We released these new instructions with a letter to State Health Officials on September 13, 2000. In addition, we are continuing a comprehensive evaluation of possible modifications to the Medicaid Statistical Information System (MSIS), which captures State eligibility and claims records on a person-level basis. The modifications will give States the option of using MSIS to supply the data elements that will meet the title XXI quarterly statistical reporting requirements. We look forward to working with States to further improve the time lines and quality of required SCHIP data. In addition, we have added a new reporting line to the quarterly reports where States indicate a ''point in time'' enrollment count that indicates enrollment as of the last day of the quarter for their SCHIP and title XIX Medicaid programs. This count is something the States already have available for their own purposes and helps provide a more complete picture of States' programs on an ongoing basis.

Comment: We received several comments requesting that HCFA require States to collect data pertaining to one or more of the following categories of information about enrollees and their SCHIP coverage: gender, ethnicity, race, primary language, English proficiency, age, service delivery system, family income, and geographic location. Certain commenters suggested that this data be collected and reported to HCFA in the State evaluations, annual reports, and/or quarterly statistical reports. These commenters felt this information would help target outreach, retention, enrollment, and service efforts to under-represented groups. These commenters also indicated that such reporting requirements are consistent with the goals of Healthy People 2010 and recently enacted legislation directing the Secretary of Commerce to produce statistically reliable annual State data on the number of uninsured, low-income children categorized by race, ethnicity, age, and income. One commenter indicated that HCFA should require States to document the appropriate range of services and networks of providers available, given the various language groups represented by enrollees. Additionally, some commenters noted that HCFA should require States to provide an assessment of their compliance with civil rights requirements.

Response: We agree with several of the comments summarized above. Section 2107(b)(1) of the Act requires that ''a State child health plan shall include an assurance that the State will collect the data, maintain the records and furnish the reports to the Secretary, at the times and in the standardized format the Secretary may require in order to enable the Secretary to monitor State program administration and compliance and to evaluate and compare the effectiveness of State plans.'' The proposed rule at § 457.740(a) had included requirements on States to collect and submit data by age categories, service delivery categories and by countable income. In an effort to streamline data reporting requirements, we had only encouraged States to collect data with respect to gender, race and ethnicity, and did not propose to require the collection or the reporting to HCFA of such data. We received many comments expressing concern about this policy and urging us to require States to report data on gender, race, ethnicity and primary language of SCHIP enrollees to HCFA.

We have reviewed our proposed policy and have decided that it is consistent with overall program goals, as well as the civil rights requirements, to require States to report data, on a quarterly basis, on the race, ethnicity, and gender of SCHIP enrollees using the format prescribed by the OMB Statistical Directive 15—Standards for the Maintaining, Collecting and Presenting Data on Race and Ethnicity. We have therefore amended § 457.740(a)(2) to reflect this requirement. Because primary language of SCHIP enrollees is not one of the data elements on standardized reporting formats, we will require States to report on this information as part of the Annual Report, and have amended § 457.750(b)(8) to reflect this change. We understand that nearly all States have already been collecting this information through the application process. Although States may request information on gender, race, ethnicity and primary language at the time of application, States may not require families to report this data as a condition of application to, or enrollment in the SCHIP program. The information must be collected from SCHIP applicants and enrollees on a voluntary basis. Having this data will enable States and the Department to see how and if minority children and other categories of children are being covered by the SCHIP program and to identify opportunities for more effective outreach and retention strategies.

Furthermore, required reporting of this data is consistent with Departmental priorities to more effectively identify racial disparities in the provision of health care and to assure that language barriers do not interfere with children's ability to secure health care. HCFA will modify its data base to permit States to report these data on the same system as they report enrollment data. We understand States may incur additional administrative costs to comply with this requirement. However, the potential benefits for the States and for the Department are significant.

Comment: Commenters asserted that neither the State nor the health insurance purchasing cooperative has the legal authority to require employer-sponsored insurance carriers to report claims data. Therefore, commenters noted, States with premium assistance programs would have difficulty reporting program expenditures and participants by age, income, delivery system, and program type as required by HCFA.

Response: Since States or their contractors would be completing the eligibility process for children enrolling through premium assistance programs, States would have data available on the child's age, family income, the type of child health insurance program offered by the State, and the expenditures being made on behalf of the child. We are not requesting individual claims data used by group health plans providing SCHIP

coverage. Service delivery systems could be ascertained by the State by reviewing the benefit package available through each employer. This might present difficulties if an employer had several options with varying delivery systems available at the same cost to the State. Should this be the case, we would work with States on a case-by-case basis to consider other options for collecting this data.

Comment: One commenter noted that the collection report Form HCFA–64, revised in December 1998, requires additional information that is not reflected in § 457.740, including number of months enrolled, and the number disenrolled per quarter. Several commenters suggested that HCFA require States to report this data to HCFA on a quarterly basis.

Response: In § 457.740, we did not intend to specify each data element that we will be requiring, because we wanted to be able to review and modify specific elements as the program evolves. We have authority under section 2107(b)(1) to specify at § 457.720, that States must provide data ''at the times and in the standardized format * * *'' to enable the Secretary to monitor State program administration and compliance and to evaluate and compare the effectiveness of State plans under title XXI. This includes the number of months enrolled and number disenrolled per quarter.

The forms referenced by the commenter are quarterly reports used by State Medicaid agencies to report to HCFA their actual Medicaid expenditures and the numbers of SCHIP children and other children being served in the Medicaid program. HCFA uses these forms to ensure that the appropriate level of Federal payments for the State's Medicaid expansion program expenditures, and to track, monitor and evaluate the numbers of SCHIP children being served by the Medicaid expansion program. HCFA uses a similar quarterly reporting form, the HCFA–21, to collect comparable information on separate child health programs.

Comment: One commenter noted that the collection of data to measure the effectiveness of SCHIP should include the number and types of services actually delivered in addition to the number of children enrolled. This commenter suggested that we revise the regulations to specify that data can be collected and reported by the State using American Dental Association procedure codes to reflect total number of actual services rendered to eligible individuals.

Response: We agree States should consider utilization measures in developing Statewide performance measures of progress toward meeting State performance goals and strategic objectives. We also envision that States may want to measure care and service delivery so that they may determine numbers of participating providers and health networks needed for the program. The regulation provides States with flexibility in developing these measures and appropriate data collection methodologies.

As the Department works on developing and implementing a common core of standardized performance measures and performance goals, we will consider the outcome measures suggested by the commenter.

Comment: One commenter generally supported the quarterly reporting requirements but requested one additional required report measure. Specifically, the commenter urged HCFA to require reporting (either annually or quarterly) on the number of newborns who are enrolled at birth and the number of infants who are enrolled within the first three months of life. The commenter believed this information could be used by States to assess whether income-eligible newborns are experiencing gaps in coverage between the time of birth and SCHIP enrollment.

Response: We strongly encourage the States to collect the required information on age of participants in such a way that they may analyze the health coverage patterns of newborns and infants. We have not required States to report this information to HCFA. However, we will consider the commenter's suggestion as we develop the national core set of performance measures and goals.

Comment: One commenter urged HCFA to require States to describe their income calculation methodologies and changes in those methodologies and to make that information available to the public.

Response: We agree with the commenter's suggestion and note that income calculation methodologies and changes to these methodologies were requested to be provided by States as part of their State evaluations (due to HCFA on March 31, 2000). Because of the importance of having this information in a standardized manner, as well as keeping the information current, we have included this as an element of subsequent State annual reports. We have compiled and reviewed the submissions from the States thus far, and the information is available to the public along with the rest of the States' evaluations on the HCFA web site.

In addition, we discussed in our July 31, 2000 guidance on SCHIP section 1115 demonstrations that in order to receive approval for a demonstration proposal, States must have submitted all of their required statistical reports and evaluations to HCFA, dating back to the implementation of their program.

Comment: One commenter found the detailed reporting requirements problematic, cumbersome, and difficult to comply with under current automated systems.

Response: We recognize the commenter's concerns. However, we will continue to require the collection and quarterly reporting to HCFA of the data required in this section. We will continue to offer technical assistance to States having difficulty reporting the required data due to automated system difficulties. As noted previously, States are able to report data to HCFA through a web-based reporting system on the Internet, to provide States with easier access to the reporting system. In addition, we have developed a set of revised reporting instructions to facilitate reporting by States in a standardized format. We believe these modifications will result in a reporting system with which States can comply with minimal difficulties.

In addition, we are continuing a comprehensive evaluation of possible modifications to the Medicaid Statistical Information System (MSIS), which captures State eligibility and claims records on a quarterly basis. The modifications will give States the option of using MSIS to supply data related to separate child health programs as well as Medicaid expansion programs and will promote overall consistency among SCHIP and Medicaid data in the long term.

Comment: We received several comments applauding our recognition of the interrelationship of Medicaid and SCHIP and the requirement of similar reporting for regular Medicaid, Medicaid expansion, and separate child health programs. However, one commenter opposed the requirement that all States, including those operating separate child health insurance programs, report changes in enrollment in both the SCHIP program and the Medicaid program. The commenter noted that some States operate separate child health programs that are administered by different staff, governing boards, budgets, etc. than the State Medicaid program. The commenter opposed a requirement that a separately administered SCHIP program have a contractual requirement

to obtain data from a Medicaid agency. The commenter stated that if HCFA wished to review Medicaid data, it should develop new Medicaid regulations to require such data and to provide reimbursement to the Medicaid agency as the SCHIP program has no budget or legal authority to collect Medicaid data. The commenter added that additional administrative requirements from HCFA should be accompanied by additional administrative dollars, or they represent unfunded mandates that exacerbate the 10 percent administrative-cost limit problem.

Response: The statute anticipates that State agencies implementing SCHIP and Medicaid will coordinate activities and share information. Section 2108(b)(1)(C) of the Act requires States to report on or before March 31, 2000 ''an assessment of the effectiveness of other public and private programs in the State in increasing the availability of affordable quality individual and family health insurance for children.'' In addition, section 2108(b)(1)(D) specifically requires States to report on coordination with other public and private programs providing health care and health financing, including Medicaid programs. Furthermore, these requirements are not specific to the State agency administering SCHIP or Medicaid, but rather apply to the State as a condition of receiving grant funding under these programs, regardless of how the State internally delegates responsibilities under these programs.

In addition, section 2107(b)(1) of the Act requires that the State plan contain certain assurances regarding the collection of data and submission of reports to the Secretary. In addition, § 431.16 of the Medicaid regulations specifies that a State plan must provide that the Medicaid agency will submit all reports required by the Secretary, follow the Secretary's instructions with regard to the format and content of those reports, and comply with any provisions that the Secretary finds necessary to verify and assure the correctness of the reports. These statutory and regulatory provisions serve as our authority for requiring Medicaid State expenditure and statistical reporting at § 457.740. State agencies can reasonably be expected, as directed in the statute, to coordinate among programs, including by sharing and reporting information.

Since Medicaid agencies receive Federal financial participation under title XIX for administrative costs, such as those associated with data collection, sharing this information with the States' title XXI programs should not exacerbate any difficulty States may have in staying within the 10 percent administrative cost limit in SCHIP.

6. Annual Report (§ 457.750)

Section 2108(a) of the Act provides that the State must assess the operation of the State child health plan in each fiscal year, and report to the Secretary, by January 1 following the end of the fiscal year, on the results of the assessment. In addition, this section of the Act provides that the State must assess the progress made in reducing the number of uncovered, low-income children. We proposed to implement the statutory provision requiring assessment of the program and submission of an annual report at § 457.750(a).

At proposed § 457.750(b), we set forth the required contents of the annual report. Specifically, in accordance with the statute, the annual report must provide an assessment of the operation of the State plan in the preceding Federal fiscal year including the progress made in reducing the number of uncovered, low-income children. In addition, we proposed to require that the State report on: (1) progress made in meeting other strategic objectives and performance goals identified by the State; (2) successes in program design and implementation of the State plan; and (3) barriers in program design and implementation and the approaches under consideration to overcome these barriers. We also proposed to require that the State report on the effectiveness of its policies for discouraging the substitution of public coverage for private coverage. Further, we proposed to require that the annual report discuss the State's progress in addressing any specific issues, such as outreach, that it agreed to monitor and assess in its State plan.

In accordance with section 2107(d) of the Act, we also proposed that a State must provide the current fiscal year budget update, including details on the planned use of funds for a three-year period and any changes in the sources of the non-Federal share of plan expenditures. We also proposed that the State must identify the total State expenditures for family coverage and total number of children and adults covered by family coverage during the preceding Federal fiscal year.

We proposed that, in order to report on the progress made in reducing the number of uncovered, low-income children in the annual report, a State must choose a methodology to establish an initial baseline estimate of the number of low-income children who are uninsured in the State and provide annual estimates, using the chosen methodology, of the change in this number of low-income uninsured children at two poverty levels: 200 percent FPL and at the current upper eligibility level of the State's SCHIP program. We noted in the preamble to the proposed rule that, in making these estimates, a State would not be required to use the same methodology that it used in identifying the estimated number of SCHIP eligibles in the State plan.

We proposed to require that a State base the annual baseline estimates on data from either: (1) The March supplement to the Current Population Survey (CPS); (2) a State-specific survey; (3) other statistically adjusted CPS data; or (4) other appropriate data. We also proposed that a State must submit a description of the methodology used to develop these estimates and the rationale for its use, including the specific strengths and weaknesses of the methodology, unless the State bases the estimate on the March supplement to the CPS. We indicated in the preamble to the proposed rule that, once a State submits a specific methodology in the annual report for estimating the baseline numbers, the State must use the same methodology to provide annual estimates unless it provides a detailed justification for adopting a different methodology. We also noted therein that traditionally, most national estimates of uninsured children have been based on the Bureau of Census March Current Population Survey (CPS). We further noted in the preamble that, as the only data source with the capacity to generate State-by-State estimates of uninsured children, the CPS generally is relied upon by policy makers to provide an overall estimate of insurance status and insurance trends in the nation. We also mentioned other major surveys that provide insight into the number of uninsured Americans.

Comment: One commenter recommended that we require annual reports to contain reasonable utilization measures indicating quality and access to care for children with special needs in addition to the general child population. The commenter believed that the Secretary should conduct a focused study of children with special needs. Another commenter noted that States providing dental benefits should report annually on the assistance provided to recipients in accessing needed services.

Response: We are very concerned about services for special needs children, and we agree with the commenters that quality and access are important both with respect to special needs and dental benefits and States are encouraged to address these important

areas in their annual reports. However, requiring such reporting would be inconsistent with the flexibility permitted under the statute. At § 457.495(b) of this final rule, we require States to provide assurances of appropriate and timely procedures to monitor and treat enrollees with chronic, complex or serious medical conditions, including access to specialists experienced in treating the specific medical condition. We leave it to the States to determine what systems and procedures they will implement to ensure enrollees with such conditions have access to quality care consistent with this standard.

In order for States to create systems which fit their unique programs, the methodology for complying with § 457.495 is best left to the State. Reporting on access to dental benefits is subsumed under § 457.495(a), which requires States to include in their plans a description for assuring the quality and appropriateness of care provided under the plan including access to covered services listed in § 457.402(a). Dental services is one of the optional services States may cover under the definition of child health assistance located at § 457.402(a)(16). To the extent that States cover dental services in their SCHIP plans, they must assure access to those services. Therefore, we have not adopted the commenter's suggestion to add a separate requirement regarding dental services.

Comment: One commenter asserted that HCFA exceeds its authority in the annual report requirements at § 457.750(c) that requires States to provide a rationale and description of the methodology used to establish the baseline estimate, if the estimate is based on a source other than the CPS. The commenter contended that the purpose of the annual report is for States to assess the operation of their programs. The commenter also argued that HCFA lacked authority to compel States to adopt the CPS standard. The commenter referred to section 2108 of the Act, which provides that the State shall assess its performance and submit that assessment to the Secretary. The commenter noted that providing a rationale for a methodology made States take additional steps that were not prescribed by the statute. In requiring this rationale, the commenter suggested HCFA came perilously close to dictating the CPS standard, which violates the express terms of title XXI and Executive Order 13132, regarding Federalism. The commenter indicated that under Executive Order 13132, HCFA is required to justify the imposition of any national standard and to look for less burdensome alternatives. The commenter expressed the view that the proposed rule improperly shifts the burden of justifying standards used to evaluate programs from HCFA to the States.

Response: Section 2107(b)(1) of the Act expressly gives the Secretary the authority to require data collection, records maintenance, and reports from the States ''at the times and in the standardized format the Secretary may require in order to enable the Secretary to monitor State program administration and to evaluate and compare the effectiveness of State plans.'' In order to effectively monitor State program effectiveness in reducing the number of uninsured children, the method of detecting the numbers of uninsured in States and the decline or increase in the uninsured must be known and understood in a standardized manner when possible. The statute uses CPS for formula allocating, so it was suggested as the best available source for State uninsurance levels among low-income children. Most States elected to use the CPS in establishing their initial baselines. However, we recognize the shortcomings of CPS for many States and have therefore provided flexibility to use other sources, both initially and prospectively. The requirement that States explain their alternative methodology is necessary and appropriate in order for HCFA to be able to identify and assess the data provided by States. In addition, we have further clarified that if States elect to use a different data source in re-establishing a baseline, the State must also note in the annual report the CPS estimate for that year, both as a means of providing standardized information across States, using a consistent baseline and to ensure that States are given credit for progress in enrolling children back to the beginning of their programs.

Comment: One commenter requested that HCFA allow States to use biennial State survey figures in assessing changes in uninsurance rather than the annual figures from the CPS. The commenter noted that the CPS data is unreliable for its State and administering an annual survey would be cost-prohibitive for some States.

Response: Section 457.750(c)(1)(ii) provides that a State may base its estimate of the number of uninsured, low-income children from a State-specific survey. Thus, States may use biennial data from State surveys, utilizing statistically relevant adjustments in the off-survey year or by supplementing the biennial data with additional State-specific data from other sources to fulfill the annual reporting requirements of this section. We note that, as stated in the previous response, States will be required to provide a description of the methodology and rationale for using the State-specific survey, in accordance with § 457.750(c)(2).

Comment: One commenter urged HCFA to revise the proposed rule to reflect provisions of the Balanced Budget Refinement Act of 1999 (BBRA), which require that the March Supplement of the CPS be expanded to allow State-level estimates of the number of uninsured children. The commenter believed that using these updated estimates would be preferable to allowing States to establish their own methodologies for estimating the number of uninsured children.

Response: We note that provisions of section 703(b) of BBRA amended Section 2109 of the Act to modify the March Supplement of the CPS to detect real changes in uninsurance rates of children. The BBRA requires future modifications to the Current Population Survey in order to produce statistically reliable annual State-level data on the number of low-income children without health insurance coverage. One modification to the CPS is to include data on children by family income, age, and race, and ethnicity. Adjustments to be made include expanding sampling size used in State sampling units and expanding the number of sampling units in a State. Therefore, with the creation of this requirement, Congress sought to help provide all States with access to more reliable State-level data on the uninsured population through the CPS March Supplement. We have not modified the regulation text to reflect this change, as this data is not expected to be available until October or November 2001. We wanted to leave the regulation text open to future improvements to the CPS or other data sources. Even with the CPS adjustments, there are States that believe they can provide more accurate estimates of the level of uninsured children in their State with methodologies that use other data sources or sources that supplement the CPS data. We believe it is important to allow States this flexibility in developing the most reliable estimate for their State.

Comment: One commenter supported the required collection of information in the annual report, and recommended we require States to also report on the following information in the annual reports:

—Progress in addressing the barriers to access experienced by minority children;

—Grievances, complaints of problems reported relating to enrollment, access, and quality of care as a means of measuring consumer satisfaction, ensuring they are adequate to resolve complaints within a reasonable time frame and that plans use grievance and complaint data to improve quality;
—Cultural competency measures;
—Continuity of care between plans, providers, or programs;
—Special attention to under-served or under-identified populations (for example, homeless children);
—Systematic integration with schools and other community groups;
—Whether primary care and pediatric specialty care capacity is adequate for the number of enrollees;
—Whether plans meet standards for access within reasonable time frames;
—Whether care is in accordance with clinical practice guidelines for quality of care; and
—The proportion of providers who are both Medicaid and separate SCHIP providers among those serving Medicaid and separate SCHIP beneficiaries, and the difference in payment rates to plans or providers in Medicaid and separate SCHIP programs.
—Estimates of the number of uninsured children under the regular Medicaid income thresholds as well as those under the 200 percent FPL and under the State's SCHIP income threshold;
—Data on the method of application for Medicaid and SCHIP (mail-in, outstation-site, Internet, etc.) and enrollment procedures for each program;
—Data on the portion of applicants denied and reason for denial;
—Number of children disenrolled for any reason, the reason for disenrollment, and the number of children disenrolled for nonpayment of premiums;
—Number of children continuously enrolled in Medicaid and/or separate SCHIP program for one year or more;
—Number of children identified by screening as Medicaid eligible and, of those, the number enrolled in Medicaid;
—Number of former Medicaid recipients enrolled in separate SCHIP;
—Data on the number of applicants denied eligibility and the reason for the denial, including that they were disqualified due to current insurance coverage as well as the number of children disqualified due to insurance coverage in a past period, where applicable;
—Number of children who lose coverage at redetermination and the reason for loss of coverage; and
—Data comparing the proportion of children enrolled and using services by gender, race, ethnicity, and primary language to the proportion of such children in the service area.

Response: As noted earlier, HCFA participated in a workgroup led by the National Academy of State Health Policy to develop a template for States' annual reports that have provided an opportunity for States to report the information required in § 457.750 in a standardized way. NASHP released this template to the States and the public in November 2000 for States to use in completing their annual reports for FY 2000. In addition to budget and expenditure data, this will include information from States on their progress in reducing the number of uninsured low-income children, meeting strategic goals and performance measures, the effectiveness of States' policies for preventing substitution of coverage, and identifying successes and barriers in the States' plan design. In addition, the reports provide a forum for evaluating States' progress in addressing specific issues (such as outreach) and the primary language of SCHIP enrollees. We will work with NASHP to include these elements in a revised version of the annual report framework upon publication of this final rule. States will not be expected to address these new elements until they submit their FY 2001 reports. In addition, because the information can be more appropriately displayed in the annual report than in the quarterly reports, we have added a new § 457.750(b)(7) to require States to provide information on primary language of SCHIP enrollees in their annual reports. HCFA will continue to closely review the data collected and reported by the States in their annual reports.

We note that many of these assessment elements were provided by States in their State evaluations. Specifically, as part of the evaluation, States were required, as specified in section 2108(b)(1) of the Act and laid out in the NASHP evaluation framework, to provide information on baseline numbers of uninsured low-income children in the State by income level; levels of previous insurance coverage for applicants and enrollees; and quarterly enrollment statistics including: number of children ever enrolled; new enrollment; number of member months enrolled; average months enrolled; disenrollment including the reasons for disenrollment; unduplicated count of enrollment; and enrollee characteristics, such as income. Many States provided additional information on enrollees' gender, race and ethnicity in the reports. The annual report template is not as extensive as the evaluation template, but many of the same elements are included. Therefore, States will have the ability to indicate in subsequent annual reports that no update is needed since the evaluations were submitted.

Finally, it should be noted that, as we work toward developing and implementing a national core set of performance measures and goals, we will consider the performance goals suggested by the commenters.

Comment: One commenter noted that the preamble to proposed § 457.750(c)(1) was unclear as to whether the program referred to in the phrase ''upper eligibility level of the State's program'' is Medicaid or SCHIP.

Response: The requirements of subpart G of the regulations regarding strategic planning, reporting, and evaluation apply to separate child health programs and Medicaid expansion programs. Thus, in § 457.750(c)(1), we are referring to the upper eligibility level of the State's SCHIP program, which would be the upper eligibility level of either a Medicaid expansion or a separate child health program. If a State operates a combination program, the upper eligibility level would be the highest eligibility level of either the Medicaid expansion or the separate program.

Comment: One commenter recommended that specific measures be defined either for all SCHIP programs or separately for employer-sponsored insurance model programs based on HEDIS or Healthy People 2000 guidelines, to ensure that all States report similar guidelines and that common agreements could be used across States. Given that some States plan to use an employer-sponsored insurance model for coverage, the commenter suggested that HEDIS measures would seem the most appropriate approach on which to base data collection and reporting systems. For States using an employer-sponsored insurance model, contracts or agreements between the State and carriers would be needed for collection and data provision, this commenter stated. In this commenter's view, States would have to create specific data collection and reporting mechanisms to do this.

Response: The regulations do not require States, including States with premium assistance programs, to collect data on specifically defined measures, except with respect to any core set of performance measures that may be developed by the Secretary at a later

date. We encourage States to work with health plans, HCFA, and each other to create standards that meet their mutual needs for data. We particularly encourage States using premium assistance program models for SCHIP to explore effective methods of data collection, but recognize that data collection will present particular challenges to these types of programs because the State may not have direct contractual relationships with employer group health plans or with health insurance issuers offering group health insurance coverage. States may need to explore alternative methods of data collection for premium assistance programs, such as consumer surveys and polling.

Comment: One commenter expressed concern that the requirement at § 457.750(b)(5) stating that the annual report must include an updated budget is unnecessary and duplicative of other ongoing requirements, including the HCFA form 37, ''Medicaid Program Budget Report—State Estimate of Quarterly Grant Award.''

Response: The requirement for updated budgets in the annual report is necessary for the sound administration of SCHIP. Annual reporting of updated budgeting with three-year projections, including changes in sources of non-Federal funding and details on the planned uses of all funds, is essential to sound financial management of this program. Annual updated reports are also essential to HCFA as it monitors and anticipates the financial needs of States implementing SCHIP programs. Because States have up to three years to spend each annual allotment, a three-year budget is useful to show if States are planning to use their unused allotments in the succeeding two fiscal years or if they anticipate a shortfall in Federal funding. Therefore, we have decided to retain this requirement for a three-year budget in the final regulation. However, we are no longer requiring a three-year budget with all amendments. Instead, we have limited the requirements at § 457.80 to a one-year budget only with amendments that have a significant budgetary impact. A more detailed discussion of this issue can be found in the comments and responses to § 457.80.

Comment: One commenter noted that in § 457.750(b)(5) of the proposed rule, States are required to include in the annual report an updated budget for the current Federal fiscal year. The commenter states that HCFA did not take into account the State appropriations process and the fiscal year used by the State as opposed to the Federal fiscal year. For example, Illinois has a July-June fiscal year, with the legislature appropriating funds for the final Federal quarter (July-September) in May. Therefore, the commenter noted, the last quarter in the SCHIP annual report will be an estimate. The commenter believed that the regulations regarding the annual report should be revised to permit States to estimate budgets for the final Federal quarter.

Response: We have modified § 457.750(b)(5) as proposed. Instead of requiring an annual budget for the current fiscal year, we now require an annual updated budget for a three-year period. We realize that the three-year budgets States are required to submit annually in fulfilling the requirements of § 457.750(b)(5) are based on projections and may vary from actual expenditures for a variety of reasons. However, we believe it is important to have this information to ensure that States have adequately planned for the program and to analyze spending allotments.

7. State Evaluations (§ 457.760)

In proposed § 457.760 we set forth the requirement that States submit a comprehensive evaluation by March 31, 2000 that analyzes the progress and effectiveness of the State child health program. In the evaluation, a State must report on the operation of its Medicaid expansion program, separate child health program, or combination program. As specified in section 2108(b)(1)(B) of the Act, the State evaluation must include all of the following:

- An assessment of the effectiveness of the State plan in increasing the number of children with creditable health coverage. In addition, the State must report on progress made in meeting other strategic objectives and performance goals identified by the State plan.
- An assessment of the State's progress in meeting other strategic objectives and performance goals identified by the State plan.
- A description and analysis of the effectiveness of elements of the State plan, including the following elements:
  - —The characteristics of the children and families assisted under the State plan, including age of the children and family income. The State also must report on children's access to, or coverage by, other health insurance prior to the existence of the State program and after eligibility for the State program ends (the child is disenrolled). As an optional strategy, the State also should consider reporting on other relevant characteristics of children and their families such as sex, ethnicity, race, primary language, parental marital status, and family employment status.
  - —The quality of health coverage provided under the State process or other process that is used to assure the quality and appropriateness of care.
  - —The amount and level of assistance including payment of part or all of any premiums, copayments, or enrollment fees provided by the State.
  - —The service area of the State plan (for example, Metropolitan Statistical Area (MSA) or non-MSA).
  - —The time limits for coverage of a child under the State plan. As an optional strategy, the State should consider reporting the average length of time children are assisted under the State plan.
  - —The extent of substitution of public coverage for private coverage and the State's effectiveness in designing policies that discourage substitution.
  - —The State's choice of health benefits coverage, including types of benefits provided and the scope and range of these benefits, and other methods used for providing child health assistance.
  - —The sources of non-Federal funding used in the State plan.
- An assessment of the effectiveness of other public and private programs in the State in increasing the availability of affordable quality individual and family health insurance for children.
- A review and assessment of State activities to coordinate the SCHIP plan with other public and private programs providing health care and health care financing, including Medicaid and maternal and child health services.
- An analysis of changes and trends in the State that affect the provision of accessible, affordable, quality health insurance and health care to children.
- A description of any plans the State has for improving the availability of health insurance and health care for children.
- Recommendations for improving the SCHIP program.

Comment: One commenter indicated that the State evaluation requirements should be less prescriptive and require an analysis of the effectiveness of elements the State may include rather than requiring an analysis of all eight elements listed at § 457.760(c). The commenter asserted that such policy would allow States to identify and address areas relevant to their own State plans. The commenter suggested that we revise this section to provide that ''a description and analysis of elements of the State plan *may* include:'' the elements in paragraph (c) of this section.

Response: States were statutorily required to report on the progress of the elements set forth in § 457.760(c) in the State evaluation, due to HCFA on March 31, 2000, and we modeled the proposed regulation text after the statute. Section 2108(b) of the Act specifies the contents of the State evaluation. HCFA therefore does not have discretion to make these requirements optional for States. In addition, because all the States have submitted the required evaluation, we have removed this provision from the final rule. Any request for future evaluations will be based upon the requirements in the statute for evaluations and annual reports on the program.

Comment: We received several comments expressing appreciation that the guidance set forth in the preamble to the proposed rule regarding the evaluation closely followed the evaluation framework developed by NASHP and the State workgroup. However, several commenters asserted that the information provided in State evaluations should not be used to establish model programs and practices. Rather, they noted, States should be given the freedom to design programs that best suit the needs of their population and circumstances, and information provided in the evaluation should focus on how the States have used the flexibility allowed by the program to create unique and successful plans.

Response: We are using the evaluations to identify model practices. We believe that the identification of model practices should not involve comparing unlike programs or overlooking the unique circumstances of each State. Many States have been eager to learn about other State practices. We envision model practices as a means of sharing information with States and other interested parties on how other States have successfully implemented certain parts of their program. We develop model practices not as a means of judging or evaluating programs, but rather as a means of sharing those practices that have proven successful for one State so that other States may determine the merit of adopting similar practices in their own SCHIP implementation.

Comment: One commenter recommended that we require States to report on the provision of services as well as the participation rates of pediatricians and other child health care providers in the program. Additionally, the commenter recommended that we require States to report the average cost-sharing requirements for families who choose to enroll in SCHIP rather than employer-provided coverage. The commenter believed that we should also require States to include an evaluation of the impact States' efforts to minimize substitution have had on children with special health care needs and their access to services. The commenter believed that HCFA should also require States to include evaluations of their screen and enroll processes.

Response: We do not agree with the commenter's suggestion. The evaluation template developed by the National Academy for State Health Policy reflects those elements specified in section 2108(b)(1)(B) of the Act. To this extent, it did include assessment questions on the State's cost sharing and its effects on participants as well as questions regarding the State's screen and enroll process and its substitution policies and results of monitoring rates of substitution. We have further included a provision at § 457.353 that specifically requires States to monitor and evaluate the effectiveness of the screening process. The regulatory requirements are consistent with the statute. In some cases, States included additional data or other information such as the data suggested by the commenter, in their SCHIP evaluations as additional measures of their progress toward strategic objectives of that State.

Comment: One commenter supported the proposed categories of evaluation, but requesting that we require more frequent reporting and evaluation.

Response: Section 2108(b) of the Act, as implemented in § 457.760, required States to submit evaluations by March 31, 2000. We believe the information States will be providing through the quarterly and annual reports required by § 457.740 and § 457.750 respectively, will be sufficient to allow ongoing assessments of States' SCHIP programs, making more frequent reporting and formal evaluations unnecessary and overly burdensome on States. The statute did not include a subsequent requirement for an annual evaluation and we have, therefore, removed this provision from the final rule.

Comment: One commenter recommended that HCFA clarify § 457.750(c)(1) by replacing the phrase ''coverage by other health insurance prior to the State plan'' with ''coverage by other health insurance prior to coverage under the State plan.''

Response: Because we have deleted this provision from the final rule, we have not adopted the commenter's suggestion.

Comment: One commenter recommended that HCFA encourage States to build on existing data collection efforts and systems, including State title V efforts, in developing overall SCHIP evaluation efforts and in collection of data.

Response: We encourage States to build on existing databases and title V efforts, as well as public-private partnerships in order to facilitate the development and implementation of information tracking systems and SCHIP program evaluation efforts.

G. Subpart H—Substitution of Coverage

1. Basis, Scope, and Applicability (§ 457.800)

Title XXI requires that States ensure that coverage provided under SCHIP does not substitute for coverage under either private group health plans or Medicaid. Section 2102(b)(3)(C) of the Act requires that State plans include descriptions of procedures used to ensure that the insurance provided under the State child health plan does not substitute for coverage under group health plans. Another provision in title XXI relating to substitution of coverage is section 2105(c)(3)(B), which sets out the conditions for a waiver for the purchase of family coverage as described in § 457.1010. Under this provision, States must establish that family coverage would not be provided if it would substitute for other health insurance provided to children.

In addition, title XXI contains several provisions aimed at preventing SCHIP from substituting for current Medicaid coverage. First, sections 2102(a)(2) and 2102(c)(2) of the Act requires States to describe procedures used to coordinate their SCHIP programs with other public and private programs. Second, section 2105(d) of the Act includes ''maintenance of effort'' provisions for Medicaid eligibility. That is, under section 2105(d) of the Act, a State that chooses to create a separate child health program cannot adopt income and resource methodologies for Medicaid children that are more restrictive than those in effect on June 1, 1997. Furthermore, section 1905(u)(2)(b) of the Act also provides that a State that chooses to create a Medicaid expansion program is not eligible for enhanced matching for a separate coverage provided to children who would have been eligible for Medicaid in the State under the Medicaid standards in effect on March 31, 1997. Finally, section 2102(b)(3)(B) of the Act requires that any child who applies for a separate child health program must be screened for Medicaid eligibility and, if found eligible, enrolled in Medicaid.

This subpart interprets and implements section 2102(b)(3)(C) of the Act regarding substitution of coverage

under group health plans and sets forth State plan requirements relating to substitution of coverage in general and specific requirements relating to substitution of coverage under premium assistance programs. These requirements apply only to separate child health programs.

Comment: Many commenters questioned the magnitude of the risk for substitution of private group health plan coverage by SCHIP coverage for children. Because the size of the risk of substitution by SCHIP coverage offered under both employer-sponsored insurance programs and non-employer-sponsored insurance programs is unclear, and because of the harm that substitution prevention policies may inflict, the commenters encouraged HCFA not to put forth a policy to prevent substitution that goes beyond what is clearly required by the statute. Many commenters also recommended that we revisit our policy on substitution because of their concern that waiting periods and other substitution prevention policies are causing significant harm to families with children with special health care needs and argued that such families can ill afford to go without coverage for any period of time.

Response: We have revisited our policy on substitution and made several changes. With respect to substitution policies outside of the context of premium assistance programs, we note that the proposed regulatory text at § 457.805 requires only that the State plan include reasonable procedures to prevent substitution. This approach permits State flexibility and implementation of policies based on the emerging research regarding substitution and on State experiences with substitution.

Our review of States' March 31, 2000 evaluations indicated that in those States with data on substitution of private coverage with SCHIP coverage, there was little evidence that substitution was as great an issue as initially anticipated.

Thus, we have revised the policy stated in the preamble to the NPRM regarding substitution procedures relating to SCHIP coverage provided outside of programs that offer premium assistance for coverage under group health plans as follows: States that provide coverage to children in families with incomes at or below 200 percent of FPL must have procedures to monitor the extent of substitution of SCHIP coverage for existing private group health coverage, as was the policy for such coverage provided to families under 150 percent of FPL proposed in the preamble to the NPRM.

States that provide coverage to children in families with incomes over 200 percent of FPL should, at a minimum, have procedures to evaluate the incidence of substitution of SCHIP coverage for existing private group health coverage. In addition, States offering coverage to children in families over 200 percent of FPL must identify in their State plans specific strategies to limit substitution if monitoring efforts show unacceptable levels of substitution. States must determine a specific trigger point at which a substitution prevention mechanism would be instituted, as described in the State plan. For coverage above 250 percent of the FPL, because evidence shows that there is a greater likelihood of substitution at higher income levels, States must have substitution prevention strategies in place, in addition to monitoring.

Although a period of uninsurance is one possible substitution prevention procedure, we invite States to propose other effective strategies to limit substitution. States may submit amendments to their State plans if they would like to modify their current policies in light of the policies discussed here. We plan to work closely with each State to develop appropriate substitution strategies, monitoring tools, and trigger mechanisms.

For premium assistance programs, we have revised our substitution policy in this final rule in two areas. We have eliminated the requirement for a 60 percent minimum employer contribution. We will no longer mandate a specific level of contribution, since a substantial employer contribution must be made in order for coverage subsidized through employer plans to be cost-effective, as required under § 457.810. States will be expected to identify a reasonable minimum employer contribution level and provide justification for that level, including data and other supporting evidence, that will be reviewed in the context of the State plan amendment process. In addition, as proposed in the NPRM, States with premium assistance programs must monitor employer contribution levels over time to determine whether substitution is occurring and report their findings in their State annual reports.

The identification of the minimum employer contribution and the monitoring process will help ensure that SCHIP funds are being used to supplement the cost of employer-sponsored insurance, not supplant the employers' share of the cost of coverage. While these revisions are intended to provide additional State flexibility to develop premium assistance programs and provide coverage to families, it is important to note that the cost-effectiveness test established by title XXI and set forth in § 457.810 must be met in all cases.

The second change we are making relates to the required waiting period of uninsurance. We have retained the requirement for a minimum 6-month period without group health coverage, but will permit exceptions to the waiting period, as discussed in more detail in the comments and responses to section § 457.810.

2. State Plan Requirements: Private Coverage Substitution (§ 457.805)

The potential for substitution of SCHIP coverage for private group health plan coverage exists because SCHIP coverage may cost less or provide better coverage than coverage some individuals and employers purchase with their own funds. Specifically, employers who make contributions to coverage for dependents of lower-wage employees could potentially save money if they reduced or eliminated their contributions for such coverage and encouraged their employees to enroll their children in SCHIP. At the same time, families that make significant contributions towards dependent group health plan coverage could have an incentive to drop that coverage and enroll their children in SCHIP if the benefits would be comparable, or better, and their out-of-pocket costs would be reduced.

In accordance with section 2102(b)(3)(C) of the Act, we proposed at § 457.805 to require that each State plan include a description of reasonable procedures that the State will use to ensure that coverage under the State plan does not substitute for coverage under group health plans.

We opted not to propose specific procedures to limit substitution. Instead, we discussed in detail reasonable procedures that States may use to prevent substitution of coverage. Specifically, we stated in the preamble to the NPRM that we would consider the following to be reasonable procedures for addressing the potential for substitution:

- States that provide coverage to children in families at or below 150 percent of the Federal poverty line (FPL) should, at a minimum, have procedures to monitor the extent of substitution of that coverage for existing private group health coverage.
- States that provide coverage to children in families between 150 and

200 percent of FPL should, at a minimum, have procedures to study the incidence of substitution of that coverage for existing private group health coverage. In addition, States should specify in their State plans the steps they will take to prevent substitution in the event that the States' monitoring efforts discover substitution has occurred at an unacceptable level.

• States that provide coverage to children in families above 200% of FPL should implement, concurrent with program implementation, specific procedures or a strategy to limit substitution.

We noted that we would ask States to assess the procedures to limit substitution in their evaluations submitted in March of 2000. We also asked all States that specified in their plans that they would monitor substitution to submit information on substitution in their annual reports.

We also addressed the issue of applying substitution provisions to the Medicaid eligibility group for the ''optional targeted low-income children'', which was added to section 1902(a)(10)(A)(ii)(XIV) of the Act pursuant to section 4911 of the BBA. In the NPRM we clarified that States may not apply eligibility-related substitution provisions, such as periods of uninsurance, to the ''optional targeted low-income children'' group, because such eligibility conditions are inconsistent with the entitlement nature of Medicaid. We have retained this policy in this final regulation. States that currently apply eligibility-related substitution provisions to optional targeted low-income children will need to come into compliance with this clarified policy. States that have not already come into conformity with this policy will have 90 days from the date of this notice to do so and must submit a State plan amendment in compliance with § 457.65(a)(2). We recognize that States expanding Medicaid to optional targeted low-income children at higher income levels may be particularly concerned about the potential for substitution of coverage. States that want to maintain waiting periods for the optional targeted low-income children group may want to submit section 1115 demonstration requests for approval of substitution provisions. HCFA will consider section 1115 demonstration requests on a case-by-case basis.

Comment: Although neither the preamble nor the proposed regulatory text explicitly prescribed a mandatory waiting period or period without group health insurance, as a condition of eligibility in separate child health programs that are not providing premium assistance for group health plans, many commenters expressed their dislike for the Department's policy implemented in the course of approving State plans and plan amendments, of mandating the imposition of periods without insurance for populations over 200 percent of the FPL.

Many commenters indicated that waiting periods are unnecessary in general because they block access to care without any proof of their effectiveness in preventing substitution. Some commenters stated that the data on the significance of substitution has been inconclusive. One commenter referred to recent data from the Current Population Survey (CPS) on trends in coverage for low-income children that, in their view, raised serious questions about the magnitude of any crowd out effect of expansions in publicly-funded coverage for children. Another concern raised was that waiting periods without insurance impose a significant hardship for families who may be struggling to keep up premium payments, obtain care for children with special health care needs, or get by with inadequate private coverage for their children.

Response: Our review of States' March 31, 2000 evaluations indicated that in those States with data on substitution of private coverage with SCHIP coverage, there was little evidence that substitution was as great an issue as initially anticipated. However, because of the current lack of conclusive data around the level of substitution which may be occurring below 200 percent of FPL, we maintain that monitoring of substitution of coverage in SCHIP is critical.

As noted above, we have revised the policy stated in the preamble to the NPRM regarding substitution procedures relating to SCHIP coverage provided outside of programs that offer premium assistance for coverage under group health plans as follows:

• States that provide coverage to children in families at or below 200 percent of FPL must have procedures to monitor the extent of substitution of SCHIP coverage for existing private group health coverage, as was the policy for such coverage provided to families under 150 percent of FPL proposed in the preamble to the NPRM.

• At a minimum, States that provide coverage to children in families with incomes over 200 percent of FPL should have procedures to evaluate the incidence of substitution of SCHIP coverage for existing private group health coverage. In addition, States offering coverage to children in families over 200 percent of FPL must identify in their State plans specific strategies to limit substitution if monitoring efforts show unacceptable levels of substitution. States must monitor the occurrence of substitution and determine a specific trigger point at which a substitution prevention mechanism would be instituted, as described in the State plan.

• For coverage above 250 percent of the FPL, because evidence shows that there is a greater likelihood of substitution at higher income levels, States must have substitution prevention strategies in place, in addition to monitoring.

Although a period of uninsurance is one possible substitution prevention procedure, we invite States to propose other effective strategies to limit substitution. States may submit amendments to their State plans if they would like to modify their current policies in light of the policies discussed here. We plan to work closely with States to develop appropriate substitution strategies, monitoring tools, and trigger mechanisms. As part of monitoring for substitution of coverage, States should also study the extent to which anti-substitution policies require children who have lost group health coverage through no fault of their own or their employer to wait to be enrolled in SCHIP. To the extent that monitoring finds that such children are forced to go without coverage, States should consider adjustments to their substitution prevention policies that permit exceptions for children who should not be the target of such policies. We will continue to ask States to assess their substitution prevention procedures in their annual reports.

Finally, we note that because the regulatory text at § 457.805 required that the State plan include reasonable procedures to prevent substitution and made no distinction for eligibility levels for coverage under State plans, we have not revised the regulation text. It is consistent with our revised policy.

Comment: Several commenters believed that States should be allowed to establish guidelines that would allow families to drop coverage without penalty of a SCHIP-required waiting period and to enroll the child or children in the State's SCHIP program if they are paying more than they can afford for the child's insurance. The commenters indicated that, in some cases, the child may have special health needs and/or the family may be paying for insurance that does not cover many of the child's needs but serves only as insurance against a catastrophic event. In addition, some commenters suggested that States not be allowed to impose periods of uninsurance that impede the

delivery of preventive care and immunizations consistent with the AAP Guidelines for Health Supervision III and Bright Futures Guidelines for Health Supervision of Infants, Children and Adolescents.

Response: As stated above, periods of uninsurance will not be required unless coverage is provided via premium assistance through group health plans, coverage is provided to children with significantly higher income levels, or substitution has been identified as a problem in the State. Furthermore, in the case of States with premium assistance programs, we continue to permit States to cover such children under a separate child health program (outside of coverage through premium assistance programs) during the waiting period, as stated in the preamble to the proposed rule. The required period of uninsurance applies only to SCHIP coverage provided through group health plans.

States are therefore able to enroll special needs children, and those in need of preventive care and immunizations, in SCHIP in a timely fashion so as not to disrupt the provision of needed health care services. To the extent a State chooses to adopt periods of uninsurance, the State may want to consider exceptions to the period of uninsurance to address issues raised by the commenters. We note, however, that access to immunizations is unlikely to be proposed as an exception since virtually all younger children would thereby be exempt.

Comment: One commenter urged the Department to view State substitution prevention efforts as a comprehensive plan, rather than isolating specific pieces that may or may not measure up to artificial Federal guidelines. In addition, the commenter noted that each State has developed a substitution prevention strategy that is applicable to the demographic and economic situation in the State, and State plans should therefore be judged in their entirety, not in a piecemeal fashion.

Response: We agree that State's substitution prevention efforts should be considered in the context of the entire State plan with consideration given to a State's particular needs and goals. To this end, we have retained a flexible regulatory requirement regarding substitution and indicated that HCFA will incorporate additional flexibility in its plan review process.

Comment: One commenter agreed with the language in proposed § 457.805 and suggests that HCFA limit States' discretion to use fears about substitution as an excuse to deny health coverage and recommended that final regulations bar waiting periods (outside of the premium assistance arena) that either: (1) Impose harm on children by going beyond 6 months or deny coverage (except where the employee voluntarily drops employment-based coverage without any change in circumstances) for pregnant women, children with disabilities, or children with preexisting conditions as defined by HIPAA; or (2) deny SCHIP benefits to children without employer-sponsored insurance for reasons unrelated to SCHIP (recent adoption, loss of job, end of COBRA coverage, death of a parent, moving outside the plan's service area, or an increase in premiums that was unaffordable to the family).

Response: As indicated above, outside of premium assistance programs, States have broad discretion to develop substitution prevention policies that best serve their particular populations. States that choose to retain or impose periods of uninsurance are encouraged to include exceptions that help prevent the imposition of undue hardship under a range of circumstances, including loss of insurance through no fault of the family, extreme economic hardship, death of a parent, etc.

Comment: One commenter indicated that, while in agreement that our proposed policy on substitution for the lower income population is reasonable, HCFA should carefully monitor State programs for children under 200% FPL to assure that no substitution problems emerge.

Response: We will continue to review State plan amendments to ensure that States monitor the occurrence of substitution at all income levels, and to review annual reports for any reported experiences of substitution. As stated in previous guidance from HCFA, in the event monitoring efforts indicate unacceptable levels of substitution, HCFA may reconsider the requirements intended to prevent substitution of coverage.

Comment: One commenter indicated confusion about the preamble language which ''does not require'' the use of eligibility-related substitution prevention provisions such as periods of uninsurance for the Medicaid eligibility group for the ''optional targeted low income children,'' but goes on to say that States that currently apply eligibility-related substitution prevention provisions to optional targeted low-income children ''will need to come into compliance with this proposed policy.'' The commenter believed our language should have indicated we would ''not allow'' such States to impose a waiting period as opposed to ''not require.''

Response: The commenter is correct. The policy is that the Medicaid statute does *not allow* the use of eligibility-related substitution prevention provisions such as periods without insurance for ''optional targeted low income children'' (outside of demonstration projects under the authority of section 1115 of the Act).

Comment: One commenter asked for clarification whether the proposed requirements with respect to substitution at § 457.800(c) applied only to separate child health programs and not to Medicaid expansion programs.

Response: As noted by the commenter, this point needs clarification. This subpart, as stated at § 457.800(c), applies only to separate child health programs. We have removed the reference to subpart H at § 457.70, which had indicated the requirements that apply to Medicaid expansion programs.

Comment: Several commenters indicated support for the clarification that waiting periods are not allowed in Medicaid expansions (outside of section 1115 demonstrations). One commenter asserted that this is consistent with Congressional intent that all Medicaid rules should apply to title XXI expansions of Medicaid. Another commenter suggested using caution when granting 1115 demonstrations to implement substitution prevention provisions when expanding Medicaid eligibility.

Response: We agree with the first two points and note the concerns raised in connection with section 1115 demonstrations.

Comment: One commenter indicated that States should be permitted the flexibility to implement the substitution provisions that they determine are necessary for their own SCHIP programs, and that this should be the rule whether the program is a Medicaid expansion or a separate program. Another commenter believed that it is unfair not to require a six-month waiting period for Medicaid expansion programs because it presents an unfair barrier to separate child health programs.

Response: The final rule allows States the flexibility to identify and implement substitution prevention provisions that are necessary for their own separate child health programs, within the parameters discussed above. Title XXI explicitly requires States to have substitution policies. By contrast, waiting periods are not permitted in Medicaid expansion programs outside of section 1115 demonstrations.

Comment: One commenter stated that HCFA should consider whether the imposition of substitution provisions, such as mandated periods of uninsurance applied to adults under family coverage waivers, would have an undesirable effect on the children's access to services.

Response: We agree that waiting periods may have an adverse impact on children's access to care. In this final rule, HCFA is requiring States to monitor the extent to which substitution prevention policies require children who have lost group health coverage, through no fault of their own or on the part of their employer, to wait to be enrolled in SCHIP. If monitoring shows that such children are forced to go without coverage, States should consider adjustments to their substitution prevention policies that permit exceptions for children who should not be the target of such policies. Because research shows that the risk of substitution is greater when a State operates a premium assistance programs, we will continue to require that such coverage be available after a six month period of uninsurance. However, this policy does not prevent States from covering SCHIP enrollees, whether children or families, through a separate child health program or through Medicaid. The final rule also permits States to adopt reasonable exceptions to the waiting period requirement. (See the discussion of the comments and responses on § 457.810.) Thus, the premium assistance substitution policy does not require that children be uninsured prior to enrolling in a premium assistance program.

Comment: One commenter believed that collaboration with the Child Support Enforcement Program is necessary and that any efforts to monitor potential substitution of private employer group coverage should include a review for coverage which may already be provided by a noncustodial parent, or which may potentially be available through a noncustodial parent pursuant to a support order. The commenter also asked that the definition of substitution be clarified and recommended a definition of ''equivalent to SCHIP coverage'' or some State-defined minimum requirements. The commenter appeared to believe that coverage inferior to SCHIP coverage carried by a noncustodial parent should not be considered health insurance coverage when determining whether SCHIP coverage is substituting for private group health insurance coverage.

Response: We agree that a State's SCHIP program should coordinate with the State's Child Support Program and that coverage under, or available through, a noncustodial parent's health plan should be considered by the State with respect to its substitution policies. The commenter is concerned that coverage available from the noncustodial parent be equal to SCHIP coverage or some State-defined minimum coverage before a concern for substitution should arise. We note that this final rule does not require that children be denied SCHIP coverage if the noncustodial parent has insurance that could cover the child. CSE agencies should be informed about the availability of SCHIP coverage because, as the commenter suggests, SCHIP coverage might provide better access to care than coverage potentially available through the noncustodial parent. The statutory provisions do, however, preclude SCHIP eligibility for a child who already has coverage under a group health plan or health insurance coverage, as those terms are defined under HIPAA. The only exceptions to this policy are if the child does not have ''reasonable geographic access'' to coverage, as described in subpart C, or if the policy meets the definition of ''excepted benefits'' under HIPAA.

3. Premium Assistance Programs: Required Protections Against Substitution (§ 457.810)

We proposed under § 457.810 to require any State that implements a separate child health program under which the State provides premium assistance for group health plan coverage, to adopt specific protections against substitution. A State must describe these protections in the State plan. In the NPRM, we proposed that the following four requirements would need to be met to protect against substitution:

• *Minimum period without group health plan coverage.* The child must not have been covered by a group health plan during a period of at least six months prior to application for SCHIP. States may require a child to have been without such insurance for a longer period, but that period may not exceed 12 months. States may permit exceptions to the minimum period without insurance if the prior coverage was involuntarily terminated. We noted that newborns who are not covered by dependent coverage would not be subject to a waiting period. We also noted that the waiting period applies only to coverage through a group health plan, not SCHIP or Medicaid coverage. If an otherwise eligible child does not meet the requirement for a minimum period without group health plan coverage, the State can enroll the child in SCHIP under a separate child health program without purchasing employer-sponsored coverage for the interim waiting period, and can still consider the child uninsured for purposes of the waiting period. That is, coverage under a separate child health program or Medicaid does not count as group health insurance coverage for purposes of the required waiting period prior to enrollment in SCHIP coverage provided via premium assistance programs.

• *Employer contribution.* The employer must make a substantial contribution to the cost of family coverage, equal to 60 percent of the total cost of family coverage. States proposing a minimum employer contribution rate below this standard must provide the Department with data that demonstrate a lower average employer contribution in their State and support a State's contention that the lower contribution level will be equally effective in ensuring maintenance of statewide levels of employer contribution. In addition, the employee must apply for the full premium contribution available from the employer.

• *Cost-effectiveness.* The State's payment under its premium assistance program must not be greater than the payment that the State otherwise would make on the child's behalf for other coverage under the State's SCHIP program.

• *State evaluation.* The State must collect information and evaluate the amount of substitution that occurs as a result of payments for group health plan coverage and the effect of those payments on access to coverage. To conduct this evaluation, States must assess the prior insurance coverage of enrolled children. States may obtain information on prior coverage through the enrollment process, separate studies of SCHIP enrollees, or other means for reliably gathering information about prior health insurance status. In the preamble to the NPRM, we set forth specific examples of questions States could include in SCHIP applications to evaluate the prevalence of substitution. We noted that we would reevaluate our position on the requirements for States that subsidize employer-sponsored plans based on our review of the State evaluations due March 31, 2000.

Comment: One commenter noted that employer ignorance of changing public benefit rules is one of the most effective safeguards against widespread substitution, and things such as competitive market pressures and rising health costs, not changing Medicaid and SCHIP coverage rules, drive reductions in employer subsidies for health

coverage. Further, the commenter stated that the safeguard of employer ignorance ends when the employer is contacted by a State agency and becomes a partner in purchasing SCHIP coverage. Another commenter indicated their belief that HCFA is inconsistent by indicating that it will scrutinize SCHIP programs subsidizing employer-sponsored insurance while suggesting (in § 457.90) that ''Employer-based outreach is another avenue for providing * * * information on children's insurance programs.''

Response: We note these comments and have sought to craft a substitution prevention policy that reflects the different pressures on the employer market and that balances States' desire for developing premium assistance programs with the risk that such programs will not expand coverage for children, but merely substitute employer contributions with SCHIP funds. There are both benefits and risks of partnering with employers in designing premium assistance programs. We have provided new flexibility to States to design such programs under these final rules, while retaining some requirements that are critical for preventing substitution.

Comment: Many commenters indicated their strong disagreement with the mandatory six-month minimum period without group health insurance coverage prior to application for SCHIP premium assistance coverage through group health plans. Their arguments against this policy included that it has no basis in statute, that it is inconsistent with other SCHIP strategies to prevent substitution which allow State flexibility, and that waiting periods block access to coverage and care for an arbitrary period without evidence of the effectiveness of any particular length of waiting period in preventing substitution. Some of these commenters added that if HCFA maintains a requirement for a period without employer-sponsored insurance prior to eligibility for SCHIP coverage obtained through premium assistance programs, that the minimum period be changed to 3 months. One commenter noted that there is no State system in place to confirm if and when an individual was previously covered under group health plans and that requiring States to establish such a system would be onerous and administratively costly.

Response: We have revisited and made revisions to our policy on substitution generally, and our policy on required periods of uninsurance, with respect to premium assistance for coverage under group health plans.

As discussed above, when a State operates premium assistance for group health insurance coverage, the State is no longer required to comply with the requirement that the employer contribution be at least 60 percent of the premium cost. The other requirements described in the proposed rule would continue to apply; namely, the requirements that the employee eligible for the coverage apply for the full premium contribution available from the employer, that such coverage be cost-effective, and that the State evaluate the amount of substitution that occurs as a result of payments for group health insurance coverage and the effect of those payments on access to coverage.

In addition, because of the greater likelihood of substitution of SCHIP coverage for group health insurance coverage offered by employers, we are retaining the requirement for a 6-month waiting period, but allowing States greater flexibility to vary from this general requirement. The default substitution prevention mechanism will be a period of uninsurance of at least six months, and not more than 12 months, without group health insurance prior to eligibility for SCHIP premium assistance for coverage through group health insurance plans offered by employers. States may also develop reasonable exceptions to the required waiting period when they can identify limited circumstances in which substitution is less likely to occur. For example, if a State is targeting its premium assistance program to certain employers that provide only very limited health insurance coverage, a waiting period may not necessarily be required since the likelihood of substitution would be limited in those circumstances.

In proposing exceptions to the six-month waiting period, States must provide reasonable justification for such exceptions, including data and other supporting evidence, as appropriate, which will be reviewed by HCFA in the context of the State plan amendment process. We have also listed several specific exceptions to the waiting period that may be granted, including involuntary loss of coverage due to employer termination of coverage for all employees and dependents, economic hardship, and change to employment that does not offer dependent coverage. And, as noted above, States also must monitor their premium assistance programs to determine whether substitution may be occurring. We plan to work closely with States interested in providing coverage via premium assistance for group health insurance coverage in order to provide technical assistance and help achieve a balanced approach that allows premium assistance plans to be implemented with appropriate safeguards to prevent substitution.

Comment: Many commenters expressed concern about the 60 percent employer contribution requirement at proposed § 457.810(b)(2) for SCHIP coverage provided through employer-sponsored insurance because employer contributions may vary in a State based on region, type and size of business, and wage levels of employees. The commenters' expressed the position that HCFA has exceeded its statutory authority in setting this benchmark, and they argued that it is unnecessary. Furthermore, the commenters stated that few employers contributing less than 60 percent of the premium would meet the required cost effectiveness test. The commenters noted that the statutory requirement that the purchase of employer-sponsored insurance with SCHIP funds must be cost effective is the most appropriate tool to use. One commenter indicated that the employer contribution standard should not be based on a statewide average of all businesses, but should be appropriate to, and specific to, those businesses which would participate in the SCHIP program that would utilize an existing health purchasing cooperative consisting of small businesses. One commenter also indicated that the level of substitution is unlikely to be affected by the 60 percent requirement, because employers would probably not base their health coverage decisions on the needs of employees eligible for premium assistance who, for many companies, represent only a small fraction of their overall employee pool. The commenter stated that crowd out occurs because of individual rather than corporate decisions, such as when individual employees elect to drop private coverage for low-cost or no-cost public assistance. Finally, the 60 percent would be problematic for some commenters' States because those States are operating under approved 1115 demonstrations to allow premium assistance when employers contribute at least half the cost of coverage.

Another commenter cited a survey that showed that in regions other than on the east coast, very few employers pay any part of the dependent premium. The recent survey indicated on average, large employers pay 85.51% of the employee premium and 17.62% of the dependent premium, and that small employers contribute 78.06% of the employee premium and 5.14% of the dependent premium. According to this commenter, HCFA's requirement

actually prevents access for many children.

Several commenters that disagreed with the 60 percent employer contribution requirement suggested it be deleted in favor of maintaining a cost-effectiveness test while requiring States to simply describe how they plan to monitor employer contribution percentages to detect any reductions in the contributions and assess whether reductions may be related to SCHIP premium assistance. Other commenters also recommended subjecting employers to a maintenance of effort requirement with respect to the contribution level.

One commenter recommended that if a minimum requirement is maintained, States be permitted to establish different standards for different kinds of employers, including making distinctions based on whether or not the employer has previously offered health insurance coverage and on the wage distribution of the employer's work force.

It was one commenter's opinion that failure to allow State flexibility on the employer contribution will stifle many potential innovative approaches to reach uninsured children of low-wage workers and that States will be unable to enroll sufficient numbers of children in these programs to justify the administrative expense. In addition, in this commenter's view, the 60 percent requirement may result in many families who would prefer premium assistance being forced to enroll their children in the regular SCHIP program, and force the State to forego any employer contribution. The commenter also noted that, if more low-wage workers decline dependent coverage when it is offered, employers with many low-wage workers may stop offering coverage, causing a long-term, population-wide shift from private to public sources of coverage.

Another commenter stated that the small employers in its State do not pay 60 percent of family health coverage premiums and, in fact, most do not cover dependents. The commenter believed that they should be allowed to include in premium assistance programs employers who are currently not covering dependents. They suggested a rule that would only include employers who did not cover dependents as of a certain date, or who paid less than a predetermined amount for coverage as of that date. The State would then use local objective data (and not ''outdated, national surveys of large employers'') to determine the contribution amount appropriate for the locality. One commenter indicated that our proposed policy would punish families who find jobs with employers who contribute less than 60 percent and encourage them to take jobs with employers that don't offer family coverage.

A commenter also suggested that whatever standard is adopted, there should be exceptions in instances in which employer contribution percentages drop solely because of an increase in premiums or where an employer drops its level of contribution because of documented and significant economic declines. In such cases, the commenter argued, crowd out isn't a factor in the reduced employer contribution level, and failure to allow employers in such circumstances to reduce their contribution levels may result in employees and their families losing their insurance. One commenter said, regarding the 60 percent employer contribution, that HCFA should not presume the cost neutrality of State initiatives to link title XIX/XXI coverage to low-wage workers, and said that the proposed regulations indirectly restrict a State's discretion to define eligibility and thereby exceed Congressional intent. Moreover, in this commenter's view, by establishing such a high level of employer contribution, HCFA effectively is excluding dependents of small business employees from participating in SCHIP.

Another commenter stated that a required percentage of employer contribution for participation in SCHIP premium assistance programs would give employers a target that could be misused. If an employer arbitrarily reduced its percentage of contribution, the employer could eliminate the opportunity for additional SCHIP-eligible employees to purchase employer health insurance with the help of premium assistance. In the commenter's State, only 2.5 percent of eligible individuals with access to employer-sponsored health coverage have access to family coverage where the employer pays 60 percent or more of the premiums. For nearly 30 percent of the State's eligibles with access to family coverage via an employer, the employer contributes about 10 percent less than the 60 percent minimum. In this commenter's view, our proposed rule would eliminate the opportunity for these individuals to be covered under a premium assistance program.

One commenter expressed disappointment that HCFA did not deviate from the policy expressed in the February 13, 1998 letter and indicated that the guidance is overly prescriptive and biased against the development of State approaches to SCHIP using employer-sponsored coverage. The commenter suggested providing additional State flexibility in determining the amount of employer contribution as long as plans certify that issues related to crowd out and substitution are addressed. If, upon evaluation, State efforts do not result in permissibly low levels of substitution, the commenter stated they would be happy to assist in the development of more detailed and specific guidelines. If the 60 percent requirement is not eliminated, this commenter suggested that States should be allowed to develop an alternative State average based on size of business, number of employees, number of low-wage employees or some other relevant factor.

Another commenter stated that there is no evidence in its Health Insurance Premium Program (HIPP) that employers have reduced their contribution because HIPP is paying the premium, and the commenter would not expect employers to act differently with respect to SCHIP. The commenter indicated that employers have other employees to consider and there is no evidence to support the position that employers will reduce their contribution because some employees are subsidized. They stated their belief that the majority of employers recognize the value of providing health care coverage to their employees and want them insured.

In this commenter's view, HCFA's position penalizes employees of employers who are not financially able or willing to contribute more, especially when health plans impose large premium increases. Also, the commenter believed that HCFA's position penalizes States by limiting their ability to buy-in to cost effective employer coverage and increasing the administrative burden for States. The commenter recommended that, if the employer plan is cost effective, States should have the flexibility to take advantage of the coverage, regardless of the amount of employer contribution.

Response: We appreciate the concerns raised by these commenters and we have revised our policy in this final rule to provide additional flexibility for States wishing to utilize premium assistance programs. We will no longer require States to implement a minimum employer contribution of 60 percent. We agree with the commenters' position that the cost-effectiveness requirement of the statute reduces the need for a uniform minimum employer contribution level, because it is likely that a substantial employer contribution would be necessary in order to meet the test of cost-effectiveness. However, States must identify a specific minimum employer contribution level to ensure

that SCHIP funds are used to supplement the cost of employer-sponsored insurance rather than supplant the employers' share of the cost of coverage, and we have maintained the requirement that States evaluate substitution in the context of their premium assistance program in their annual reports. While allowing for significant new flexibility, this policy also encourages States to require the highest possible employer contribution level that is reasonable given the circumstances in their State. In addition, the rules maintain the requirement that the employee eligible for the coverage must utilize the full premium contribution available from the employer.

We recognize that it may be necessary to revisit this policy as States gain experience with the provision of SCHIP coverage and we receive further evaluations of substitution with respect to SCHIP coverage provided through premium assistance for employer-sponsored insurance. The requirements set forth in this final rule represent our position on the steps necessary to implement the statutory provisions of section 2102(b)(3)(c) of the Act in light of what is now known about the interaction between private and public coverage. The rules provide considerable flexibility, allowing States and HCFA room to adjust the approach to substituion based on experience with the program.

Comment: One commenter agreed with the proposed rule's flexibility to allow less than 60 percent employer contribution to family coverage if the State average is less than 60 percent.

Response: We appreciate the support and as stated above, we have dropped the 60 percent contribution requirement in part because we recognize the variation in levels of average employer contributions across States.

Comment: One commenter strongly disagreed with our proposal to allow States to set a lower standard for employer contributions than 60 percent. The commenter asserts that because of the lack of data on ''average'' employer contributions to dependent coverage, especially with regard to small employers, and the fact that the average contribution among employers with 50 or fewer employees is zero percent, and in the commenter's State large employers also often contribute nothing, the commenter believes our proposed policy of allowing a less than 60 percent contribution would permit the allowance of premium assistance programs even where the employer contributes nothing at all.

Response: A contribution level of less than 60 percent is permitted under these final rules, as long as the cost-effectiveness test is met. We do not agree that premium assistance programs likely would be allowed when there is no employer contribution, as the commenter suggested, because the cost-effectiveness test is unlikely to be met without a substantial employer contribution.

Comment: One commenter suggested that HCFA clarify whether (and how) the NPRM's preamble discussion of determining cost-effectiveness under family coverage waivers applies with respect to using employer-sponsored insurance to provide coverage under SCHIP.

Response: The cost-effectiveness requirement in § 457.810(c) applies when a State provides premium assistance programs for SCHIP eligible children. The cost-effectiveness test for premium assistance for group health insurance coverage requires a comparison of the cost of coverage of the child that would otherwise be available under SCHIP to the State's cost to provide premium assistance for group health insurance coverage for that child. We have modeled the discussion of the cost-effectiveness test in the regulation text after the provision related to States that wish to cover family members, in addition to targeted low-income children at § 457.1015. We have specified that the State's cost for coverage for children under premium assistance programs must not be greater than the cost of other SCHIP coverage for these children. Consistent with cost-effectiveness test for family coverage, the State may base its demonstration of cost-effectiveness on an assessment of the cost of coverage for children under premium assistance programs to the cost of other SCHIP coverage for these children, done on a case-by-case basis, or on the cost of premium assisted coverage in the aggregate.

See the discussion at § 457.1015 for further details on cost-effectiveness for family coverage waivers.

Comment: One commenter indicated that the 60 percent requirement would unrealistically require a large base of employers to report data on contribution levels to the State in order for the State to satisfy the contribution requirement. Other commenters suggested we require States to evaluate the percent of income families would have had to spend to maintain employment-based or individual coverage during the period they waited for SCHIP coverage in assessing their substitution prevention procedures for their March 2000 evaluations and annual reports. They recommended that State evaluations and annual reports assess whether individual employers are terminating coverage for low-wage workers while maintaining coverage of higher wage workers and executives. Such an assessment should also examine increases in the amounts that employers are asking low-wage workers to contribute toward employment-based insurance coverage. Another commenter noted that few States will have implemented the employer buy-in option by the time of the March 2000 evaluations for HCFA to establish policy based on those evaluations.

Response: We are no longer imposing a minimum employer contribution requirement and recognize that there is not much experience to-date with premium assistance programs. As HCFA and the States gain experience, we will be in a better position to evaluate the extent of substitution taking place. We recognize that there is limited data regarding employer coverage and contributions based on wage-levels of employees as well as State based information on the percent of income families would have had to spend to maintain private coverage while waiting for SCHIP coverage. In addition, we note that market forces other than SCHIP may influence the level of employer contribution and further complicate such analyses. We encourage States to assess these issues but recognize that data to support such assessments may be difficult to obtain and therefore do not require it.

Comment: Several commenters noted concern about HCFA's policy permitting States to provide direct SCHIP coverage to children during the six-month waiting period via the State's separate child health program (other than premium assistance programs). Commenters indicated that this policy itself would actually facilitate crowd out as families dropped their privately-funded coverage in favor of publicly-funded benefits and that the privately-funded coverage would not resume until six months of publicly-funded coverage passed. In addition, one commenter noted that coverage under the State's regular SCHIP program is less cost-effective than its coverage under a premium assistance program.

Response: To the extent that the part of State's separate child health program that does not involve premium assistance requires either no period of uninsurance or a shorter one, there would be nothing to prohibit a child from being enrolled in that portion of the program even if the family had recently dropped coverage under its group health plan. There is no reason

that States should not be allowed to offer such coverage, although we believe it is unlikely that many families will drop their private group health insurance for coverage under a State's separate child health program, in part because most families would prefer to keep coverage of all the family members under one plan.

Comment: Many commenters suggested inclusion in the regulation of a mandatory list of exceptions to the proposed minimum 6-month waiting period and also encouraged the Department to prohibit waiting periods in excess of six months. Suggested exceptions included when: (1) An eligible individual is pregnant or disabled; (2) a waiting period exceeds the 63-day gap limit under HIPAA and would result in exclusion of coverage for a preexisting condition under the coverage offered by the State's separate child health program; (3) an eligible child is a newborn or recently adopted; (4) the waiting period would block coverage of a well-baby, well-child, or immunization service according to the periodicity schedules for such services; (5) insurance is lost because of involuntary job loss; (6) insurance is lost because of death of a parent; (7) insurance is lost because of a job change to employment where the new employer does not cover dependents; (8) a family moves out of the service area of employer coverage; (9) an employer terminates insurance coverage for all of its employees; (10) COBRA insurance benefits expire; (11) employment-based insurance ends because an employee becomes self-employed; (12) insurance is lost because of long-term disability; (13) insurance is terminated due to extreme economic hardship of the employer or employee; and (14) there is a substantial reduction in lifetime medical benefits or benefit category to an employee and dependents in an employee-sponsored plan. One of the commenters also suggested an exception when there has been a loss or termination of employer-based coverage due to affordability problems that would be determined based on a percentage of income. In addition, some commenters suggested exceptions when an eligible child has insurance that only provides limited coverage such as catastrophic coverage, hospital-only coverage, or scholastic coverage with very high deductibles, because these policies wouldn't allow access to preventive medical benefits.

Response: HCFA encourages States that impose waiting periods without group health coverage to consider adopting exceptions. Many States have adopted exceptions to the period of uninsurance based on a variety of factors. We have approved exceptions for reasons such as: loss of insurance due to involuntary job loss, death of a parent, change of employment where the new employer does not cover dependents; a family moved out of the service area of employer coverage; employer termination of insurance coverage for all employees; expiration of COBRA insurance benefits; end of employment-based insurance because an employee becomes self-employed; loss of insurance because of a long-term disability; termination of insurance due to economic hardship of the employer; when the family faces extreme economic hardship; and a substantial reduction in lifetime medical benefits to an employee and dependents in an employer-sponsored plan.

We have made several changes to the list of exceptions to the minimum period without coverage under a group health plan. States may allow for exceptions to the minimum period without coverage under a group health plan when the child's coverage is involuntarily terminated due to employer termination of coverage for all employees and dependents. We have added an exception for cases when there is a change in employment that does not offer dependent coverage.

In addition, States may provide an exception when the child's family faces economic hardship. While States have flexibility to define this term, examples of economic hardship could be families who are facing unusual economic difficulties, such as the loss of a home to fire, or high out-of-pocket costs due to a family member's illness not being covered by insurance. Another example would be if a State is targeting its premium assistance program to certain employers that provide only very limited health insurance coverage, a waiting period may not necessarily be required since the likelihood of substitution would be limited in those circumstances. Finally, we would consider an exception to the waiting period requirement if a State's proposal targeted low-wage employers in its premium assistance program, because substitution is much less likely when the coverage being subsidized is offered only by low-wage employers.

We anticipate that these reasonable exceptions will help facilitate States' ability to utilize premium assistance programs to enroll children in SCHIP.

Comment: One commenter noted that their State has had a Health Insurance Premium Payment (HIPP) program for Medicaid since July 1991. Under the HIPP program, the State pays the entire cost of the employee's share of the premium necessary to provide coverage to the Medicaid-eligible family members. Based on the State's experience with this program, they stated that they do not agree with our position that allowing States to assist families in the purchase of employer-related coverage will result in substitution of coverage. In fact, the commenter noted that as a condition of Medicaid eligibility, this State requires the family to maintain the insurance when it is cost-effective for the State to buy the coverage. This State argued that its policy supports the provision of premium assistance for employer coverage and avoids substitution because the State maintains the coverage for the family.

The commenter believed that HCFA's position actually promotes substitution of coverage by making it harder for States to buy-in to employer health plans when they become available and, thus, depriving the State of the opportunity to buy coverage that is more cost effective to the State.

The commenter was particularly concerned about our proposal because they have a strong HIPP program. It appears to the commenter that, if the State is purchasing employer coverage under the HIPP program for a Medicaid-eligible child, at the time the child transitions to their separate SCHIP program, the child has health insurance through an employer (although the State was paying for it), would result in the imposition of a 6-month waiting period before the child could be eligible for SCHIP and before the State could continue buying-in to the employer coverage. The commenter wanted the flexibility to maintain employer-sponsored coverage for children when they transition between Medicaid and the separate SCHIP program.

Response: We understand the commenter's concerns and acknowledge that substitution policies raise complex issues for which there are no clear answers. We have revised our policy in a number of ways to allow States greater flexibility to design premium assistance programs and we will continue to work with States as they evaluate how these programs are working and whether employer contributions are maintained. We note that in Medicaid, unlike SCHIP, having other health insurance coverage does not preclude eligibility for the program. With respect to the problem suggested by the commenter, we note that waiting periods do not apply when a child moves from a Medicaid program into a separate child health program because of an increase in family income, even if the Medicaid coverage was provided through an

employer-based plan such as the case with the HIPP program. In this case the child would be considered to have been covered by Medicaid, rather than by group health insurance coverage.

Comment: One commenter noted that if a family has to be uninsured for six months before the children can receive coverage through premium assistance for a group health plan, the family may miss the employer's open enrollment period while it waits to have access to premium assisted coverage.

Response: We note that the minimum waiting period requirement applies to the SCHIP-eligible child, not the entire family. Thus, for example, a parent could elect self-only coverage and decline dependent coverage, and enroll immediately in the employer-sponsored health insurance. Then, once the six-month waiting period had been satisfied, the parent could enroll the child(ren) at the next open enrollment period and obtain SCHIP premium assistance. States may cover SCHIP-eligible children in their regular SCHIP programs until such time as they can be enrolled in employer plans. Because § 457.810 gives effect to an important congressional purpose related to SCHIP coverage, we are maintaining the minimum waiting period in this circumstance. However, we suggest that States adopt rules, under the scope of their regulatory authority consistent with HIPAA, to require a special enrollment opportunity in group health plans based on a SCHIP-eligible individual or family becoming eligible to enroll in the plan under a premium assistance program.

Comment: One commenter suggested that the general provisions of proposed § 457.805, which say that ''The State plan must include a description of reasonable procedures to ensure that coverage provided under the plan does not substitute for coverage under group health plans . . . '' are sufficient and that proposed section § 457.810 (''Premium assistance programs: Required protections against substitution.'') should be deleted in order to allow States the flexibility to develop innovative approaches to utilizing employer-sponsored insurance coverage for SCHIP enrollees. The commenter indicated its belief that this approach would be in accord with Congress' intent that SCHIP programs be State-designed and State-operated, and that it would allow for the fact that private insurance markets and employer-sponsored health insurance patterns vary significantly from State to State. Proposed § 457.810 would make it very difficult for the implementation of employer-sponsored insurance under SCHIP.

Response: We understand the commenters concerns and have added some significant flexibility in this section of the final rule, as discussed above. We will work closely with States to develop premium assistance programs that fit their needs in the simplest and most operationally efficient way possible, while complying with the provisions of this final rule.

Comment: One commenter suggested that the language in § 457.810(a)(1) is poorly drafted and appears to imply that children uninsured more than 12 months would not be provided SCHIP coverage.

Response: We agree and have revised the language in § 457.810(a)(1) to clarify that a State, may not require a waiting period that exceeds 12 months.

H. Subpart I—Program Integrity

We proposed in subpart I to specify the provisions necessary to ensure the implementation of program integrity measures and enrollee protections within the State Children's Health Insurance Program. In addition, this subpart discussed the President's Consumer Bill of Rights and Responsibilities as it relates to the SCHIP program. This subpart also described how the intent of the GPRA can be upheld by including program integrity performance and measures as part of the State plans.

The grievance and appeal, and privacy-related issues addressed under this Subpart of the proposed regulation are now being addressed in the new Subpart K, Applicant and Enrollee Protections.

1. Basis, Scope, and Applicability (§ 457.900)

In § 457.900, we proposed under the authority of sections 2101(a) and 2107(e) of the Act to set forth fundamental program integrity requirements and options for the States. Section 2101(a) of the Act specifies that the purpose of the State Children's Health Insurance Program is to provide funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner. In addition, section 2107(e) of the Act lists specific sections of title XIX and title XI and provides that these sections apply to States under title XXI in the same manner they apply to a State under title XIX.

The program integrity provisions contained in this subpart only apply to separate child health programs. States that implement a Medicaid expansion program are subject to the Medicaid program integrity provisions set forth in the Medicaid regulations at part 455, Program Integrity: Medicaid.

Comment: One commenter suggested that HCFA meet with the Office of the Inspector General to discuss fraud and abuse issues related to outreach to look at the legality of encouraging certain outreach strategies. The commenter noted that payment from a particular provider to a person, who the provider knows or should know would be likely to influence the individual to receive services, is prohibited.

Response: We appreciate the concern of the commenter. We routinely coordinate with the OIG regarding the review of existing and proposed regulations in accordance with the Inspector General Act, section 4(a)(2).

Comment: One commenter recommended that the entire Subpart be revised to be consistent with the requirements in the Medicare program. The commenter urged HCFA to adopt detailed requirements for both fee-for-service and managed care claims and suggested extensive revisions to the proposed rules. The commenter felt the need for flexibility did not justify State-by-State variation with respect to the applicability or enforcement of the False Claims Act.

Response: We disagree with this comment. The Medicare program is nationally funded and administered, while Medicaid and SCHIP are jointly-funded Federal-State programs that are administered by the States within broad Federal guidelines. Therefore, it would be inappropriate and infeasible to require SCHIP and Medicaid programs to conform to fraud and abuse prevention standards of an entirely Federally funded and administered program. In addition, while we recognize the significance of the False Claims Act, standardized claims requirements are not necessary for the efficient and effective operation of the SCHIP program, or for enforcement of the False Claims Act.

Comment: One commenter felt that HCFA over-emphasized the issue of program integrity at this point in the implementation process. They suggest that the States' scarce resources and personnel would be better focused on outreach, eligibility and enrollment rather than program integrity and fraud. This commenter commended our emphasis on the need for continuity with other State programs. One commenter recommended deleting §§ 457.915, 457.920, 457.925, and 457.930 because the commenter felt that the proposed rule should not mandate State activities that are subject to the

administrative cap and that are not specifically required in the statute.

Response: While we appreciate the commenter's concern, we disagree with the commenter's argument that we over-emphasized program integrity too early in the implementation process. We agree that outreach, eligibility, and enrollment are all important aspects of SCHIP programs and deserve adequate resources for development and implementation. However, program integrity initiatives are also necessary now that States' programs have been established. Program integrity is essential to protecting the SCHIP program from abuse and to ensuring that the program serves those it was intended to serve, uninsured low-income children. Therefore, to protect public funds from inappropriate and unintended uses and to preserve the SCHIP program, States must have a strong fraud prevention and detection plan early in program development so that it will be in place as programs develop and mature, and serve as a viable deterrent to potential fraud and abuse.

Comment: One commenter requested clarification on the issue of limitations on provider taxes and donations as it applies to the provider contribution toward family cost-sharing requirements.

Response: The donation rules at section 1903(w) of the Act govern donations by providers or related entities directly to the State, or to extinguish a State liability. Premiums are a liability of the recipient. When donations are given to the recipient, or to the State on behalf of the recipient, the liability of the recipient is reduced, not the liability of the State. As a reasonable safeguard, the sponsor paying the premium on behalf of the enrollee should either give the donation directly to the family, make the donation to the State tied to specific eligible individuals, or make the donation to the State which will in turn, designate the specific eligible individual(s). In the latter case, the State must assure donations are assigned to enrollees in a manner that does not favor higher income children over lower income children. In any case, the donation should not exceed the premium amount specified in the approved title XXI State plan. The section of the State plan related to cost sharing should describe the procedure for accepting such donations.

In addition, we note that providers are prohibited from giving enrollees anything of value that is likely to induce an enrollee to select a particular provider under the provisions of section 1128A(a)(5). Such conduct may subject the provider to civil monetary penalties under that section. This civil money penalty provision is administered by the Office of the Inspector General (OIG). In general, States are advised to avoid donations from providers for enrollee premiums that could unduly influence enrollees to select a particular health plan or provider. A State that is concerned that donations for enrollee's premiums may violate these provisions may wish to seek an advisory opinion from the OIG. See 42 CFR part 1008. The OIG will also participate in review of State plans or amendments proposing such donations.

Comment: One commenter noted that the many requirements included in this Subpart tacitly assume that the State will have a direct, contractual relationship with all SCHIP participating health plans, including premium assistance plans. However, they stated that, for premium assistance programs for group health coverage, no such contractual mechanism will exist. The employer, not the State, is the entity that contracts with the health plan; and the State is simply providing premium assistance to enable families to enroll their children in premium assistance programs, according to this commenter. Because there is no mechanism for enforcement here, the commenter stated that they are assuming that the requirements in this Subpart would not apply to employer plans. They suggested that the preamble should clarify this point. They cautioned that any attempt to apply requirements of this sort to employer plans will mean that no employer plans will ever qualify for premium assistance.

Response: While we have considered the commenter's concerns, States are responsible for the oversight of the use of public funds to provide child health assistance through premium assistance programs just as they are responsible for oversight in other types of children's health insurance programs. Consequently, it is not appropriate to make an exception from program integrity regulations for employer plans. In the case where the State has no direct contractual relationship with the entity providing health coverage, the State should utilize the fraud protections provided through the State insurance agency responsible for oversight of all commercial plans. For example, if State funds are provided under SCHIP to State-regulated health plans, the State insurance department anti-fraud component could conduct the State's anti-fraud oversight for its SCHIP funds. This final regulation provides flexibility to States for States to develop program integrity methods and systems that fit the needs of their particular SCHIP programs, whether or not those programs consist of premium assistance for group health plans.

2. Definitions (§ 457.902)

We proposed five definitions for the purpose of this subpart. We proposed that ''contractor'' means any individual or entity that enters into a contract, or a subcontract, to provide, arrange, or pay for services under title XXI. This definition includes, but is not limited to, managed care organizations, prepaid health plans, primary care case managers, and fee-for-service providers and insurers.

We proposed that a ''managed care entity'' is any entity that enters into a contract to provide services in a managed care delivery system, including, but not limited to managed care organizations, prepaid health plans, and primary care case managers. We proposed that ''fee-for-service entity'' means any entity that provides services on a fee-for-service basis, including health insurance services. We proposed that ''State program integrity unit'' means a part of an organization designated by the State (at its option) to conduct program integrity activities for separate child health programs.

Finally, we proposed to define the term ''grievance'' as a written communication, submitted by or on behalf of an enrollee in a child health program, expressing dissatisfaction with any aspect of a State, a managed care or fee-for-service entity, or a provider's operations, activities, or behavior that pertains to specified areas, including the availability, delivery or quality of health care services, payment for health care services and other specified areas. The grievance and appeal, and privacy-related issues addressed under this Subpart of the proposed regulation are now being addressed in the new Subpart K, Enrollee Protections.

Comment: A few commenters suggested that the definitions of ''fee-for-service entity'' and ''contractor'' raised a potential inconsistency in that the term ''fee-for-service entity'' does not include ''individual or entity'' as ''contractor'' does. This suggests that individual physicians or other practitioners are exempted from the requirement at § 457.950 to attest that any claims submitted for payment to be accurate, complete and truthful. The commenters noted that these practitioners are currently required to make this certification under Medicare and Medicaid.

Response: We agree with the comment and have modified the regulation text accordingly. We note again that we have created a new subpart intended to address more specifically the issues related to enrollee protections and because the term ''contractor'' will now apply to both this subpart and the new subpart K, we have moved the definition to § 457.10.

3. State Program Administration (§ 457.910)

In § 457.910 we proposed that the State child health plan must provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the separate child health program. We also proposed that the State's program must provide the safeguards necessary to ensure that eligibility will be determined appropriately in accordance with Subpart C of this regulation, and that services will be provided in a manner consistent with administrative simplification and with the provisions of Subpart D—Coverage and Benefits.

Comment: One commenter noted that the preamble language states that the Secretary wishes to give States ''maximum flexibility'' in the administration of their SCHIP programs. However, the commenter felt that the literal interpretation of this language translated into ''methods of administration that the Secretary finds necessary,'' giving the Secretary too much discretion to impose methods of administration on States.

Response: We understand the commenter's concerns. The commenter is correct that the Secretary has a great deal of discretion over the requirements of the SCHIP program. We remain committed to providing States with flexibility in the administration of their SCHIP programs but, as stated in the preamble to the proposed regulation, we seek to balance this need against the Federal government's need to remain accountable for the integrity of the program. The provisions of the regulation reflect this balance and the basic framework within the regulation is necessary to ensure the integrity of SCHIP. However, this framework does not dictate to the States what methods of administration they must use to prevent and detect fraud and abuse, thereby leaving the States with significant flexibility to administer SCHIP programs.

Comment: One commenter encouraged HCFA to ensure administrative simplification, not only in the operation of the program, but in the provision of services and with respect to providers.

Response: HCFA is committed to policy approaches that minimize the administrative burden that is placed on States in implementing their SCHIP programs in general. In addition, we are mindful of the need to strike a balance between ensuring access to SCHIP coverage, and the benefits provided under that coverage, without making it unduly burdensome for States to accomplish these goals. However, these rules address State requirements and are not intended to address State relationships with providers, which are a contractual matter between the State and providers.

4. Fraud Detection and Investigation (§ 457.915)

Section 2107(e) references sections 1903(i)(2) and 1128A of the Act, which provides a basis for certain fraud detection and investigation activities. Section 2107(e) states that these provisions apply under title XXI in the same manner as they apply to a State under title XIX. Moreover, these provisions are cited as authority in the Medicaid regulations at part 455, Subpart A—-Medicaid Agency Fraud Detection and Integrity Program. In the proposed rule, we discussed in detail three possible options we considered to ensure that separate child health programs develop and implement adequate fraud detection and investigation processes and procedures. We concluded that the best approach would be to require States to address, specifically, the Medicaid goals for fraud detection and investigation, but to allow States to design specific procedures needed to meet the requirements of § 455.13. We chose neither to require States with separate child health programs to follow the same procedures for fraud detection and investigation as the Medicaid program, nor did we provide States with full latitude in designing processes and procedures. We stated that this approach balances the need for maintaining State flexibility while establishing an acceptable minimum standard that will satisfy our need for accountability in the program.

We proposed that the State must establish procedures for assuring program integrity and detecting fraudulent or abusive activity. We also proposed that the procedures must include, at a minimum, the methods and criteria for identifying suspected fraud and abuse cases as well as methods for investigating fraud and abuse cases that do not infringe on the legal rights of persons involved and afford due process of law. The State may establish an administrative agency responsible for monitoring and maintaining the integrity of the separate child health program, which is referred to in subsequent provisions of the regulation as the ''State program integrity unit''. We further proposed that the State must develop and implement procedures for referring suspected fraud and abuse cases to the State program integrity unit (if such a unit is established) and to law enforcement officials. Law enforcement officials include, but are not limited to, the Department of Health and Human Services Office of Inspector General (OIG), the Department of Justice (DOJ), the Federal Bureau of Investigation (FBI), and the State Attorney General's office.

Comment: One commenter commended HCFA for recognizing that separate child health programs should not be expected to have the same fraud detection and infrastructure as required under Medicaid. However, the commenter felt that by tying goals to Medicaid fraud and abuse goals, as well as recommending the use of the State program integrity unit, HCFA was pushing the States toward Medicaid procedures without backing them up with sufficient funding levels.

Response: While we understand the commenter's concern, we specifically set out in the proposed rule a framework that attempted to provide flexibility to the States, while ensuring that States include basic, necessary protections against fraud. We are not requiring States to establish State program integrity units or to use Medicaid fraud and abuse methods or procedures to ensure the integrity of the SCHIP program. We invite States to design program integrity plans and procedures that are specific to the needs of their unique SCHIP programs within the broad framework required by the final rule. The flexibility afforded the States in this regulation allows them to structure program integrity activities that limit the administrative burden, but still ensure the integrity of the program.

Comment: One commenter found the rules overly prescriptive and recommended the elimination of paragraph (b) that describes the ''State program integrity unit'' and the deletion of the requirement to refer program integrity cases to law enforcement officials in (c).

Response: The rule encourages, but does not require, States to develop or use an entity that could be called a ''State program integrity unit''. This concept was developed in an attempt to give the States a framework to set up an effective program integrity strategy. While not required, we believe the

development of such a unit would be very beneficial to the States in designing systems to address these issues. In addition, because of Medicaid statutory provisions, States are not permitted to use existing Medicaid fraud control units (MFCUs) to conduct SCHIP program integrity activities. (While MFCUs have been given additional flexibility under the Ticket to Work Incentives Improvement Act of 1999, this flexibility only applies in cases that primarily involve Medicaid funds.) In general, States are limited to using Medicaid funds for Medicaid activities. If a State wanted to utilize the MFCU, it could only do so by hiring new staff that would be exclusively responsible for SCHIP program integrity activities and are funded by title XXI funds. (We note that this new, separately funded ''branch'' of the MFCU could be called the ''State program integrity unit''.) Therefore, we will not eliminate § 457.915(b). Finally, the inclusion of, and coordination with, appropriate Federal and State law enforcement officials as part of a State's overall fraud detection efforts, and overall program integrity efforts, is vital to the effectiveness of its program integrity activities. Therefore, we will not eliminate § 457.915(c).

Comment: Several commenters noted that they appreciated the need for fraud and abuse protections, and hoped HCFA was allowing flexibility for States to utilize provider fraud detection processes of participating health plans or other State insurance department procedures. Also, these commenters hoped that States would be given sufficient time to implement these procedures.

Response: These final rules provide a structure under which States have the flexibility to use a variety of methods to create a comprehensive fraud detection strategy. While we envision that the State insurance departments may play an important role for a State in SCHIP fraud and abuse detection and investigation, we anticipate that States may want to complement those procedures already performed by the State insurance departments with procedures and goals specific to SCHIP. Specifically, fraud and abuse stemming from procedures for, or other aspects of, participant enrollment in the separate child health program would raise distinct issues that likely fall outside of procedures established by State departments of insurance as they monitor private health plans and issuers outside of the SCHIP context. States must also address the concern that fraud and abuse may occur within a participating health plan apart from provider fraud and therefore, States must have additional procedures to detect and investigate fraud within plans. Therefore, relying on plans' processes to monitor provider fraud, while potentially useful, would not sufficiently protect against the varied types of fraud and abuse that could impact the SCHIP program in a State.

We note the commenters' concern that States need a reasonable amount of time to implement new Federal requirements. We will require that States come into conformity with new requirements within 90 days of publication of this rule, or if contract changes are necessary, the beginning of the next contract cycle. In limited cases where a new regulatory provision requires a description of procedures in the State plan, then the State must implement the procedures within the above time frame and submit the State plan amendment in compliance with § 457.65(a)(2).

Comment: One commenter noted that precise, professional guidelines regarding care issues, industry-accepted standards for fair and reasonable audits, and investigations with due process protections for providers, are essential to expand access under SCHIP.

Response: The best means of expanding access to care under SCHIP is to allow the States sufficient flexibility in designing program integrity procedures and methods as well as other aspects of their programs while maintaining a framework of Federal requirements consistent with title XXI. We encourage States to develop precise, professional guidelines as part of the design of State fraud detection and investigation methods. In addition, States should refer to industry standards in establishing audit processes as appropriate. Section 467.915(a) specifies that States must establish procedures for investigating fraud and abuse cases that do not infringe on legal rights of persons involved and afford due process of law. These requirements apply to investigations of all types of fraud and abuse under the separate child health program, including investigations that involve providers.

Comment: One commenter recommended that the language in this section be expanded to include use of procedures already in place that support these activities. In addition, they suggested revising § 457.915(c) to clarify that suspected fraud and abuse cases should be referred to ''appropriate'' law enforcement officials as determined by State law.

Response: We have revised the regulation text at § 457.915 to clarify that States must develop and implement procedures for referring suspected fraud and abuse cases to appropriate law enforcement officials, although we have not included the commenters' recommended language ''as determined by State law'' because referrals could be made to Federal law enforcement officials, as appropriate. We have listed certain law enforcement officials under § 457.915(c) because States may wish to contact these officials with fraud and abuse information to facilitate program coordination. This is not intended to be an exhaustive list of all law enforcement officials States may contact, nor is referral to all these entities required, unless it is appropriate.

5. Accessible Means To Report Fraud and Abuse (§ 457.920)

We proposed that States with separate child health programs must establish, and provide access to, a mechanism of communication between the State and the public about potentially fraudulent and abusive practices by and among participating contractors, beneficiaries, and other entities. We noted in the preamble to the proposed regulation that this communication mechanism may include a toll-free telephone number, and also noted that States are free to use their discretion regarding whether to establish toll-free services for these purposes alone or to expand upon existing services. We noted that access to toll-free service for the reporting of potentially fraudulent and abusive practices is a integral part of any sound program integrity strategy.

Comment: One commenter recommended that this provision be deleted because the rule should not mandate State activities that are subject to the administrative cap and are not specifically required by the statute.

Response: We acknowledge the commenters' point and agree that this section should be deleted. However, we have deleted this section because while we do have statutory authority to include such a provision, the provision was unnecessary and somewhat redundant.

6. Preliminary Investigation (§ 457.925)

We proposed that if the State receives a complaint of fraud or abuse from any source, or identifies any questionable practices, the State agency must conduct a preliminary investigation or take otherwise appropriate action to determine whether there is sufficient basis to warrant a full investigation. We noted in the preamble, consistent with § 457.915(b), that the State has the option of creating a ''State program integrity unit'' for separate child health

programs that would be responsible for monitoring and maintaining the integrity of the separate child health program. We also noted that each State has flexibility to define the role played by such units but that fraud and abuse activities relating to SCHIP must be funded with monies from the State's SCHIP allotment. Finally, while we proposed that preliminary investigations be conducted under the circumstances specified in § 457.925, we remained flexible with regard to the processes and procedures that separate child health programs employ in conducting preliminary investigations and did not require or specify the procedures States must take to conduct their investigation in compliance with this requirement.

Comment: One commenter recommended that this provision be deleted because the rule should not mandate State activities that are subject to the administrative cap and are not specifically required by the statute.

Response: We disagree that this section should be deleted. As noted earlier, we maintain that these program integrity activities are necessary for the effective and efficient administration of the State plan as required in § 2101(c)(2) of the statute, in addition to being based on the sound precedents set by the Medicare and Medicaid programs.

Comment: One commenter recommended that HCFA specify that States must undertake a preliminary investigation within a reasonable time not to exceed 60 days.

Response: We agree with the commenter's suggestion that a State must undertake a preliminary investigation within a certain amount of time. We have not prescribed a specific number of days, but suggest that 60 days is indeed a reasonable amount of time to undertake a preliminary investigation. We have made the appropriate change to the regulation text.

7. Full Investigation, Resolution, and Reporting Requirements (§ 457.930)

We proposed that the State must establish and implement effective procedures for investigating and resolving suspected and apparent instances of fraud and abuse. We further proposed that, once the State determines that a full investigation is warranted, the State must implement certain procedures, including, but not limited to, the procedures specified at paragraphs (a) through (c) of § 457.930.

We noted in the preamble to the proposed rule that States may model their approaches after procedures for fraud and abuse investigation, resolution, and reporting used by the Medicaid State agency as outlined in §§ 455.15, 455.16, and 455.17 of the Medicaid regulations. Medicaid funding cannot be used for fraud investigation activities in separate child health programs. MFCUs may only use Medicaid funding for fraud and abuse activities in States that provide child health assistance under a Medicaid expansion program. MFCU professional staff being paid with Medicaid dollars must be full-time employees of the Medicaid fraud agency and devote their efforts exclusively to Medicaid fraud activities. To the extent that States want to allocate additional non-MFCU full-time staff, using SCHIP dollars, to work exclusively on fraud and abuse investigation in separate child health programs, they may do so. We noted that expenditures for this purpose would be subject to the 10 percent cap on administrative costs under section 2105(c)(2) of the Act.

Comment: One commenter suggested that a better alternative to traditional law enforcement would be to work through the provider fraud processes established by participating health plans, under which the expenditures might be considered a benefit cost rather than an administrative cost.

Response: While we intended to provide flexibility in implementing program integrity strategies, as noted in response to a comment on § 457.915, States must be aware that fraud and abuse may stem from within a participating health plan or apart from providers. Therefore, States must have procedures at the State level to detect and investigate plan and issuer fraud and abuse, as well as provider fraud and abuse. Relying on plan and issuers to monitor themselves for fraud and abuse would not be in the public interest.

It is true that capitated payments made to plans in conjunction with the provision of health benefits coverage that meets the requirements of title XXI and for which the plan is at risk are not considered administrative costs. Therefore, plan activities covered by these payments are considered as expenditures for child health assistance. However, health plan processes for the detection, investigation and resolution of fraud and abuse, and that protecting program integrity is not the only concern States must consider in designing their program integrity strategies. They must design strategies that accomplish the goals of, and comply with the requirements of, this subpart, thereby protecting against a range of potential fraud and abuse concerns, such as, but not limited to, any potentially problematic health plan activity.

Comment: Several commenters recommended that HCFA allow States the authority to enter into agreements with other investigative bodies, not strictly law enforcement officials, and not necessarily a State-established program integrity unit; rather, they recommended that States be able to contract with bodies such as health plan investigative divisions. To this aim, commenters recommended paragraph (c) be rewritten to include referring the fraud and abuse case to an appropriate investigative body as designated by the State.

Response: We agree that States should be able to structure their fraud and abuse activities in different ways; however, the inclusion of coordination with any law enforcement officials is an integral part of an effective program integrity process. We have modified the regulation text to clarify that State should be able to determine the appropriate law enforcement officials to whom they should refer suspected fraud and abuse cases but we do not agree with the recommendation that States should not have to coordinate with any law enforcement officials. We reserve the right to review the States' program integrity procedures to ensure their compliance with the requirements and goals of title XXI and this regulation.

Comment: One commenter believed that it is unreasonable to judge States' applications or amendments based on consistency of their fraud and abuse procedures with other State programs.

Response: States are required to design and implement procedures for fraud investigation, resolution, and reporting. States are not required to file State plan amendments with HCFA in order to implement a program integrity fraud and abuse detection and investigation strategy. Therefore, HCFA will consider State's statement assuring the development and implementation of a program integrity system to be a requirement that is subject to review through HCFA's ongoing monitoring.

Comment: We received a few comments noting that requiring States with separate child health programs to set up separate structures other than Medicaid Fraud Control Units to do the same function is a waste of resources, and that requiring separate processes is burdensome and costly. One commenter recommended that States have the option to allow the MFCU to conduct SCHIP fraud investigations, assuming tracking and claiming are conducted appropriately. Another commenter recommended deleting the provision because the rule should not mandate

State activities that are subject to the administrative cap and are not specifically required by the statute.

Response: As noted above, the Medicaid statute does not permit MFCUs to conduct program integrity activities that are not related to the Medicaid program. We disagree that this section should be deleted. We maintain that program integrity activities are necessary for the effective and efficient administration of the State plan as required in section 2101(c)(2) of the statute, in addition to being based on the sound precedents set by the Medicare and Medicaid programs. While we recognize that some of these activities could be duplicative, we do not have the authority to blend the funding for fraud and abuse prevention efforts among the Medicaid and SCHIP programs.

Comment: One commenter suggested that States must have *written* procedures for investigating and resolving suspected and apparent instances of fraud and abuse.

Response: We agree that States should have written procedures for investigating and resolving suspected and apparent instances of fraud and abuse to ensure the effective and efficient administration of SCHIP programs. However, we are not requiring that States submit to HCFA such written procedures. We anticipate that States may continue to develop and to modify fraud investigation and detection procedures as SCHIP programs develop. Therefore, we anticipate the methods and rules relating to program integrity will evolve as they are implemented. We wish to give the States the flexibility to improve fraud and abuse detection systems as they develop, rather than tying States to an initial written plan. However, HCFA reserves the right to review a States' program integrity procedures, and to request that they be described in writing, as part of its ongoing monitoring.

8. Sanctions and Related Penalties (§ 457.935)

Under the authority of sections 2101(a) and 2107(e) of the Act, and consistent with the requirements under Federal and State health care programs, we proposed that a State may not make payments for any item or service furnished, ordered, or prescribed under a separate child health program to any contractor who has been excluded from participating in the Medicare and Medicaid programs. We noted that this provision is necessary to implement section 1128 of the Act regarding exclusion of certain individuals and entities from participation in Medicare and State-administered health care programs. We proposed that the separate child health programs be subject to program integrity provisions set forth in the Act including: (1) Section 1124 relating to disclosure of ownership and related information; (2) section 1126 relating to disclosure of information about certain convicted individuals; (3) section 1128A relating to civil monetary penalties; and (4) section 1128B(d) relating to criminal penalties for acts involving Federal health programs. We also proposed to make separate child health programs subject to Part 455, subpart B of chapter IV of title 42 of the Code of Federal Regulations. In an effort to promote enforcement of this subsection and to provide HCFA and the Secretary with critical fraud and abuse data, we also proposed that the separate child health programs be subject to the requirements of section 1128E of the Act in the same manner as under the Medicare and Medicaid programs. In accordance with section 1128E of the Act, we proposed that the separate child health program be subject to the requirements pertaining to the reporting of final adverse actions on liability findings made against health care providers, suppliers, and practitioners. In addition, we noted in preamble that States should share such information and data with the Office of the Inspector General in an effort to promote enforcement.

We did not receive any comments on this section and will therefore implement the regulation language as proposed.

9. Procurement Standards (§ 457.940)

Section 2101(a) of the Act requires that States provide services in an effective and efficient manner. In order to meet our obligation to ensure that States use SCHIP funds in a cost-effective manner, we set forth provisions at proposed § 457.940 regarding procurement standards. The proposed provisions did not include Federal oversight of provider payments. Rather, we proposed to require that States set rates in a manner that most efficiently utilize limited SCHIP funds.

We proposed to require that States provide HCFA with a written assurance that title XXI services will be provided in an effective and efficient manner. We also proposed that the assurance must be submitted with the initial SCHIP plan or, for States with approved SCHIP plans, with the first request to amend the SCHIP plan submitted to HCFA following the effective date of these regulations.

If States contract with entities for SCHIP services, they must provide for free and open competition, to the maximum extent possible, in the bidding of all contracts for coverage or other title XXI services in accordance with the procurement requirements of 45 CFR 74.43.

Alternatively, we proposed that States may base title XXI payment rates on public or private payment rates for comparable services. We noted in preamble that this applies to fee-for-service and capitated rates. We proposed that, if a State finds it necessary to establish higher rates than would be established using either of the above methods, it may do so if those rates are necessary to ensure sufficient provider participation or to enroll providers who demonstrate exceptional efficiency or quality in the provision of services. For example, this method will allow States the flexibility to establish higher rates to attract providers in under-served areas or to enroll more costly specialty providers.

We also proposed that States must provide to HCFA, if requested, a description of the manner in which they develop SCHIP payment rates in accordance with the requirements of §§ 457.940(b)(2) and (c). The description would include an assurance that the rates were competitively bid or an explanation of the applicability of the exceptions of 45 CFR part 74, or a description of the public or private rates that were used to set the SCHIP rates, if applicable, and/or an explanation of why rates higher than those that would be established using either of these two methods are necessary. HCFA may request the description when a State first determines its rates or, for approved SCHIP plans, when it updates its rates or changes its reimbursement methodology.

Comment: We received several comments recommending with regard to § 457.940(b)(1) that procurement standards in 45 CFR part 92 are more appropriate for non-entitlement programs such as SCHIP because they allow States to utilize their own procurement standards when purchasing services with Federal grant money. Flexibility will enable States to make cost-effective and quality health plan selections. One commenter noted that flexibility to establish higher rates to ensure provider participation should be coupled with stricter enforcement.

Response: We disagree with the commenter's suggestion for changing the procurement standards applicable to SCHIP. We believe the procurement requirements of 45 CFR 74.43 are more appropriate for separate child health

programs because they allow for accountability as well as State flexibility in implementation. We expect all States, not just those establishing higher rates to ensure provider participation or for other permitted purposes, to strictly enforce the procurement standards of this section.

Comment: Several commenters requested that § 457.940(b)(2) be rewritten as follows: ''Basing title XXI payment rates on public and/or private payment rates for comparable services for comparable populations.'' Several commenters felt this section should be expanded to allow States, where such comparisons cannot be made for lack of data, the ability to explain their analysis of why the rates are within acceptable parameters.

Response: We acknowledge the distinctions in rates that may need to be made based on the populations being served and have added ''for comparable populations'' to the regulation text as recommended. However, we disagree with the suggestion to change the regulation to allow States to explain why the payment rates are within acceptable parameters absent sufficient supporting data. The final regulation text includes a significant amount of flexibility for States to explain how they meet the standards of § 457.940(c) regarding the need for higher rates than otherwise permitted and received many comments recognizing its flexibility. We have retained the proposed language in § 457.940(c) regarding acceptable bases for such higher rates because we believe rates should only be permitted to be higher under those specific circumstances.

Comment: One commenter supported the intent of the section and noted the importance of setting adequate reimbursement levels to ensure provider participation and efficient provision of services. The commenter found it problematic that about half of the States set payment rates for separate child health programs at the same levels as they do for Medicaid. The commenter encouraged HCFA to work with States to establish more reasonable rates.

Response: Each State has the authority to set reasonable rates for its SCHIP population providers. It would be inappropriate for us to dictate to the States what specific rates they should pay to participating providers, especially in those States that have a sufficient number of providers to furnish quality care to all SCHIP participants. However, in accordance with § 457.495, we encourage States to set rates and generally administer their SCHIP programs in a way that will provide access to providers and attract an adequate number of highly qualified, experienced providers with the appropriate range of specialties and expertise.

Comment: One commenter suggested that HCFA incorporate a standard that the SCHIP rates for MCEs be actuarially sound and that we should clarify the meaning of actuarial soundness in the managed care context. In addition, another commenter suggested that HCFA require States to justify or prove the methodology used to establish the payment rate.

Response: We agree with the comment that rates should be actuarially sound. Actuarially sound capitation rates means that they have been developed in accordance with generally accepted actuarial principles and practices, that are appropriate for the populations and services to be covered under the contract, and that have been certified by an actuary (or actuaries) meeting the qualification standards established by the Actuarial Standards Board. The text of the regulation at § 457.940(b)(3) has been changed to reflect this and a definition is included at § 457.902—Definitions.

Comment: One commenter supported giving States maximum flexibility to take advantage of local market forces in establishing SCHIP payment rates. In this commenter's view, States should provide reimbursement for obstetric and gynecologic services sufficient to assure that SCHIP enrollees have access equal to that of privately insured patients. This commenter also noted that providing these types of services to adolescents is often quite time consuming due to the various developmental and psycho social issues they face, and recommended that compensation for physicians should be determined accordingly.

Response: We appreciate support for the policy of giving States flexibility in their procurement and rate setting. However, it is important for States to set rates high enough to provide sufficient access to, and quality of, care for all SCHIP participants for all services. However, it is not appropriate to specify the need for enhanced payment rates for certain types of providers or services in regulation. The requirement that States provide for free and open competition in procurement or demonstrate that their rates meet the requirements of (b) or (c) should ensure that SCHIP enrollees have access to providers that are compensated appropriately within their local health care markets.

Comment: We received one comment recommending that § 457.940(a) include a specific reference that States must comply with all applicable civil rights requirements in accordance with § 457.130.

Response: Section 457.130, contained in subpart A (which is the subpart that sets forth many general State plan requirements), requires States to include in their State plan an assurance that the State will administer their SCHIP program in compliance with applicable civil rights requirements. We maintain that this provision sufficiently assures this compliance.

10. Certification for Contracts and Proposals (§ 457.945)

In addition to the proposed requirements in § 457.950, which specify that contractors must certify that payment data is accurate, truthful, and complete, we proposed to specify in § 457.945 that entities that contract with the State under a separate child health program must also certify the accuracy, completeness, and truthfulness of information in contracts, and proposals, including information on subcontractors, and other related documents, as specified by the State.

Comment: One commenter asserted that the requirements in this section are overly burdensome for States. Because so many of the SCHIP programs utilize managed care delivery systems, the commenter noted that managed care entities are required, by virtue of executing their contracts with the States, to provide accurate, complete and truthful information. The commenter felt that a separate and distinct certification document is unnecessary.

Response: While we appreciate the administrative challenges States may face in implementing SCHIP programs, we do not believe the requirements of this section are overly burdensome for States. The unique nature of the SCHIP program and its relationship with plans and issuers merits the inclusion in contracts of the specific certifications required by this section, and that compliance with this standard will protect against fraud and abuse in this government-funded program. The commenter may have interpreted this provision to require a separate certification document but, in fact, the required certification could be provided as part of, or together with, any of the contracts or related documents into which the State and its contractors have entered, and should entail minimal additional administrative effort.

11. Contract and Payment Requirements Including Certification of Data that Determines Payment (§ 457.950)

At § 457.950, we proposed that when SCHIP payments to managed care

entities are based on data submitted by the MCE, the State must ensure that its contracts with MCEs require the MCE to provide enrollment information and other information required by the State. We also proposed that the State ensure that its contract requires the MCE to attest to the accuracy, completeness, and truthfulness of claims and payment data, upon penalty of perjury. As a condition of participation in the separate child health program, MCEs must provide the State with access to enrollee health claims data and payment data, as determined by the State and in conformance with the appropriate privacy protections in the State. We also proposed that managed care contracts must include a guarantee that the MCE will not avoid costs for services, such as immunizations, covered in its contract by referring individuals to publicly supported health care resources (for example, clinics that are funded by grants provided under section 317 of the Public Health Service Act).

We proposed that when SCHIP payments are made to fee-for-service entities, the State must establish procedures to ensure and attest that information on provider claim forms is truthful, accurate, and complete. We also proposed that, as condition of participation in the State plan, fee-for-service entities must provide the State with access to enrollee health claims data and payment data, as determined necessary by the State.

Comment: One commenter agreed that agents of the State need access to payment information and that payment decisions must not be made without proper information and involvement of providers.

Response: We appreciate support for the requirements in § 457.950 regarding State access to claims and payment data. As noted in the preamble, compliance with § 457.950(b)(2) requires States to establish procedures to ensure and attest to the accuracy of information on provider claim forms. The State thereby must involve the provider community to the extent necessary to comply with this requirement and the rest of § 457.950, as noted in the comments.

Comment: One commenter recommended amending this section to include a requirement to comply with applicable civil rights requirements in accordance with § 457.130.

Response: Section 457.130 requires States to administer the entire SCHIP program in compliance with the Civil Rights requirements noted in the title XXI statute and we maintain that this provision sufficiently assures compliance.

Comment: One commenter noted that the wording of this section is confusing. The commenter noted that because some States may make prospective monthly payments to MCEs on the first day of each month, the MCE may not have any information other than the enrollment forms from the State itself. These States may be unclear as to whether or not this section applies to their programs.

We also received a few requests that the requirement to attest to the accuracy and completeness of the data reflect that, to the extent that data is based on projections (e.g. premium rate submissions) that plans be permitted to attest to the accuracy to the best of their knowledge, information and belief. Another commenter requested deletion of the phrase ''under penalty of perjury'' from paragraph (a) because the requirements are already enforced through contractual language and penalties. Also, commenters requested clarification that complete data refers to data that includes all elements required by the State.

Response: One of the fundamental tenets of program integrity is the need for certification of payment-related information. Prospective monthly payments are based on certified payment-related information despite the fact that they are developed retrospective of the services delivered. The submission of enrollment forms does not constitute payment-related information.

While we recognize that the clause ''under penalty of perjury'' at § 457.950(a) may not have been appropriate for the entire paragraph, the Office of the Inspector General representatives indicated that it was an essential protection. Therefore, we have deleted ''under penalty of perjury'' from the general language of § 457.950(a), but left it in § 457.950(a)(2).

12. Conditions Necessary to Contract as a Managed Care Entity (MCE) (§ 457.955)

In addition to implementing program integrity protections at the State level, we proposed under § 457.955 that the State must ensure that MCEs have in place fraud and abuse detection and prevention processes. These processes would include mechanisms for the reporting of information to appropriate State and Federal agencies on any unlawful practices by subcontractors of or enrollees in MCEs. In order to maintain privacy protections for enrollees, we proposed that the reporting of information on enrollees would be limited only to information on violations of law pertaining to actual enrollment in the plan or to, provision of, or payment for, health services. Furthermore, we proposed that the State maintains the authority and the ability to inspect, evaluate and audit MCEs, as determined necessary by the State in instances where the State determines that there is a reasonable possibility of fraudulent or abusive activity.

We noted in the preamble that States that have Medicaid expansion programs and contract with MCEs under section 1903(m) of the Act may arrange for an annual independent, external review of the quality of services (EQR) delivered by each MCE as provided for under section 1932(c)(2) of the Act. States are permitted to draw down 75 percent FFP for this activity. States with separate child health programs are encouraged to provide for EQR of each MCE under contract to provide services to SCHIP enrollees; however, expenditures for EQR would be subject to the 10 percent limit for administrative expenses under section 2105(c)(2) of the Act.

Comment: Several commenters suggested that separate SCHIP programs should not be required or encouraged (as in the preamble) to use the Medicaid external quality review of services and that there is inequity in that Medicaid expansion programs receive 75 percent FMAP for this activity while stand-alone programs are required to stay within the 10 percent limit on administrative expenditures.

Response: While the Medicaid EQR process is a good model for States implementing separate child health programs, we are not requiring the use of this process in the regulation text, therefore States have flexibility in determining the type of quality assurance processes they utilize. Thus, States retain discretion in the use of funds for administrative expenditures and how to stay within statutory limits on such expenditures.

Comment: One commenter recommended that HCFA clarify what action by MCEs are necessary to meet the requirement that MCEs contracting under a separate child health plans have administrative and management arrangements or procedures to safeguard against fraud and abuse. The commenter asked how this requirement differ from the M+C program requirement that each M+C organization have a compliance plan. This commenter also recommended that our guidance convey that the reporting requirement in this section should only apply after the completion of a reasonable inquiry and a finding of credible evidence that a violation has occurred.

Response: We did not attempt to make the provisions of this subpart consistent

with the M+C rule. As noted previously, the Medicare program is nationally-funded and administered; while Medicaid and SCHIP are funded by a combination of State and Federal funds.

We have, however, added a provision at § 457.955(b)(2) to specify that States must ensure arrangements that prohibit MCE's from conducting any unsolicited contact with a potential enrollee for the purpose of influencing an individual to enroll in the plan. This provision is added in order to prevent past abuses in which potential enrollees were influenced to join an MCE without the benefit of adequate information and education about their options in choosing an MCE and is consistent with similar provisions in Medicaid managed care, and Medicare+Choice.

Comment: We received one comment recommending that as a condition of qualification as an MCE contractor, the MCE must allow the States to inspect and audit MCEs at any time, when there is a reasonable possibility of fraud and abuse. This condition should also apply to any provider under contract to provide SCHIP services, according to this commenter.

Response: Section 457.955(d) of the NPRM states that ''the State may inspect, evaluate, and audit MCE's at any time, as necessary, in instances where the State determines that there is a reasonable possibility of fraudulent and abusive activity.'' The regulation places the burden on the State to make sure that its contracts or arrangements with MCEs allow the State to comply with this section.

13. Reporting Changes in Eligibility and Redetermining Eligibility (§ 457.960)

We proposed in this section that States choosing to require that enrollees, or their representative, report changes in their circumstances during an eligibility period, the State must: (1) establish procedures to ensure that beneficiaries make timely and accurate reports of any changes in circumstances that may affect eligibility; and (2) promptly redetermine eligibility when it receives information about changes in a child's circumstances that may affect his or her eligibility.

Comment: One commenter noted that at redetermination, a child enrolled in a separate child health plan who becomes eligible for Medicaid should have a reasonable opportunity to apply and be found eligible for Medicaid without a break in coverage. The rules should specify that the child might remain enrolled in the separate child health program for up to 45 days (or longer if cause exists) while the Medicaid application is being processed in accordance with § 457.360. In addition, the rules should specify that prior to any termination of SCHIP coverage, the State should screen for potential Medicaid eligibility and facilitate enrollment.

Response: We agree with the goal of providing seamless coverage to all children eligible for Medicaid or SCHIP. See subpart C for requirements regarding screening and enrollment. These requirements apply to both eligibility determinations and redeterminations as specified at § 457.350(a).

Comment: One commenter recommended that HCFA provide guidance regarding how the redetermination process should be conducted. States should not be permitted to request a re-application or require that enrollees provide information that is not needed to complete the eligibility determination. States should also be required to give the enrollee adequate time to respond to requests for additional information. States must also be required to describe in the State plan how the child will be enrolled in Medicaid without a break in coverage.

Response: We recognize the concerns of the commenter, however, the NPRM balances the need for maintaining State flexibility while establishing an acceptable standard that will satisfy our need for accountability in the program. It would be inappropriate for us to dictate methods of redetermination or a specific redetermination process that all States must use. Rather, we are concerned that States have a redetermination process because SCHIP programs are best served by leaving the specifics of the process to each State.

14. Documentation (§ 457.965)

To ensure the integrity of the program, we proposed to require that the State include in each applicant's record certain facts that would, if necessary, support the State's determination of a child's eligibility. This documentation should be consistent with standard State laws and procedures.

We did not receive any comments on this section. Therefore, we are implementing this provision as set forth in the proposed rule.

15. Eligibility and Income Verification (Proposed § 457.970)

In this final regulation, proposed § 457.970 has been moved from subpart I to subpart C, Eligibility to become § 457.380. We have addressed comments on proposed § 457.970 in subpart C.

16. Redetermination Intervals in Cases of Suspected Enrollment Fraud (§ 457.975)

We proposed in § 457.975 that if a State suspects enrollment fraud, the State may, at its own discretion, perform eligibility redeterminations with the frequency that the State considers to be in the best interest of the SCHIP program.

Comment: One commenter noted that States should carefully consider the effect of not allowing immediate reenrollment of otherwise eligible children in SCHIP. Though the suspected fraud is very unlikely to have been conducted by the child, the commenter noted that it is the child who will suffer.

Another commenter recommended deleting this section because they believed its provisions were not only unnecessary but also might easily be abused. The commenter expressed concern that this rule could be used to justify increased scrutiny of coverage provided to racial and ethnic minorities.

Response: We appreciate this comment. We too are concerned with excluding children from coverage under SCHIP and are committed to ensure that States maintain coverage of children for as long as they are eligible and have deleted this section from the final rule.

17. Verification of Enrollment and Provider Services Received (§ 457.980)

We proposed in § 457.980 that the State must have established systems and procedures for verifying enrollee receipt of provider services. In addition, we specified that the State must establish and maintain systems to distinguish and report enrollee claims for which the State receives enhanced FMAP payments under section 2105 of the Act. We noted that these procedures would serve as a fundamental component of other program integrity activities in this proposed rule, including the fraud detection and investigation efforts discussed under §§ 457.915, 457.925, and 457.930.

Comment: Several commenters noted that the provisions of this section could be difficult to implement in managed care plans and that verification may be burdensome in a capitated system. The commenters requested that we clarify that it would be acceptable if there were a provision in the contract with the health plan to ensure provider services. One commenter expressed concern regarding external verification of provider services received in the managed care market, especially in capitation-based plans. The commenter felt that States should be able to handle

this through the normal provider evaluation and review procedures used by managed care entities.

Response: It is necessary for the effective and efficient administration of any State separate child health insurance program to monitor and verify enrollee receipt of services for which providers have billed or received payment, or that providers have contracted to furnish regardless of the method of reimbursement. Therefore, the provisions of § 457.980(a) apply to States using managed care plans as well as other systems of health insurance and care delivery. Plans participating in SCHIP are accountable to the State for providing services and care to SCHIP participants. States must ensure, when contracting with providers, that beneficiaries are receiving care to which they are entitled and for which States have provided funds.

Comment: We received a couple of comments noting that an error may have occurred in this section as medical providers bill the State but are not billed themselves. This section should read, ''The State must establish methodologies to verify whether beneficiaries have received services for which providers have billed.''

Response: We agree and have changed the text of the regulation.

18. Integrity of Professional Advice to Enrollees (§ 457.985)

To address our concern that enrollees have a right to make informed decisions about their medical care free from any form of financial incentive or conflict of interest involving their provider of care that could directly or indirectly affect the kinds of services or treatment offered, we proposed that States must guarantee in their contracts the protection described in proposed § 457.985(e). We proposed to require that States must include in their contracts for coverage and services, provisions regarding enrollee access to information related to actions that could be subject to appeal in accordance with the ''Medicare+Choice'' regulation at § 422.206, which discusses the protection of enrollee-provider communication and at § 422.208 and § 422.210(a) and (b) which discuss physician incentive limitations. We remain committed to ensuring that appropriate actions are taken to guarantee the protection of enrollee rights regarding their health care services under the Medicare, Medicaid, and SCHIP programs.

Comment: One commenter expressed its support for the requirement to provide enrollee access to information related to actions involving inappropriate arrangements that could be subject to review and appeal. One commenter noted its support for the requirement in § 457.985(e) that States prohibit gag rules and establish principles for disclosure of physician financial arrangements that could affect treatment decisions.

Response: We appreciate the support and have retained these requirements with some modification in the final rule. Section 457.985(e) has now been redesignated as § 457.985(a) and (b).

Comment: One commenter believed that HCFA does not have the authority to apply the M+C physician incentive requirements to separate child health plans.

Response: We disagree with the commenter. Under Section 2101(a) of the Act, the purpose of title XXI is to provide funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner. A State cannot provide child health assistance in an effective and efficient manner if it allows inappropriate physician incentive plans that have the effect of reducing or limiting health services.

Comment: Several commenters are concerned about the reference in proposed § 457.985(e)(1) prohibiting interference with medical communications between health care professionals and patients. The proposed rule refers to M+C regulations at § 422.206. The commenters would like to include only a specific reference to § 422.206(a) rather than to the whole section. Section 422.206(b) includes a ''conscience protection'' that appears to allow plans to refuse to include in their benefit package any counseling or referral service to which the plan asserts a moral or religious objection. Some commenters noted that there is an explicit statutory provision in the M+C portion of the Balanced Budget Act that deals with conscience-based refusals to provide services and the M+C regulatory provision parallels the statute, but there is no similar statutory requirement in SCHIP. The commenters noted that the regulation also should not reference § 422.206(b) in order to preserve access to health care services and information about them. According to this commenter, a health plan that refuses to provide counseling or referral services impairs access to those services, and typically the services most at risk are reproductive health services provided to women. The commenters further argued that this provision conflicts with the CBRR goal of open communication between health care professionals and patients in all cases, without qualification or exception.

Response: We agree that the regulation should reference only § 422.206(a). The remainder of § 422.206 contains requirements for reporting to HCFA sanctions for Medicare+Choice organizations that are not applicable in a separate child health program. However, not all providers are required to offer all services in the SCHIP benefit packages. If a State contracts with providers that have a moral or religious objection to providing particular services, the State retains the responsibility to assure that enrollees are informed of and have access to all services included as a part of the benefit package consistent with § 457.495.

Comment: One commenter noted that the preamble to the proposed rule (p. 60928), which cross-references § 422.208 of the M+C regulations, appears to apply the physician incentive requirements to separate child health programs. However, § 457.995(d) and § 457.985(e) appear to apply only the disclosure requirements, not the substantial financial risk requirements, to the SCHIP program. This commenter recommended that HCFA clarify this requirement.

Response: A State must guarantee compliance with all of the provisions of § 422.208 (relating to limitations on physician incentive plans) and § 422.210 (relating to disclosure of physician incentive plans) of this chapter as stated in § 457.985.

Comment: One commenter recommended that States should be allowed to provide protections against the gag rule and physician incentives in accordance with their own State law.

Response: While we appreciate State efforts to prohibit gag rules and inappropriate physician incentive plans, it is necessary to require compliance with § 422.208 and § 422.210 of this chapter to ensure nationwide protection of enrollees in separate child health programs consistent with the CBRR.

I. Subpart J—Allowable Waivers: General Provisions

1. Basis, Scope, and Applicability (§ 457.1000)

This subpart interprets and implements the requirements for a waiver under section 2105(c)(2)(B) to permit a State to exceed the 10 percent limit on expenditures as specified in section 2105(c)(2)(A), and for a waiver to permit the purchase of family coverage under section 2105(c)(3) of the Act. This subpart applies to a separate child health program and to a Medicaid expansion program only to the extent

that the State claims administrative costs under title XXI and seeks a waiver of limitations on such claims for use of a community-based health delivery system.

Comment: One commenter noted that there appears to be a word missing in § 457.1000(c). The sentence ends with ''seeks a waiver of limitations such claims in light of a community-based health delivery system.'' The commenter believes that ''on'' should be inserted after ''limitations,'' although the meaning is still unclear.

Response: We have corrected § 457.1000(c), as suggested by the commenter, by adding the word ''on''. We have also edited the sentence for clarity. The first part of the sentence now indicates that the requirements of this subpart apply to a separate child health program. The second part of the sentence clarifies that the requirements of this subpart also apply for States that operate Medicaid expansion programs if the State claims administrative costs under title XXI and seeks a waiver of limitations on such claims for cost-effective coverage through a community-based health delivery system.

Comment: One commenter suggested that the same time frames for HCFA approval that are proposed for State plan and State plan amendment approvals be included for waivers.

Response: We have amended the regulation text by adding a new § 457.1003 to clarify that we will review the waivers under this subpart as State plan amendments under the time frames as specified in § 457.160. In practice, State proposals for these waivers have been reviewed as part of the initial State plan or amendment and within the 90-day review period permitted under statute. These waivers must be reflected in the State plan and updated accordingly. It should be noted that the 90-day time frame for review does not apply to HCFA review of section 1115 demonstration proposals under this title.

2. Waiver for Cost-Effective Coverage Through a Community-Based Health Delivery System (§ 457.1005)

Section § 457.1005 interprets and implements section 2105(c)(2)(B) of the Act regarding waivers authorized for cost-effective alternatives. In § 457.1005, we proposed requirements for a State wishing to obtain a waiver of the 10 percent limit on expenditures not used for child health assistance in the form of health benefits coverage that meets the requirements of § 457.410. This section also clarifies the extent to which the State will be allowed to exceed the 10 percent limitation on such expenditures in order to provide child health assistance to targeted low-income children under the State plan through cost-effective, community-based health care delivery systems.

To receive payment for cost-effective coverage through a community-based health delivery system under an approved waiver, we proposed that the State must demonstrate that—

- Such coverage meets the coverage requirements of section 2103 of the Act and subpart D of this part; and
- The cost of coverage through the community-based health care delivery system, on an average per child basis, does not exceed the cost of coverage that would otherwise be provided under the State plan.

We noted in the preamble to the proposed rule that a State may define a community-based delivery system to meet the specific needs and resources of a community, as long as it ensures that its community-based delivery system (either through direct provision or referral) can provide all appropriate services to targeted low-income children in accordance with section 2103 of the Act. We also proposed that all community-based providers must comply with all other title XXI provisions.

We proposed that an approved waiver will remain in effect for two years and that a State may reapply three months before the end of the two-year period. We also proposed that, notwithstanding the 10 percent limit on expenditures described in § 457.618, if the cost of coverage of a child under a community-based health delivery system is equal to or less than the cost of coverage of a child under the State plan, the State may use the cost savings for—

- Child health assistance to targeted low-income children and other low-income children other than the required health benefits coverage, health services initiatives, and outreach; or
- Any reasonable costs necessary to administer the State Children's Health Insurance Program.

Comment: One commenter suggested that HCFA adopt the definition of ''health services initiatives'' set forth in the August 6, 1998 letter to State Health Officials. In the letter, the term is defined as ''activities that protect the public health, protect the health of individuals or improve or promote a State's capacity to deliver public health services and/or strengthens resources needed to meet public health goals.'' In addition, the commenter suggested that the preamble make clear that all immigrant children, regardless of their status or date of entry, can participate in, and benefit from, health services initiatives.

Response: We agree with the commenter. We have added the definition of ''health services initiatives'' as set forth in the August 6, 1998 letter to the definitions section of the regulations text at § 457.10. We note that this definition of health services initiatives includes ''other low-income children,'' which can include immigrant children, regardless of their status or date of entry, and children who are eligible for Medicaid but not enrolled. As specified in our January, 14, 1998 letter to State Health Officials, health services initiatives may benefit the health of all low-income children, including but not limited to children eligible to receive services under title XXI. Therefore, health services initiatives such as health education activities, school health programs and direct services (such as newborn hearing and lead testing programs), could be targeted to low-income, immigrant communities.

Comment: One commenter proposed that States be permitted to use title XXI funds under this waiver to pay for primary care services provided by community-based providers to children who are not targeted low-income children eligible for the State's title XXI program, in order to increase access to medically necessary primary care for uninsured SCHIP-eligible children who are not yet enrolled in the State's title XXI program.

Response: States may provide primary care services to children who are not targeted low-income children through a ''health services initiative under the plan for improving the health of children (including targeted low-income children and other low-income children).'' These expenditures would be subject to the 10 percent limit as specified in section 2105(c)(2)(A), except to the extent that the State pays for these services through the use of savings from the waiver for a cost-effective alternative delivery system. In this case, the State could use the savings for primary care services for unenrolled low-income children and those expenditures would not be subject to the 10 percent cap.

Another option for States to consider is using this waiver in conjunction with presumptive eligibility (provisional enrollment). The costs associated with a period of provisional enrollment are benefit costs when the child subsequently is determined eligible for either Medicaid or a separate child health program. However, the costs associated with a period of provisional enrollment for a child who is later

determined ineligible for either Medicaid or a separate child health program are costs that are normally subject to the 10 percent limitation. When services are provided during a period of provisional enrollment to a child who is low-income and whom the State later determines to be ineligible for either Medicaid or a separate child health program, the costs of providing benefits to these low-income, ineligible children could be funded through the use of the waiver for a cost effective alternative delivery system. Again, the benefits provided would have to meet all the requirements of § 457.410.

Comment: One commenter suggested allowing States to set aside a portion of their title XXI allotment for a community-based provider program. The commenter noted 90 percent of the set-aside funds would pay for services to SCHIP eligible children and 10 percent of the set-aside funds would pay for administration.

Response: The Act does not dictate how States set their budgets generally or set budget priorities relating to community-based waiver programs. Section 2105(a) authorizes the Secretary to pay a State from its allotment based upon actual expenditures for child health assistance. The State might be able to make expenditures according to the proportions described above. However, as specified in section 2105(c)(2)(A), the amount of administrative expenditures that a State can claim is directly tied to the amount of expenditures they claim for child health assistance.

Comment: One commenter believed that the language in section § 457.1005(b)(2) is unclear and asked whether the ''State plan'' referred to is the Medicaid State plan or the SCHIP State plan.

Response: The waiver described in proposed § 457.1005(b)(2) is a program waiver under title XXI and, therefore, the State plan referred to in this section is the title XXI State plan, as defined in § 457.10.

Comment: One commenter recommended amending § 457.1005(b)(1) regarding requirements for obtaining a waiver to incorporate a reference to the cost-sharing protections in subpart E and the various beneficiary protections provided in other subparts of the rule and summarized in § 457.995. The commenter was concerned that children receiving care in a community-based health delivery system would not benefit from the consumer protections provided in the regulation, and that States should be not permitted to utilize this waiver as a means of circumventing the protections that are afforded to other SCHIP applicants and enrollees.

Response: As proposed, the regulation text at § 457.1005(b) required States obtaining a waiver for cost-effective coverage through a community-based health delivery system to demonstrate that (1) the coverage meets the coverage requirements of section 2103 of the Act and subpart D of this part; and (2) the cost of such coverage, on an average per child basis, does not exceed the cost of coverage under the State plan. In the preamble to the proposed rule, we stated that, for the purposes of a waiver, all participating community-based providers must comply with all other title XXI provisions. On further consideration, we have clarified the policy under the final regulation. Section 457.1005(b)) now requires that, in providing child health assistance through the waiver, the coverage must meet all the requirements of this part, including subparts D and E. Therefore, the final regulation clarifies that all title XXI protections will apply under a waiver for a community-based delivery system in order to assure that all children receive the same protections regardless of where they receive services.

Comment: One commenter believes that HCFA's example of coverage for a special group, such as children who are homeless or who have special health care needs, does not consider that the care for these children may cost more than the care for the average child. The commenter recommended that HCFA reconsider § 457.1005 and provide options for States to proceed with caring for children with special needs in a manner that allows payment above the cost of providing coverage to the ''average'' child.

Response: Section 2105(c)(2)(B)(ii) of the Act specifies that the cost of coverage through the community-based health care delivery system, on an average per child basis, may not exceed the cost of coverage that would otherwise be provided under the State plan. In an August 6, 1998 letter to State Health Officials, we stated that the amount paid to the community-based delivery system on a Federal fiscal year, per child basis must not be greater than the amount that would otherwise have been paid for that child to receive coverage under title XXI. For example, if the amounts that the State pays health plans under the State plan reflect the risk entailed in providing care to special needs children (because the State risk adjusts its capitation payments, or because the State provides services to these children on a fee-for-service basis), these above-average costs for the special needs children in fact, will be reflected in the cost-effectiveness calculation. Therefore, the cost-effectiveness calculation required under § 457.1005(b)(2) does not preclude the State from adjusting its payments for the care of special needs children to provide for higher payment for such care.

Comment: One commenter applauded HCFA's interpretation of waivers as stated in the proposed rule and agreed with the statement that the purpose of this waiver was to increase health services and not to increase funds for administration.

Response: The preamble of the proposed rule set forth our belief that Congress did not intend that the waiver be used primarily to allow for more administrative spending or spending on outreach services under section 2105(a)(2). While we appreciate the support of the commenter, we also point out that States do retain flexibility regarding the use of any savings obtained as a result of this waiver pursuant to § 457.1005(d).

Comment: A number of commenters recommended that approved waivers should initially remain in effect for three years, to coincide with the time frames at section 2104(e) of the Act for spending the funding allotment for each year, and to provide time to evaluate the waiver's impact and to demonstrate cost-effectiveness. Following the initial approval period, one commenter recommended that the duration be five years, in keeping with the typical duration of 1115 waivers.

Response: We agree with the commenters' suggestion that a 3-year approval period would coincide with statutory time frames for the expenditure of allotments and provide a more adequate period of time in which to determine cost-effectiveness. Therefore, we have revised § 457.1005(c) to provide that the duration of time for which waivers for cost-effective coverage through a community-based health delivery system are approved is three years. We will continue to determine cost-effectiveness upon application and renewal for the waiver. However, we have not accepted the recommendation to extend the waiver period to five years because it is important to assess the cost-effectiveness of community-based health delivery systems on a more frequent basis. We have also revised the regulation at § 457.1005 to indicate that a State may reapply for approval 90 days before the end of the three year period for consistency with the 90 day review period that apply to State plan amendments.

3. Waiver for Purchase of Family Coverage (§ 457.1010)

We proposed that a State must apply for a family coverage waiver when any title XXI funds are used to purchase coverage for adult family members in addition to targeted low-income children. We proposed at § 457.1010 that a waiver for family coverage will be approved by the Secretary if—

- Purchase of family coverage is cost-effective under the standards described in § 457.1015 of this subpart;
- The State does not purchase such coverage if it would otherwise substitute for health insurance coverage that would be provided to such children but for the purchase of family coverage; and
- The coverage for the child otherwise meets the requirements of this part.

We requested comments on whether the benefits specified in title XXI also apply to adults covered by a family coverage waiver. For example, if a State offers ''wraparound coverage'' to bring an employer's benefits up to the title XXI standards, we solicited comments as to whether the State should be required to offer this additional coverage to adults under the family waiver.

We noted that there is no statutory definition of family coverage for the purposes of this subpart and we solicited input from commenters on the definition of ''family'' for purposes of this subpart.

Comment: Many commenters questioned whether States covering parents of SCHIP children through a family coverage waiver must provide the benefits specified in title XXI to the family members who would not otherwise be eligible for SCHIP coverage. These commenters asserted that this decision should be left to State discretion. Commenters did not believe that there is any statutory basis for such a rule. Commenters also indicated that such a requirement would dramatically restrict States' ability to achieve cost-effectiveness in family coverage and would result in a reduction in the number of children that could be insured through the program. Commenters also noted that such a requirement could further complicate the States' administration of benefit and/or cost-sharing upgrades for premium assistance programs because of the difficulty in administering benefit upgrades.

Response: We appreciate the commenters' consideration of this issue, but disagree with the recommendation and rationale because we do not believe it gives weight to the congressional interest in a standard minimum benefit package for all covered individuals. Congress clearly intended that title XXI funds be used to provide a comprehensive benefit package meeting the requirements of section 2103. Children's benefits under a premium assistance program must meet requirements in section 2103, and benefits offered under group health plans typically do not differ for adults and children. In addition, title XXI provides considerable flexibility for States to choose a benchmark package against which they can compare the benefits offered under a group health plan. Therefore, we have decided to require that any health benefits coverage provided under a family coverage waiver must comply with the benefit requirements of § 457.410 and have revised the language at § 457.1010(c) to reflect this change.

Section 2105(c)(3)(A) provides the authority for this policy because it requires that the purchase of family coverage must be cost-effective relative to the amounts that the State would have paid to obtain ''comparable coverage'' for only the targeted low-income children involved. Therefore, this provision clearly contemplates that the coverage offered to non-eligible family members under a family coverage waiver would be comparable to the coverage that would be offered to targeted low-income children. We believe that requiring the family coverage to meet title XXI standards best assures this comparability and is most consistent with the intended use of title XXI funds. However, we have interpreted the statute's use of the term ''comparable'' to permit the coverage of non-SCHIP eligible family members to be based on a different title XXI benchmark than the targeted low-income children's coverage.

While we recognize the cost of family coverage will increase if the State provides wrap-around coverage to adults in addition to the benefits provided by the group health plan, the degree of cost increase is unclear. For example, when the ''wrap-around'' supplemental coverage provided by the State to meet the section 2103 requirements is coverage only for well-baby and well-child services, there would be no additional costs to provide coverage that meets the requirements of section 2103 for adults, because this ''wrap-around'' coverage is not relevant for adults.

Comment: One commenter stated that it is not clear what would be included in a benefits upgrade for adults. For instance, the commenter questioned if there would need to be a prohibition on cost sharing for adult preventive care visits and services to reflect the statutory prohibitions on copayments or cost sharing for well-baby or well-child care. If this were the case, the commenter indicated that the cost of implementing such a provision would obviously be significant.

Response: While States must ensure that health benefits coverage provided to all family members, including adults, meets the requirements of section 2103, not all benefits are relevant to adult enrollees. For instance, while the statute requires the provision of well-baby and well-child care and prohibits cost sharing for these services, these services are not applicable or available to adults. Therefore, States would not be required to provide coverage to adults for these services, and the specific cost-sharing restrictions applicable to these services also would not apply to adults. However, general cost-sharing limitations do apply to covered services for adults and children under the family coverage waiver. For example, some States have expressed interest in providing coverage to families above 150% of the FPL and, for this income level, the cumulative cost-sharing maximum of 5% of family income would apply.

Comment: One commenter suggested that HCFA clarify how wrap-around coverage programs could be designed to make family coverage waivers viable, cost effective and simple to administer for group health plans.

Response: We recognize the challenges faced by States in establishing and operating premium assistance programs. The challenges result from the fact that title XXI primarily was designed for targeted low-income children receiving health benefits coverage through programs operated directly by the State, rather than for families receiving health benefits coverage through group health plans. Nonetheless, it is possible to address these challenges. For example, some States are structuring their premium assistance programs to permit direct billing from providers to the State for services or cost sharing that is not covered by the group health plan. In addition, there is flexibility for States to select from among a variety of benchmark benefit packages, and States should carefully consider this flexibility when designing premium assistance programs. We will continue to share new approaches with States as they are developed.

Comment: Commenters encouraged the use of ''family'' as defined by States, employers, and/or the individual contracting health insurance plans. One

commenter believed that States and the Federal government do not need to, and in fact cannot, develop a standard definition. Commenters noted that family coverage waivers will likely be provided through employer-sponsored plans, where the issue of which family members may be included under the employer plan is regulated by contract with insurers and State insurance law. One commenter is planning to submit a request to subsidize employer-sponsored insurance that involves several premium tiers based on which family members are covered and suggests that the definition of ''family'' include the employee, spouse and children, or employee, and children depending on family composition and the coverage tier selected. Other commenters felt that HCFA should not create a definition of ''family,'' because such a definition could restrict the ability of group health plans or health insurance issuers from defining what constitutes family coverage. One commenter also noted that a more flexible approach would ease administration and maximize the availability of the family coverage waiver option. Another commenter suggested that the definition be left to State discretion and that once HCFA reviews a wide range of proposals, it can revise the regulations to include a definition if necessary.

Response: We have not defined ''family'' for the purposes of this regulation in general and, after considering these comments, we agree with the commenters that one standard definition of ''family'' could unnecessarily restrict States' ability to utilize a family coverage waiver. Therefore, the decision regarding how to define ''family'' is left to States' discretion.

Comment: One commenter urged that the definition of ''family'' include adult pregnant women without other family members. The commenter believes that this expansion of the definition is integral to ensuring that all pregnant women have access in their community to readily available and regularly scheduled obstetric care, beginning in early pregnancy and continuing through the postpartum period.

Response: While we support States' efforts to cover pregnant women, title XXI does not support an expansion of coverage to include pregnant women who are not family members of SCHIP-eligible children. Section 2105(c)(3) permits payment to a State for family coverage under ''a group health plan or health insurance coverage that includes coverage of targeted low-income children.'' The statute requires the State to compare the cost of coverage ''only of the targeted low-income children involved'' with the cost of coverage for the family. A State wishing to cover a pregnant woman who is not a family member of a targeted low-income child would not be able to perform the required cost-effectiveness test. Therefore, a pregnant woman can be covered through a family coverage waiver only to the extent that a targeted low-income child in her family is eligible for SCHIP coverage.

Comment: A commenter noted that in the preamble to the proposed rule, we stated that States must apply for a family coverage waiver when any title XXI funds are used to purchase coverage for adult family members in addition to targeted low-income children. We also noted that States may purchase coverage for children through premium assistance programs using employer-sponsored insurance without a family coverage waiver when the costs of such children are identifiable. One commenter was concerned that the premium tier structures available to most employers do not permit the costs of children to be identified. The commenter noted that employers offer only two coverage tiers, employee-only and family coverage, which does not permit this kind of determination, because other family members, such as spouses, also may be covered under the family coverage tier. The commenter asserted that the options permitted in the proposed rule for determining the cost of children under employer-sponsored coverage will mean that most States seeking to cover a significant number of uninsured children under a premium assistance program will need to obtain a family coverage waiver.

Because States may wish to utilize employer-sponsored insurance without subsidizing coverage for the adults in the family, the commenter suggested an alternative method for determining the cost of targeted low-income children covered through employer-sponsored coverage. The commenter proposed that States be permitted to pay a proportion or percentage of the cost of employer-sponsored family coverage without obtaining a family coverage waiver, as long as the portion the State pays is based on a reasonable actuarial estimate of what proportion of the cost of family coverage is attributable to the children, and as long as it meets the cost-effectiveness test.

The commenter suggested that the actuarial determination of the proportion to be paid could be made once a year, based on typical group health coverage plan available in the State, and the percentage could then be applied to the actual premium for family coverage under the specific employer's plan.

Response: We have reconsidered the requirement in the preamble to the NPRM that a family coverage waiver is needed when any title XXI funds are used to provide coverage for adult members of the family. We will not require States to obtain a family coverage waiver in cases where the employee's premium is not subsidized and there is no intention on the part of the State to cover family members other than targeted low-income children. We also agree that the suggestion offered by the commenter appears to offer another possible option for States to identify the costs of enrolling only the eligible child or children in the family into a premium assistance program, and thereby enroll the children without obtaining a family coverage waiver. As described in the proposed rule, child-only costs can be identified when a State is purchasing a child-only policy, or in markets in which carriers offer policies with a sufficient number of premium tiers to identify the costs of the SCHIP-eligible child or children. Such tiers might include an employee-only premium tier, and an employee-plus-children premium tier, such that the former can be subtracted from the latter to determine the cost of the child or children. However, as the commenter points out, these premium tier structures may not be common or uniformly available in most States.

In a more typical group health insurance market that offers coverage tiers for employee-only or family coverage, the employee contribution amounts for employee-only and for family coverage are known. The difference between the two is the cost for dependent coverage. Again, if title XXI only subsidizes the difference between employee-only and family coverage, a family coverage waiver is not needed as long as there is no intention to cover non-SCHIP eligible family members. However, as an alternate approach, the State could decide to allocate the cost for dependent coverage between the spouse and children on a reasonable actuarial basis and a family coverage waiver would not be required if the State then pays only that portion allocated to coverage of the targeted low-income child or children. An actuary familiar with the State's group health market could produce an estimate of the cost of one adult relative to the cost for one child under a group health plan. This ratio could then be applied to the family composition to determine what portion of the premium pays for the spouse's coverage and what

portion pays for the children's coverage. The State would then pay only that portion attributable to the child or children.

We note, however, that this method may be difficult for States to implement in practice given the need to obtain sufficient data to perform the necessary actuarial estimates. In addition, the subsidy amount determined under this method does not cover the family's full premium cost, which may discourage some families from enrolling. For these reasons, calculating the difference between employee-only and family coverage costs may be a preferable alternative to obtaining actuarial estimates of the costs of only the targeted low-income children for many States. We also note that when a State subsidizes family coverage, but is covering only targeted low-income children (that is, no payment is being made for the employee portion of the premium, and there is no intention to cover family members other than the targeted low-income children and the costs do not exceed the cost-effective amount), the requirements of this part apply to only the targeted low-income children. We reiterate that family coverage waivers are subject to the same 90-day review period as any other title XXI State plan amendment and need not be unduly burdensome to obtain.

In order to assist States in designing premium assistance programs to cover only targeted low-income children using employer sponsored insurance, we will work with States on their specific proposals to develop mechanisms for identifying the cost of covering the targeted low-income children using reasonable methods, for the purposes of determining cost-effectiveness.

Comment: Several commenters indicated that family coverage waivers will be challenging for States to implement. One commenter expressed concern that the standards for family coverage waivers are impossible to meet and should be made easier to accomplish via a statutory change. Another commenter supported States' interest in developing programs to provide coverage to whole families and urged HCFA to provide more support and technical assistance and to grant more family coverage waivers.

Response: We are committed to sharing best practices and providing guidance to States designing and implementing family coverage waivers and premium assistance programs. To date, three States have received approval for family coverage waivers. As States gain more experience with their premium assistance programs and their family coverage waivers, we will work to disseminate information about the challenges and successes of these programs.

Comment: A number of commenters were concerned that the proposed regulations are too restrictive regarding when a family coverage waiver is needed. Some noted that, while Congress intended to expand coverage to children, recent research suggests that expanding parents' access to health care coverage also increases children's enrollment, as parents are more likely to apply for and enroll their children in a health insurance program if the whole family is covered by the same plan. They encouraged HCFA to permit States to experiment with both title XIX and title XXI funds to cover parents as an effective strategy to increase enrollment levels of children. They also noted that most States have not spent a significant portion of their title XXI allotments, and may be able to expand coverage further if more flexibility is granted for enrolling parents under title XXI.

Response: We recognize the link between children's enrollment and parental access to SCHIP coverage. We have provided flexibility on this as permitted by the statute. Section 2105(c)(3) sets forth certain requirements relating the coverage of families through a family coverage waiver, and § 457.1010 of this regulation implements that section. However, we will continue to work with States that wish to design and implement programs under a family coverage waiver to help facilitate the enrollment of parents of SCHIP-eligible children in a manner consistent with title XXI.

Comment: One commenter stated that the proposed rule indicates that the community-based waiver applies to Medicaid expansion programs, but the family coverage waiver does not. It is the commenter's opinion that family coverage waivers should be allowed in Medicaid expansion programs.

Response: Family coverage waivers are required whenever States are funding coverage for any non-SCHIP eligible family members with title XXI funds under a separate child health program. Under Medicaid, States are able to purchase employer-sponsored coverage for regular Medicaid and Medicaid expansion enrollees under section 1906 of the Act, which permits States to pay premiums, deductibles, and coinsurance on behalf of Medicaid beneficiaries eligible for enrollment in employer-based group health plans when it is cost-effective to do so. The only exception to this distinction between family coverage in Medicaid expansions and separate child health programs is within the context of our authority under section 1115 of the Act. Section 1115 demonstrations are not subject to regular Medicaid rules when those rules are modified under the Secretary's authority to grant certain waivers, to provide federal funds for costs that would not otherwise be matchable and to impose special terms and conditions for such demonstrations. In all cases, we are committed to working with States interested in using either funding source, either separately, or in conjunction with each other. As mentioned previously, a family coverage waiver is not needed when the coverage of adult family members is only incidental.

Comment: Several commenters supported coverage of adult family members under family coverage waivers. One commenter supported State flexibility to cover family members but believed that before granting a family coverage waiver, HCFA should ensure that States have utilized their options for expanding health coverage to lower-income adults in non-title XXI funded programs. The commenter notes that HCFA and ACF, in their publication ''Supporting Families in Transition,'' indicated that before expanding coverage under title XXI, States will need to implement a Medicaid expansion under section 1931 of the Act to avoid an anomalous result in which higher income families are covered under SCHIP, while parents of lower-income children lack coverage. Another commenter suggested that HCFA encourage States to apply for Medicaid waivers to expand insurance coverage to adult pregnant women and to facilitate the more rapid enrollment of their infants.

Response: We agree that States' ability to use Medicaid rules to expand coverage to other family members is an important option, and we have been working with States to clarify the flexibility that exists to do this. Under Medicaid, States may purchase family coverage through employer-sponsored coverage under section 1906 of the Act, which permits States to pay enrollee premiums in employers' group health plans when it is cost-effective to obtain coverage for Medicaid-eligible individuals (deductibles, coinsurance and other cost sharing for ineligible family members may not be paid as medical assistance).

In addition, States may submit proposals for demonstrations under section 1115 of the Act to expand coverage to parents of children covered under SCHIP. HCFA released guidance on July 31, 2000 regarding parameters for consideration of such proposals.

Comment: Several commenters proposed that States should meet prerequisites before receiving approval for family coverage waivers. Some commenters proposed that States must eliminate the asset test under Medicaid and SCHIP and adopt simplified application, enrollment and redetermination procedures for children. Other commenters suggested that States should expand coverage for children with family income up to at least 200 percent of FPL (or 50 percentage points above the State's Medicaid applicable income threshold) throughout the areas of the State; ensure that all eligible children are promptly enrolled into a State's title XXI program without being subject to a waiting list; and, if the State operates a separate child health program, adopt a joint Medicaid/SCHIP application and assure that the same or directly comparable application, enrollment and redetermination procedure is used for children under Medicaid and the separate State program. Another commenter proposed that States should first be required to ensure that there is no lessening of SCHIP benefits or increase in cost sharing associated with a waiver using this method of calculating cost-effectiveness.

Response: While we support all of these goals, title XXI provides no statutory authority for requiring States to meet these goals prior to the approval of a family coverage waiver. We have been working with States to clarify Federal law and to provide technical assistance regarding the implementation of such policies in order to support States' efforts to undertake activities that will expand and simplify eligibility, increase the number of children who enroll in States' programs, and to make the enrollment and redetermination processes less burdensome on States, applicants and enrollees.

4. Cost-Effectiveness (§ 457.1015)

This section defines cost-effectiveness and describes the procedures for establishing cost-effectiveness for the purpose of a family coverage waiver.

We proposed that cost-effectiveness means that the cost of purchasing family coverage under a group health plan or health insurance coverage that includes coverage for targeted low-income children is equal to or less than the State's cost of obtaining such coverage only for the eligible targeted low-income child or children involved. Stated more simply, cost-effectiveness for the family coverage waiver means that the cost of providing family coverage (including coverage for the parents) is equal to or less than the cost of covering only the SCHIP-eligible children.

We proposed that a State may demonstrate cost-effectiveness by comparing the cost of family coverage that meets the requirements of §§ 457.1010 and 457.1015 of this subpart, to the cost of coverage only for the targeted low-income child or children under the health benefits packages offered by the State under the State plan for which the child is eligible. Alternatively, we proposed that the State may compare the cost of family coverage to any child-only health benefits package that meets the requirements of § 457.410, even if the State does not offer it under the State plan. We stated that we would examine other alternatives and we invited comment on additional methods for demonstrating cost-effectiveness. We set forth an illustration of cost comparison in the proposed rule.

We proposed that the State may demonstrate the cost-effectiveness of family coverage by applying the cost of family coverage for individual families assessed on a case-by-case basis, or for family coverage in the aggregate. We noted that if a State chooses to apply the cost-effectiveness test on a case-by-case basis, the State must compare the cost of coverage for each family to the cost of coverage for only the child or children in the family under SCHIP. We further explained that if a State chooses to apply the cost-effectiveness test in the aggregate, the State must provide an estimate of the projected total costs of the family coverage program compared to the cost the State would have incurred for covering just the children in those families under the publicly-available SCHIP plan. If the State chooses to assess the cost of family coverage in the aggregate, we also proposed that, on an annual basis, the State must compare the total actual cost of covering all families for whom the State has purchased family coverage to the cost the State would have incurred covering just the children in those families under the publicly-available SCHIP plan. If the aggregate cost of family coverage was less than the cost to cover the children under the publicly available program, then the family coverage would be considered cost-effective. If the State determines through its annual assessment of cost-effectiveness that family coverage is not cost-effective in the aggregate, we proposed that the State must begin to apply the cost-effectiveness test on a case-by-case basis.

Comment: Many commenters indicated that, given the two-year length of approved waivers, the cost-effectiveness assessment should be done for the life of the waiver.

Response: Section 457.1015 addresses cost-effectiveness for family coverage waivers only, and does not address the cost-effectiveness of waivers for a community-based delivery system. Cost-effectiveness of waivers for a community-based delivery system is determined each time a State applies for or renews its waiver. As stated earlier, we have agreed to extend the period of time for which these waivers are approved from two years to three years.

Family coverage waivers are part of the State plan and are approved for an open-ended period of time after an initial demonstration of cost-effectiveness. However, we will continue to require a State to demonstrate the cost-effectiveness of the family coverage waiver on an annual basis, whether done on a case-by case or aggregate basis, consistent with § 457.1015(d). Because we have little information about the costs associated with family coverage waivers, we want to assure that States' premium assistance programs are being administered in the most cost-effective manner possible, and to be able to obtain results so as to share best practices with other States.

We have reconsidered the proposed provision that would have permitted States to conduct its cost comparison against any child-only policy even if it is not offered under the State plan. The revised language requires that the cost comparison be done relative to the State's actual costs under the State plan in order to assure coverage is provided in the most cost effective manner.

Comment: Several commenters wrote to express support of the rule as written with regard to the cost-effectiveness test. One commenter supported permitting States to perform retrospective cost-effectiveness evaluations but suggested that the cost-effectiveness comparisons should be clarified. Specifically, the commenter indicated that the first example (64 FR 60932) omits any costs for the supplemental coverage that will likely need to be provided and included in the cost-effectiveness test because employer plans may not always cover some services that must be covered under title XXI or exempt well-baby and well-child care from cost sharing.

Response: Although the example in the NPRM did not include the cost of supplemental benefits, the cost of supplemental benefits must be reflected in States' cost-effectiveness analyses. For example, assume the cost to cover two targeted low-income children under the State plan is $200 per month and the cost to cover the family in the employer

plan is $120 per month. The State also provides supplemental coverage for benefits and cost sharing that costs $40 per month per family. This $40 would be added to the $120 for a total of $160 which is still cost-effective in comparison to the $200 that would have been paid under the State plan for only the children. We have also revised the provision at § 457.1015 to indicate that cost-effective means that the cost of purchasing family coverage that includes coverage for targeted low-income children is equal to or less than the State's cost of obtaining coverage under the plan only for the targeted low-income children involved. We have eliminated the specific reference to the cost paid under a group health plan or health insurance coverage in order to clarify that all costs associated with providing family coverage, including any supplemental coverage, must be considered when determining cost-effectiveness.

Comment: Some commenters believed that because the Department has not developed standards or guidance regarding budget neutrality, State determinations of cost-effectiveness must be accepted and reasonable waivers and family coverage variances should be approved in a timely fashion.

Response: We have clarified the requirements for determining cost-effectiveness under the waiver for cost-effective coverage through a community based delivery system and the waiver for family coverage in both the NPRM and this final rule. Budget neutrality is a relevant consideration with respect to section 1115 demonstration projects, but not with respect to waivers discussed under subpart J. We are committed to working with States interested in designing and implementing the waivers under subpart J to find the best way possible to comply with these regulations and effectively implement their programs.

J. Subpart K—Applicant and Enrollee Protections

In response to public comment, in this final rule, we relocated certain provisions involving applicant and enrollee protections to this new subpart K, ''Applicant and Enrollee Protections.'' Specifically, we moved to this subpart certain provisions of proposed § 457.902, which set forth definitions applicable to enrollee protections, proposed § 457.985, which set forth requirements relating to grievances and appeals, and proposed § 457.990, which set forth requirements for privacy protections. Public comments received on the relocated proposed provisions and changes made to them are discussed below.

To eliminate inconsistency and potential confusion, and in response to public comment, we decided to remove from the regulation text proposed at § 457.995, which provided an overview of the enrollee rights provided in this part. Instead, we provide an overview of the enrollee protections contained throughout the part in the preamble to this final regulation. We respond below to the general comments on proposed § 457.995, as well as to any general comments relating to the Consumer Bill of Rights and Responsibilities (CBRR). To the extent that a comment on proposed § 457.995 relates to a specific enrollee protection provision cross-referenced in the proposed overview section, but located elsewhere than subpart I of the proposed regulation, we responded to that comment earlier in this final rule in conjunction with comments and responses relating to that specific provision.

The most significant changes reflected in this subpart were made to the proposed ''grievance and appeal'' provisions at § 457.985. Given the lack of clarity regarding the use of the terms ''grievances'' and ''appeals,'' as noted by some of the commenters, we removed these terms from the final regulation. We opted instead, as we make clear in our responses to comments, to refer to the procedural protections required under this regulation as the ''review process.'' We also note that in clarifying the scope and type of matters subject to review, we narrowed the range of matters subject to review from those defined in the proposed regulation. The minimum requirements for a review process identified in this regulation will apply only to separate child health programs, and States retain a significant amount of flexibility in designing their processes.

In this final regulation, a State is required to include in its State plan a description of the State's review processes and, pursuant to § 457.120, to offer the public the opportunity to provide input into the design of the review process. We also clarify that matters involving eligibility and enrollment, on the one hand, and health services, on the other, are subject to somewhat different review requirements. Core elements for a review process applicable to reviews of both types of matters; States may adopt their own policies and procedures for reviews that address these core elements. Such policies and procedures must ensure that—(a) Reviews are conducted by an impartial person or entity in accordance with § 457.1150; (b) review decisions are timely in accordance with § 457.1160; (c) review decisions are written; and (d) applicants and enrollees have an opportunity to—(1) represent themselves or have representatives of their choosing in the review process; (2) timely review their files and other applicable information relevant to the review of the decision; (3) fully participate in the review process, whether the review is conducted in person or in writing, including by presenting supplemental information during the review process; and (4) receive continued enrollment in accordance with § 457.1170. Under the provisions of this final rule, a State could use State employees, including State hearing officers, or contractors to conduct the reviews, reviews could be conducted in person, by phone or based on the relevant documents, and a State could choose to use the same general process or different processes for reviews of eligibility and enrollment decisions and health services decisions.

With respect to enrollment matters, States must provide an applicant or enrollee with an opportunity for review of: (1) A denial of eligibility; (2) a failure to make a timely determination of eligibility; or (3) a suspension or termination of enrollment, including disenrollment for failure to pay cost sharing. States are not required to provide an opportunity for review of these matters if the sole basis for the decision is a change in the State plan or a change in Federal or State law (requiring an automatic change in eligibility, enrollment, or a change in coverage under the health benefits package that affects all applicants or enrollees or a group of applicants or enrollees without regard to their individual circumstances). For example, if a State amends its plan to eliminate all speech therapy services, a review would not be required if an individual appeals the denial of speech therapy. The final rules also establish that States must complete the review within a reasonable amount of time and that the process must be conducted in an impartial manner by a person or entity (*e.g.* a contractor) who has not been directly involved with the matter under review. For matters related to termination or suspension of enrollment, including a disenrollment for failure to pay cost sharing, the rules require that a State ensure the opportunity for continued enrollment pending the completion of the review.

As to adverse health services matters, a State must provide access to external review of decisions to delay, deny, reduce, suspend, or terminate services, in whole or in part, including a

determination about the type or level of services; or of a failure to approve, furnish, or provide payment for health services in a timely manner. The external review must be conducted in an impartial and independent manner, by the State or a contractor other than the contractor responsible for the matter subject to external review. All reviews must be completed in accordance with the medical needs of the patient. The rules establish an overall 90-day time frame for external review, including any internal review that may be available. The rules also establish a 72-hour expedited time frame in the case where operating under the standard time frames could seriously jeopardize the enrollee's life or health or ability to attain, maintain or regain maximum function. In such situations, the enrollee has access to internal and external review, then each level of review may take no more than 72 hours. If the enrollee's physician determines the review should be expedited then it must be conducted accordingly, both for internal (if applicable) and external review.

In addition, we clarify the notice requirements at § 457.1180, and require a State in § 457.110(b)(6) to make available to potential applicants, and provide to applicants and enrollees information about the review processes that are available to applicants and enrollees. The rules also require that States ensure that enrollees and applicants are provided timely written notice of any determinations required to be subject to review under § 457.1130 that includes the reasons for the determination; an explanation of applicable rights to review of that determination, the standard and expedited time frames for review, and the manner in which a review can be requested; and the circumstances under which enrollment may continue pending review. Section § 457.340(d) requires that in the case of a suspension or termination of eligibility, the State must provide sufficient notice to enable the child's parent or caretaker to take any appropriate actions that may be required to allow coverage to continue without interruption.

We provide States with flexibility under § 457.1190 related to coverage provided through premium assistance programs to assure that all SCHIP eligible children have access to these enrollee protections, while recognizing States' reduced ability, or in some cases inability, to affect group health plan review procedures. This section provides that in States choosing to offer premium assistance programs, if the group health plan(s) through which coverage is provided are not found to meet the review requirements of §§ 457.1130(b), 457.1140, 457.1150(b), 457.1160(b), and 457.1180, the State must give applicants and enrollees the option to obtain health benefits coverage other than coverage through that group health plan. The State must provide this option at initial enrollment and at each redetermination of eligibility.

1. Overview of Enrollee Rights (Proposed § 457.995)

In the proposed rule, we set forth in § 457.995 an overview of certain enrollee rights that we provided throughout the proposed rule. In determining the scope of consumer protections to apply to separate child health programs, we considered the Secretary's statutory authority under title XXI and, within that authority, we attempted to balance the goal of ensuring consumer rights for SCHIP-eligible children with the need to afford States flexibility to design their separate child health programs. In this spirit, we proposed the enrollee protections listed in proposed § 457.995 for enrollees in separate child health programs, and we also solicited public comments on how best to balance these interests in this regulation.

As noted above, while we removed proposed § 457.995 from the regulation text in response to public comment, we respond to the general comments on proposed § 457.995 below. We respond to comments on the specific provisions cross-referenced in the § 457.995 overview and contained in other subparts along with the responses to other comments on those cross-referenced provisions. For example, proposed § 457.995 contains a cross-reference to § 457.110 and the comments to proposed § 457.995 also included comments on § 457.110. We respond to the latter set of comments on § 457.110 together with the other comments on § 457.110. Below you will find our responses to the general comments on § 457.995. Following our responses to general comments on this section is an overview of the enrollee protections provided in this final regulation.

Comment: One commenter suggested that HCFA either (1) consolidate all of the sections that relate to enrollee protections in one or two sections; or (2) leave the protections in different parts of the proposed rule, ensure that the protections are consistent with the CBRR, and provide a summary of the protections in the preamble only. While this commenter strongly supported HCFA's attempt to address the CBRR, the commenter believed that the proposed rule does not incorporate the rights and requirements in a logical fashion. They noted that § 459.995 merely summarized requirements found in other sections of the rule, so it seemed redundant and, at times, inconsistent. According to this commenter, for example, § 457.110(b) provided that information provided to enrollees must be ''accurate'' and ''easily understood'' and that the information must be ''made available to applicants and enrollees in a timely manner.'' Proposed § 457.995(a)(4), however, provided that ''information must be accurate and easily understood and provide assistance to families in making informed health care decisions.'' These two provisions addressed similar issues but included slightly different requirements, and this commenter argued that these inconsistencies are difficult to reconcile and therefore could result in inappropriate interpretations by States, courts, and enrollees. This commenter generally requested that HCFA reconcile the substantive requirements in other sections of the regulations with the requirements in § 457.995(a) and (b).

The commenter also recommended that the provision relating to ''assistance'' include a reference to ''application assistance'' in § 457.361(a) and to translation services. The same commenter suggested that HCFA correct the citations referenced in § 457.995(a)(3). A different commenter noted that there is no § 457.735(c), and the reference in § 457.995(b) to § 457.735(c) should instead be to § 457.735(b). One commenter also suggested that HCFA divide § 457.995(c) regarding access to emergency services into two separate sections: ''access'' and ''cost sharing for emergency services.''

Response: We agree with the comments about the inconsistency between § 457.995 and certain other substantive sections of the regulation. As noted above, to avoid confusion, we removed proposed § 457.995 from the regulation text and provide an overview in the preamble of the enrollee protections provided throughout the regulation. As for the comments about the cross-references and the need to address certain issues separately, we made every effort to ensure that the cross-references in the final regulation are correct and that issues are adequately addressed in the regulation provisions and explained in the overview now provided in the preamble.

Comment: Many commenters expressed support for HCFA's decision to incorporate the CBRR provisions in the proposed regulations. One

commenter specifically noted that the rights to apply for assistance, to have applications processed in a timely manner, to be informed about benefits, participating providers and coverage decisions, and to have access to a fair process to resolve disputes are basic consumer protections that are critical to ensuring that the program's promise of health care coverage becomes a reality. Another commenter supported the recognition of consumer protections relating to emergency services, participation in treatment decisions, and respect and nondiscrimination. One commenter expressed support for HCFA offering States a good deal of flexibility in the application of these requirements.

Response: We appreciate the support expressed by the commenters.

Comment: Several commenters believed that HCFA exceeded its statutory authority in applying the CBRR to title XXI regulations. Several commenters recommended deleting section § 457.995 because, in their view, there is no basis for implementation of the CBRR in title XXI and, in many cases, States already have Patient Bill of Rights laws. One commenter noted that children in Medicaid expansion programs will be covered under consumer protections available in Medicaid, while children in separate child health programs will be covered under State consumer protection laws. One commenter suggested that, where a conflict exists, or similar requirements are imposed by State law, State law should prevail. This same commenter urged HCFA to consider a ''substantial compliance'' process in these instances. Several other commenters added that they support protecting health care consumers, but that, in their view, requiring the States to implement specific consumer protections for SCHIP could have additional fiscal and administrative impact on their programs.

Response: In establishing the applicant and enrollee protections, we did not simply import the CBRR. We considered our statutory authority, the nature and scope of State laws that might apply to separate child health programs, the need for minimum consumer protection standards, and the States' authority under title XXI to design their own program consistent with the requirements of Federal law. There is statutory authority under title XXI for each enrollee protection included within this final regulation as outlined in the overview and set forth in this part. We describe the statutory authority for each of the enrollee protections in the preamble to each proposed section containing an enrollee protection, in the ''Basis, Scope, and Applicability'' regulation section of each subpart containing one of the enrollee protections, and often in our responses to the specific comments on the sections or subparts of the proposed rule containing the enrollee protections. While we removed § 457.995 from the regulation text, this was done for clarity and to promote consistency, and does not reflect any change in our position regarding the statutory authority for the cited enrollee protections.

States are required to ensure that enrollees in separate child health programs are afforded the minimum consumer protections set forth in this regulation. These minimum protections set a framework within which States may design their procedures consistent with applicable State laws, and we believe it will not be difficult to ascertain whether Federal or State law prevails. If a contractor serving enrollees in a separate child health program is subject to State consumer protection law that is more prescriptive in the areas addressed in this regulation, then in complying with State law, the contractor will comply with this Federal regulation as well. For example, if a State law requires the completion of its review processes for certain health services decisions within a shorter time frame than does this regulation, the State will comply with both Federal and State law when it complies with the shorter State-required time frame. On the other hand, if the Federal time frame requirement is shorter, the Federal requirement will prevail. We have set specific time frames in only a limited number of circumstances to establish the outer boundaries of an efficient and effective system that accomplishes the purpose of the Act. Given the scope of the flexibility afforded States under these rules, we expect that the instances where these Federal rules will impose more stringent standards than those imposed by State law, in those States with an applicable State law, will be limited. In addition, the processes by which certain disputes are resolved are left completely to States' discretion; in such cases, State rules will control. By requiring that a State delineate review procedures in its State plan, we expect the State plan development process, including public notice and comment, will promote State-specific approaches to designing review procedures that reflect local issues and accommodate the State's administrative structure, while ensuring minimum protections to applicants and enrollees.

We will work with States to resolve any questions that might arise in a particular State. No additional compliance process will be instituted beyond that which is already established in subpart B of part 457 under the authority of section 2106(d)(2) of the Act, which requires States to comply with the requirements under title XXI and empowers HCFA to withhold funds in the case of substantial noncompliance with such requirements.

As for the fiscal impact of these requirements, we do not believe that the costs need to be large relative to the cost of services provided to enrollees. The protection of enrollee rights is a critical component of program costs for the provision of child health assistance. States retain broad flexibility to design and implement efficient and effective review processes. Because these regulations do not prescribe any particular review process, States have the flexibility to rely on other already established State review processes for the purpose of resolving disputes that arise in the context of their separate child health programs.

Comment: One commenter noted that, in the preamble to the proposed regulation, we cited a Presidential directive on the CBRR as justification for imposing requirements on State child health plans. This commenter believes that this justification was not sufficient because the proposal conflicted with Executive Order 13132 provisions limiting federal agencies from unnecessarily limiting State flexibility. This commenter expressed the view that HCFA lacks authority to impose the CBRR upon the States to the extent that the CBRR contradicts Congress' unambiguous intent when enacting title XXI and to the extent that it conflicts with E.O. 13132. In this commenter's view, title XXI was designed to provide flexibility to the States in creating and implementing SCHIP programs, and requires the States to describe to HCFA the different aspects of the State plans with minimal restrictions. This commenter argued that, although Congress adopted a general approach intended to allow States to design and experiment with their programs, HCFA has applied the CBRR to remove States' flexibility, and has brought the CBRR to bear most heavily on States that exercised that flexibility. This commenter asserted that a State should be able to tailor its own program to achieve the broad goals of the CBRR and should be able to do so by innovative means tailored to the needs of its population. In this commenter's opinion, we could ''cure'' the regulation (1) by eliminating proposed §§ 457.985, 457.990 and 457.995; and, more importantly, (2) by

evaluating each separate program on its own terms.

Response: As noted above, there is statutory authority for each applicant and enrollee protection outlined in the overview and set forth in this part. In considering how to develop applicant and enrollee protections for this regulation generally, we attempted to balance the important goal of ensuring consumer rights for the SCHIP-eligible population with the flexibility afforded States under title XXI to design their separate child health programs, and we have also considered the value of enrollee feedback through the review process in ensuring compliance with program requirements. In all instances, we have based our regulations on the provisions of title XXI. In our view, the final regulations comply with title XXI and are consistent with the CBRR and E.O. 13132. The regulations establish minimum standards and offer States the opportunity to design their own systems and procedures consistent with these standards. This final regulation does not require a uniform system for providing basic protections to children and their families but rather recognizes and permits significant State-by-State variation.

Comment: One State expressed concern that the level of detail of the CBRR provisions in the proposed regulation severely limits States' flexibility in contracting and hampers their ability to adjust contract provisions that are not working well. Another commenter stated that HMOs and insurers would be less likely to participate in SCHIP if they have to implement both the State requirements and the requirements within the proposed rule, which may have conflicting language.

Response: We appreciate the commenters' concerns and have taken the comments into account in these final regulations. In order to provide all applicants and enrollees the protections established by these regulations pursuant to title XXI, it is essential for contracts to reflect the provisions in this final regulation. However, while we included several important protections within this regulation, we also omitted other details and protections provided by the CBRR, to allow States to design their own review procedures and to minimize any conflict with applicable State law. States have flexibility in the design and implementation of applicant and enrollee protections and we are available to provide technical assistance to States and to facilitate discussions among States as they develop or revise contracts so that they comply with the final regulations. We will also share information about successful State practices among the other States.

Comment: One commenter recommended that HCFA use national standards in applying the principles outlined in the CBRR, such as the Standards on Utilization Management and Member Rights and Responsibilities of the National Committee for Quality Assurance (NCQA). This commenter believed that a standardized system reduces administrative complexity and cost and is more likely to benefit all managed care enrollees. The commenter recommended that the final rule include provisions that allow States to adopt other systems that comport with the BBA and HCFA's Quality Improvement Standards for Managed Care objectives (QISMC), subject to review and approval by HCFA.

Response: We appreciate the recommendation for using the standards issued by NCQA, a private organization that accredits managed care entities, on Utilization Management and Members Rights and Responsibilities. We encourage States to explore such models as a means to develop and implement high quality processes that protect applicant and enrollee rights in a comprehensive manner. While there are advantages to a standardized system, we considered such models and opted to develop minimum standards and permit States the ability to adopt or vary from such models, as long as the standards established by the final regulations are met.

Comment: Several commenters suggested that a provision be added to § 457.995 to require States to include in their managed care contracts provisions that implement all relevant State laws in the area of managed care consumer protections. One of these commenters believed that State law protections should apply to State contracts with entities arranging for the delivery of care that might not be licensed insurance carriers.

Response: While we recognize the importance of the managed care consumer protections contained in many States' laws, we do not require that the contracts comply with State consumer protection laws applicable to certain health plans. The inclusion of such protections in SCHIP contracts is a matter of State law. To the extent that a managed care entity or entity that contracts with a State in connection with its SCHIP program is subject to State insurance or business laws, the entity would be required to comply with applicable State law. We encourage States to include in their contracts with health plans, or other organizations, the applicable patient protections required under State law to the extent they do not conflict with the standards in this regulation.

Comment: One commenter suggested that this overview section also list enrollees' rights to linguistic access to services. This commenter recommended that the preamble explain these rights and provide examples, such as providing bilingual workers and linguistically appropriate materials that include recommendations on how States and contracted entities can comply. Another commenter requested that cultural competency and linguistic accessibility requirements be incorporated throughout the provisions on information, choice of providers and plans, access to emergency services, participation in treatment decisions, respect and nondiscrimination, and grievances and appeals.

Response: We addressed these comments in subpart A along with other comments on §§ 457.110 and 457.130 involving compliance with civil rights requirements and the linguistic appropriateness of information provided to enrollees.

Overview of Applicant and Enrollee Protections in Final Regulation

In this final rule, we require States to provide certain protections for applicants and enrollees in separate child health programs. Outlined below are the protections afforded under this regulation.

- Information Disclosure

Section 457.110 provides that States must make accurate, easily understood, linguistically appropriate information available to families of potential applicants, applicants, and enrollees and provide assistance to families in making informed health care decisions about their health plans, professionals, and facilities. In addition, this section that families be provided information on physician incentive plans as required by the final regulation at § 457.985. We also require, at § 457.65(b), that a State must submit a State plan amendment if it intends to eliminate or restrict eligibility or benefits, and that the State certify that it has provided prior public notice of the proposed change in a form and manner provided under applicable State law, and that public notice occurred before the requested effective date of the change.

Under § 457.350(g), we require States to enable families whose children may be eligible for Medicaid to make informed decisions about applying for Medicaid or completing the Medicaid application process by providing information in writing on the Medicaid program, including the benefits covered

and restrictions on cost sharing. Such information must also advise families of the effect on eligibility for a separate child health program of neither applying for Medicaid nor completing the Medicaid application process. Finally, § 457.525 provides that the State must make a public schedule available that contains the following information: current cost-sharing charges; enrollee groups subject to the charges; cumulative cost-sharing maximums; mechanisms for making payments for required charges; and the consequences for an applicant or enrollee who does not pay a charge, including the disenrollment protections required in § 457.570.

• Choice of Providers and Plans

The rules provide enrollees with certain protections regarding choice of providers and plans through §§ 457.110 and 457.495. Section 457.110 provides that the State must make accurate, easily understood, linguistically appropriate information available to families of potential applicants, applicants, and enrollees, and provide assistance to families in making informed health care decisions about their health plans, professionals, and facilities. Section 457.495 provides that, in its State plan, a State must describe its methods for assuring: (1) The quality and appropriateness of care provided under the plan particularly with respect to well-baby, well-child and adolescent care, and immunizations; (2) access to covered services, including emergency services as defined at § 457.10; (3) and appropriate and timely procedures to monitor and treat enrollees with chronic, complex, or serious medical conditions, including access to specialists experienced in treating the specific medical condition; and (4) that decisions related to the prior authorization of health services are completed in accordance with the medical needs of the patient, within 14 days of the receipt of a request for services.

• Access to Emergency Services

Sections §§ 457.410(b), 457.515(f), 457.555(d), and 457.495 address the right to access emergency services. Section § 457.10 defines ''emergency medical condition'' and ''emergency services'' using the ''prudent layperson'' standard recommended by the President's Advisory Commission and adopted by many States in their consumer protection laws. Section 457.410(b) requires that regardless of the type of health benefits coverage offered under a State's plan, the State must provide coverage for emergency services as defined in § 457.10.

Under § 457.555(d), for targeted low-income children whose family income is from 101 to 150 percent of the FPL, the State may charge up to twice the charge for non-institutional services, up to a maximum amount of $10.00, for services furnished in a hospital emergency room if those services are not emergency medical services as defined in § 457.10. Under § 457.515(f), States must assure that enrollees will not be held liable for cost-sharing amounts beyond the co-payment amounts specified in the State plan for emergency services provided at a facility that does not participate in the enrollee's managed care network. Section 457.495(b) provides that in its State plan, a State must describe its methods for assuring the quality and appropriateness of care provided under the plan particularly with respect to access to covered services, including emergency services as defined at § 457.10.

• Participation in Treatment Decisions

This regulation gives enrollees in separate child health programs the right and responsibility to participate fully in treatment decisions. Under § 457.110, the State must make accurate, easily understood, linguistically appropriate information available to families of potential applicants, applicants and enrollees and provide assistance to families in making informed health care decisions about their health plans, professionals, and facilities. The State must also make available to applicants and enrollees information on the amount, duration and scope of benefits and names and locations of current participating providers, among other items. In addition, under § 457.985, States must guarantee that its contracts for coverage and services comply with the prohibition on interference with health care professionals' advice to enrollees, requirement that professionals provide information about treatment in an appropriate manner, the limitations on physician incentive plans, and the information disclosure requirements related to those physicians incentive plans referenced in that provision. We also require under § 457.110(b)(5) that the State have a mechanism in place to ensure that information on physician incentive plans, as required by § 457.985, is available to potential applicants, applicants and enrollees in a timely manner. We also provide under § 457.130 that the State plan must include an assurance that the State will comply with all applicable civil rights requirements, including title VI of the Civil Rights Act of 1964, title II of the Americans with Disabilities Act of 1990, section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, 45 CFR part 80, part 84, and part 91, and 28 CFR part 35.

• Civil Rights Assurances

In § 457.130, we require in the State plan an assurance that the State will comply with all applicable civil rights requirements, including title VI of the Civil Rights Act of 1964, title II of the Americans with Disabilities Act of 1990, section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, 45 CFR parts 80, 84, and 91, as well as 28 CFR part 35. These civil rights laws prohibit discrimination based on race, sex, ethnicity, national origin, religion, or disability.

• Confidentiality of Health Information

The regulations address this right in § 457.1110, which provides privacy protections to enrollees in separate child health programs. Under that section, the State must ensure that, for medical records and any other health and enrollment information maintained with respect to enrollees (in any form) that identifies particular enrollees; the State and its contractors must establish and implement certain procedures to ensure the protection and maintenance of this information.

• Review Process

Sections 457.1130(b) and 457.1150(b) provide that enrollees in separate child health programs must have an opportunity for an independent external review by the State or a contractor, other than the contractor responsible for the matter subject to external review, of a decision by the State or its contractor to delay, deny, reduce, suspend, or terminate health services, in whole or in part, including a determination about the type or level of services; or for failure to approve, furnish, or provide payment for health services in a timely manner. Section 457.1160(b) sets a time frame under which this process must occur, including an expedited time frame in the case where an enrollee's life or health or ability to attain, maintain or regain maximum function are in jeopardy.

2. Basis, Scope, and Applicability § 457.1100

This subpart interprets and implements section 2101(a) of the Act, which provides that the purpose of title XXI of the Act is to provide funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner; section 2102(a)(7)(B) of the Act, which requires that the State plan

include a description of the methods used to assure access to covered services, including emergency services; section 2102(b)(2) of the Act, which requires that the State plan include a description of methods of establishing and continuing eligibility and enrollment; and section 2103, which outlines coverage requirements for a State that provides child health assistance through a separate child health program. This subpart sets forth minimum standards for applicant and enrollee protections that apply to separate child health programs.

3. Definitions and Use of Terms (Selected Provisions of Proposed § 457.902)

Below we will address the comments on the definitions in proposed § 457.902 and terms used in proposed § 457.985 that relate to the applicant and enrollee protections set forth in this new subpart K.

In proposed § 457.902, we defined contractor as ''any individual or entity that enters into a contract, or a subcontract to provide, arrange, or pay for services under title XXI of the Act. This definition includes, but is not limited to, managed care organizations, prepaid health plans, primary care case managers, and fee-for-service providers and insurers.'' As stated in the preamble to the proposed rule, we defined the term contractor in proposed § 457.902 because it is used most significantly in reference to accountability for ensuring program integrity. However, we also used the term in proposed § 457.985 relating to grievances and appeals. Because the term is now used in subparts I and K, we moved the definition of contractor to § 457.10. We retained the definition of contractor set forth in the proposed regulation. We defined the term ''grievance'' in proposed § 457.902 as ''a written communication, submitted by or on behalf of an enrollee in a child health program, expressing dissatisfaction with any aspect of a State, a managed care or fee-for-service entity, or a provider's operations, activities or behavior that pertains to—(1) The availability, delivery, or quality of health care services, including utilization review decisions that are adverse to the enrollee; (2) payment, treatment, or reimbursement of claims for health care services; or (3) issues unresolved through the complaint process established in accordance with § 457.985(e).'' In the preamble to the proposed rule, we indicated that we ''defined the term 'grievance' to provide some context into the section requiring States to have written procedures for grievances and appeals.'' We defined the term grievance to be consistent with the proposed Medicaid managed care regulations, and to give the States the opportunity to utilize the process that is already in place for the Medicaid program.

As noted earlier, we are now referring to the procedural protections afforded to applicants and enrollees in separate child health programs under this regulation as a ''review process.'' Because the term grievance is no longer used or needed in our provisions regarding the review process, we removed the definition from the regulation text.

Comment: One commenter noted that there is a definition of the term ''grievance,'' but no definition of the term ''appeal.'' Another commenter proposed that we delete the definition of grievance. Several commenters recommended that HCFA ensure that the terms ''grievance'' and ''appeal'' are employed consistently across all programs, including Medicare, Medicaid and SCHIP; these commenters expressed confusion about different uses of the terms ''grievance,'' ''appeal'' and ''complaint'' in these other programs. One commenter also questioned whether the reference to § 457.985(e) was intended to be to § 457.985(d). This commenter recommended that it would be clearer for HCFA to use the terminology used in the proposed Medicaid managed care regulations. Another commenter argued that federal requirements for resolving enrollee complaints and grievances will reduce plan participation because many plans will not be willing to have separate processes for SCHIP enrollees that exceed existing State statutory requirements.

Response: Consistent with our modified approach to requirements in this area, under which we give States flexibility in how they choose to handle many types of disputes, we removed the definition of ''grievance'' from the regulation text. We are now referring to the procedural protections afforded to enrollees in separate child health programs under this regulation as a ''review process.'' Therefore, we did not add a definition of ''appeal.'' We rectified the incorrect cross-reference noted by the commenter in removing the definition of grievance from the regulation text. We agree that, to the extent that we intend to impose Medicaid requirements, we should use the same terminology. In this regulation, however, we determined not to require States to adopt the Medicaid approach to review processes, but we did attempt to use consistent terminology as appropriate.

In order to assure the fair and efficient operation of SCHIP and to ensure that children eligible for coverage under separate child health programs have access to the health care services provided under title XXI, these final rules establish minimum consumer protection standards for applicants and enrollees in separate child health programs balancing a recognition that State law varies in this area with the need to assure certain protections to all children, regardless of where they live. If a contractor serving separate child health program enrollees is subject to State consumer protection law that is more prescriptive in the areas addressed by this regulation, then the contractor, in complying with State law, will comply with this Federal regulation as well.

Comment: Several commenters believed the term ''contractor'' as used in § 457.985(a) is too broad. One commenter said the definition appeared to include every fee-for-service physician that serves a participant in a separate child health program. According to this commenter, this rule makes such a physician's decision to provide Tylenol instead of an antibiotic subject to a grievance procedure. The commenter noted that this policy may discourage physician participation in the program and recommended that the statement exclude those providers to whom the enrollee is not ''locked in'' or whom the enrollee is not otherwise required to utilize. One commenter noted that inconsistency in the use of ''participating contractors'' in § 457.995(g)(1) and ''participating providers'' in § 457.985(a) resulted in confusion. Another commenter believed that the term ''participating providers'' as used in § 457.985(a) needed to be clarified because ''providers'' are generally defined as health care professionals, agencies or institutions. It was also not clear to this commenter why ''health providers'' would be included in this directive. If the term intended was contractors, in the view of this commenter, § 457.985(a) should be amended. If another meaning is intended, the commenter recommended that it be added to the definitions at § 457.902.

Response: We intended to include in the term ''contractor'' any individual or entity that would enter into a contract with a State to furnish child health assistance to targeted low-income children. As reflected in §§ 457.1130(b) and 457.1150(b), we believe enrollees must have an opportunity for an independent, external review of a

determination to delay, deny, reduce, suspend, or terminate health services, in whole or in part, including a determination about the type or level or services; or for failure to approve, furnish, or provide payment for health services in a timely manner. This right applies whether or not the actions mentioned were taken by a State directly or by a contractor. Because we believe that we accomplish this goal with the definition as proposed, we did not modify the definition of contractor. We agree that we created confusion by using ''participating contractors'' and removed § 457.995(g)(1) and its reference to ''participating contractors'' from the regulation text. We also agree that we created confusion by using the term ''participating providers'' and not defining it. Our intent was to ensure that applicants and enrollees receive written notice of decisions that they have the opportunity to challenge through a review process. In § 457.1180, we did not use the term ''participating providers,'' and clarified that a State must assure that applicants and enrollees receive timely written notice of any determinations subject to review under § 457.1130. This could be accomplished, for example, by requiring contracting managed care entities to provide notice either directly or through a provider serving as an agent of that entity.

4. Privacy Protections § 457.1110 (Proposed § 457.990)

We proposed that the State plan must assure that the program complies with the title XIX provisions as set forth under part 431, subpart F—Safeguarding Information on Applicants and Recipients. Moreover, we proposed that the State plan must assure the protection of information and data pertaining to enrollees by providing that all contracts will include guarantees that:

- Original medical records are released only in accordance with Federal or State law, or court orders or subpoenas;
- Information from or copies of medical records are released only to authorized individuals;
- Medical records and other information are accessed only by authorized individuals;
- Confidentiality and privacy of minors is protected in accordance with applicable Federal and State law;
- Enrollees have timely access to their records and to information that pertains to them; and
- Enrollee information is safeguarded in accordance with all Federal and State laws relating to confidentiality and disclosure of mental health records, medical records, and other information about the enrollees.

We proposed that State child health plans are subject to any Federal information disclosure safeguard requirements as well as requirements set forth by their State regarding information disclosure, including use of the Internet to transmit SCHIP data between and among the State and its providers. We also proposed that electronic transmission of data to HCFA must comply with HCFA's policies and requirements regarding privacy and confidentiality of data transmissions. Data transmissions between providers, health plans, and the State would be subject to these requirements. Finally, we proposed to provide that the State must assure that the program will be operated in compliance with all applicable State and Federal requirements to protect the confidentiality of information transmitted by electronic means, including the Internet.

Comment: One commenter strongly supported the inclusion of the Medicaid privacy protections for all SCHIP enrollees and the listed contract requirements regarding information protection and access for enrollees.

Response: We appreciate the commenter's support for the inclusion of the specific language relating to the Medicaid provisions, and we have retained this requirement in the final rule. As for the listed contract requirements regarding information protection and access for enrollees, we have modified slightly our requirements in the final rule. Specifically, we are requiring that for medical records and any other health information maintained with respect to enrollees that identifies particular enrollees, States and their contractors must abide by all applicable Federal and State law regarding confidentiality and disclosure; maintain records and information in a timely and accurate manner; specify the purpose for which information is used and disclosed; and except as provided by Federal or State law, ensure that enrollees may request and receive a copy of their records and request that information be supplemented or corrected. To minimize potential inconsistencies with other Federal regulations, we have removed the specific references to safeguarding electronic data transmissions, including the use of the Internet to transmit SCHIP data. Similarly, we have eliminated the language requiring safeguarding of information because subpart F of part 431 already includes such a requirement. We also clarify that original medical records and other identifiable information must be offered the same level of protection under this rule. These revisions should not be interpreted as a reduction in privacy protections. The protections addressed by the commenter will be afforded to SCHIP applicants and enrollees in separate child health programs, consistent with any other applicable law.

Comment: Two commenters supported the provision requiring that the State plan must provide that all contracts will include guarantees that protect the confidentiality and privacy of minors, subject to applicable Federal and State law. One commenter noted that both State and Federal law contain a variety of provisions that protect the confidentiality of minors. According to this commenter, minor consent statutes in every State accord minors the right to give their own consent for services and often provide confidentiality protection for minors as well. Another commenter believed that confidentiality is critical to ensure that adolescents seek health care services, particularly those related to reproductive health. Both adolescents and providers consistently identify concerns about confidentiality as a major obstacle to health care for adolescents. This commenter urged HCFA to encourage States to ensure that all information, including statements explaining benefits related to reproductive health services and family planning, is provided to enrollees in a confidential manner.

Response: We appreciate these commenters' support. The final rule requires States to abide by all applicable Federal and State laws regarding confidentiality and disclosure, including those laws addressing the confidentiality of information about minors and the privacy of minors, and privacy of individually identifiable health information.

Comment: One commenter recommended that HCFA explain in the preamble language how these privacy protections interact with the privacy standards proposed in October 1999 and the security standards proposed in August 1998. This commenter believed that it is extremely important that all of the protections are harmonized so that the legal interpretations of State and contractor obligations are not unnecessarily confusing. Other commenters noted that the SCHIP protections should be consistent with the rulemaking on Standards for Privacy of Individually Identifiable Health Information (**Federal Register**, November 3, 1999).

One commenter expressed general concern about what they viewed as the lack of consistency across the federal government and the States regarding privacy standards. The commenter noted that dual regulation increases compliance costs, which are ultimately passed on to enrollees and consumers. This commenter specifically suggested that § 457.990(b) be deleted and replaced with a requirement that the State health plan must assure the protection of information and data pertaining to enrollees by providing that all contracts contain identical privacy protections as required under current federal Medicaid contract requirements. If this change was not acceptable, the commenter had alternative suggestions. The commenter first noted that the term ''authorized individuals'' is not defined in § 457.990(b)(2) and § 457.990(b)(3) and suggested that clarification is necessary to ensure that this definition includes all parties needing access to enrollee information for treatment, administration, payment, health care operations and other appropriate purposes consistent with Medicaid standards. Second, this commenter suggested the need to clarify in § 457.990(b)(5) that enrollees' right to access information pertaining to them falls under the Federal Privacy Act of 1974.

Response: We agree with the need to harmonize the SCHIP privacy requirements and other Federal privacy law and policy, and as a result have made several changes to this section. In revising § 457.1110, we examined the proposed Medicaid Managed Care regulation (63 FR 52022), the proposed Medicare+Choice regulation (63 FR 34968), and the proposed requirements set forth under the authority of the Health Insurance Portability and Accountability Act (HIPAA). Additionally, we acknowledge the commenters' point that ''authorized individuals'' was not defined and have deleted it from the final regulations so as not to conflict with Federal or State law addressing permissible disclosures. We also elected not to specify particular Federal or State laws in the final regulation (in order to clarify that we intend to require that States follow all applicable Federal and State laws, including laws and regulations not yet finalized or developed).

Comment: One commenter recommended that HCFA review the American Academy of Pediatrics policy statement, ''Privacy Protection of Health Information: Patient Rights and Pediatrician Responsibilities'' (Pediatrics Vol. 104 No. 4, October 1999).

Response: We appreciate the suggestion that we review the Academy's report, and in our review found that it provided useful information regarding patient rights and pediatrician responsibilities from the Academy's perspective. We encourage providers and others to review the report for additional information on complying with aspects of Federal and State privacy law. For the purposes of this regulation, however, we attempted to harmonize the privacy requirements for separate child health programs with other applicable Federal law, and opted not to adopt additional measures.

Comment: One commenter expressed that § 457.995(f) is awkward in that it excludes confidentiality protections and access rights afforded by other laws, such as local or tribal laws, as well as industry practices that are more protective of confidentiality and provide greater access to health information. This commenter recommended removing the words ''only'' and ''federal and State law'' from § 457.995(f) so that it reads: ''States must ensure the confidentiality of a enrollee's health information and provide enrollees access to medical records in accordance with applicable law (§ 457.990).''

Response: As noted above, we removed § 457.995(f) from the regulation text. We considered this comment, however, with respect to proposed § 457.990(b)(1), (b)(4), and (b)(6). We did not intend the proposed privacy protections to preclude greater local or tribal protections or protections of enrollee access to information. However, depending upon the applicable Federal or State law, it is possible that local or tribal protections could be preempted if the Federal or State law in questions requires a preemption.

Comment: One State indicated that its separate child health program uses a premium assistance program under which it would not contract for health services and therefore would not have a mechanism to enforce the proposed privacy requirements. The State indicated that the mechanism available to impose these requirements is the State Insurance Code, and recommended it be recognized.

Response: States are required to ensure that enrollees in separate child health programs are covered by the minimum privacy protections defined under § 457.1110 of this regulation, regardless of what model is used to deliver services under a separate child health program funded with Federal SCHIP funds. If the premium assistance program is subject to State insurance law that requires the minimum privacy protections consistent with those set forth by this regulation, then the State will be in compliance with this requirement. If a group health plan participating in the State's premium assistance program does not comply with the minimum privacy requirements set forth in this regulation, then the State may not provide SCHIP coverage to separate child health program enrollees through that group health plan.

5. Review Processes §§ 457.1120–457.1190 (Proposed § 457.985)

In the proposed rule, we provided that the State and its participating providers must provide applicants and enrollees written notice of the right to file grievances and appeals in cases where the State or its contractors take action to: (1) deny, suspend or terminate eligibility; (2) reduce or deny services provided under the State's benefit package; (3) disenroll for failure to pay cost sharing. In addition, proposed sections §§ 457.365, 457.495, and 457.565, respectively, required that § 457.985 apply in these specific circumstances. In § 457.361(c), we proposed to require that the State must send each applicant a written notice of the decision on the application and if eligibility is denied or terminated, the specific reason or reasons for the action and an explanation of the right to request a hearing within a reasonable amount of time.

We further proposed in § 457.985(d) that the State must establish and maintain written procedures for addressing grievances and appeal requests, including processes for internal review by the contractor and external review by an independent entity or the State agency. We proposed that these procedures for grievances must comply with the State requirements for grievances and appeals that are currently in effect for health insurance issuers (as defined in section 2791(b) of the Public Health Service Act) within the State. We proposed that procedures must include a guarantee that the grievance and appeals requests will be resolved within a reasonable period of time.

We also proposed that States may elect to use the grievance procedures as described in part 431, subpart E regarding fair hearings for Medicaid applicants and recipients, and the Medicaid grievance and appeal procedures for Medicaid managed care entities, which were set forth in the Medicaid Managed Care proposed rule (63 FR 52022).

We further proposed to require that the States and their contractors must

have in place a meaningful process for reviewing and resolving complaints that are submitted outside of the grievance and appeals procedures as part of the quality assurance process.

In addition, we proposed at § 457.985(e) that the State must guarantee, in all contracts for coverage and services, enrollee access to information related to actions which could be subject to appeal in accordance with the ''Medicare+Choice'' regulation at § 422.206, which prohibits ''gag rules'' and protects enrollee-provider communications, and § 422.208 and § 422.210, which address limitations on physician incentive plans and requirements for information disclosure to enrollees related to those plans.

Following are responses to comments on proposed § 457.985.

Comment: One commenter suggested reorganizing § 457.985 into a more logical format to keep all of the grievance sections in one subpart, with cross-references as appropriate.

Response: We agree with this comment and made appropriate changes to the regulation text to consolidate provisions relating to the review process. In this final regulation, we moved proposed § 457.985(a),(b),(c), and (d) relating to review procedures from subpart I to subpart K, and further revised and clarified these sections.

We retained subparagraph (e) related to provider-enrollee communications and limits on physician incentives as the whole § 457.985 in subpart I. In addition, to improve clarity and to be responsive to comments, we revised that section.

Sections §§ 457.1120–457.1190 are the provisions of the final regulation that represent the reworking of proposed § 457.985. Subpart K now contains most of the provisions relating to the review process, and related provisions in other subparts were revised or deleted as appropriate, to be consistent with the provisions of subpart K.

Comment: Many commenters noted that the lack of minimum standards may cause lengthy time periods for completion of grievance and appeals processes, leaving many enrollees without needed benefits. The commenters believed that, despite the difficulties in establishing a grievance and appeals system that addresses the needs of States, participating contractors, Medicaid, and SCHIP, consistency between the Medicaid and SCHIP procedures is integral to ensuring ease of administration for providers and quality care for enrollees. The commenters noted that because enrollees may transfer between Medicaid and SCHIP at different times, consistency in the application of grievances and appeals processes would eliminate confusion. The commenters recommended that HCFA establish a set of minimum standards the States and participating providers must meet when providing services to enrollees.

Response: In finalizing this regulation, we attempted to strike a balance between State flexibility and enrollee protection consistent with the provisions and framework of title XXI. Rather than requiring Medicaid grievance and appeal requirements for separate child health programs, we adopted core elements for a review process under § 457.1140, and minimum standards for impartial review, under § 457.1150, that States with separate child health programs must meet. We also included, under § 457.1160, specific time frames for review of health services matters and a requirement that review of eligibility and enrollment matters be completed within a reasonable amount of time. We also required, in both cases, that States consider the need for expedited review in appropriate circumstances. We recognize that enrollees will often move between the two programs, and we encourage States to standardize the review processes to the extent possible and rely on Medicaid procedures when it is advisable to do so. In § 457.110, we also require that States notify potential applicants, applicants and enrollees of the procedural protections afforded to applicants and enrollees under the separate child health program. This information should help ease transition between Medicaid and separate child health programs, to the extent that a State chooses to implement different review systems.

Comment: Several commenters believed that grievance and appeal rights are inappropriate for title XXI. Likewise, one commenter believed that SCHIP is not an entitlement program and should not be subject to the grievance procedures required for entitlement programs. In the view of this commenter, HCFA has exceeded its statutory authority in applying the CBRR to the title XXI regulations. One commenter recommended deleting § 457.985 because, in their view, there is no basis for the development of Federal grievance or appeal processes in title XXI, and expressed that States should have the flexibility to develop and apply processes consistent with State law. Another commenter recommended also deleting § 457.365 because they believed we had exceeded our authority, and recommended that in the final rule a reference to all eligibility actions (denial, suspension, and termination) be incorporated in § 457.361(c).

Response: We acknowledge that a separate child health program may be quite different from a State's Medicaid program, and the final regulation does not require States to comply with the Medicaid requirements for grievance and appeal procedures. However, we believe that States operating separate child health programs under title XXI need to establish a review process and comply with minimum standards. While title XXI provides States with a great deal of flexibility, section 2101(a) of the Act provides that the ''purpose of the title is to provide funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner.'' As we asserted in the preamble to the proposed rule, review processes that meet certain minimum standards are essential components of State programs in order to assure that child health assistance is provided in an effective and efficient manner.

Moreover, section 2102(b)(2) requires that a State plan include a description of methods ''of establishing and continuing eligibility and enrollment.'' Procedures to address adverse determinations related to eligibility or enrollment are necessary for ensuring accurate assessments of initial and ongoing eligibility. Section 2102(a)(7)(B) requires a State in its State plan to describe methods used ''to assure access to covered services.'' This section supports our requiring minimal standards for a review process designed to ensure that eligible children have access to covered services, including an expedited review process when there is an immediate need for health services. Section 2103 also requires a specific scope of coverage, and provides the authority for the provisions of the final regulation that seek to assure that a meaningful review process is in place to enforce that access requirement. In the final regulation, eligibility actions and procedural protections related to such actions are described in §§ 457.1130(a), 457.1140, 457.1150(a), 457.1160(a), 457.1170, and 457.1180.

Comment: Several commenters believed States should be allowed to use existing appeal mechanisms for managed care. One commenter noted opposition to Federal requirements that would force the States to alter standard commercial plan contracts (for example, specific appeals criteria or procedures), and urged HCFA to allow States to develop appeals and grievance procedures that are consistent with State insurance regulations. Another

commenter noted that under New York law, Child Health Plus enrollees are granted broad grievance and utilization review rights, as well as external appeal rights for certain determinations. These rights are set forth in detail in the member handbook or contract, and whenever services under the program are denied as not medically necessary, individuals are advised of their appeal rights. This commenter supported allowing States to use existing procedures in lieu of ''Medicaid-style'' procedures. One commenter noted that such an approach is more efficient and that a separate grievance process would be problematic because the costs of it would be subject to the 10 percent administrative cap.

Response: As noted above, we do not require any particular type of review process. States have discretion under these rules to design their own review process and we fully expect that such procedures may vary from State to State while still operating consistent with the requirements adopted here. We recognize, however, that our review process requirements might necessitate changes in standard commercial contracts if such contracts are used in separate child health programs. However, we believe that these changes are likely to be minimal given the broad discretion left to States to establish their review procedures. The regulations provide a minimum level of protection to applicants and enrollees in separate child health programs. To the extent that the State health insurance law on reviews is more stringent than, but also complies with, these requirements and the State or its contractor is subject to that State health insurance law, these rules will not impose any new requirements on States or their contractors. We believe that title XXI ensures that enrollees enjoy some minimal procedural protections regardless of the State in which they reside.

Comment: Several commenters believed that HCFA should clarify that States with separate child health programs have flexibility in setting up appeals processes to determine what appeals are submitted to whom, and do not need to use the Medicaid procedures. For example, the commenters asked for clarification that, if a State uses the health plan or another appeals body for its review process, the State can have grievances sent directly to that entity.

Response: While the use of Medicaid fair hearing procedures for a separate child health program may be efficient for some States as it may eliminate the need for two parallel, and to some extent, duplicative processes, the use of Medicaid procedures is not required in a separate child health program. States may determine the structure of their review process as long as it complies with the minimum standards of this regulation. In order to alleviate any confusion created by the language of proposed § 457.985(c), which noted that States have the option to adopt the Medicaid procedures, we removed that language from the final regulation text.

Comment: One commenter believed that HCFA should clarify that States that have implemented Medicaid expansions must provide applicants and recipients all of the Medicaid protections.

Response: To clarify, States that implement Medicaid expansions must provide applicants and enrollees all of the Medicaid protections. Subpart K only applies to separate child health programs.

Comment: One commenter was concerned about the grievance procedures proposed in the Medicaid managed care regulations. The commenter was concerned about the meaning of the term ''complaint;'' obligations to submit the decision and case file to the State agency; issues arising from the State fair hearing process; the obligation of a managed care entity to issue a notice of intended action; administrative issues regarding how the organization handles complaints and grievances; and continuation of benefits obligations pending appeal.

Response: This commenter's concerns relate to the final regulation for Medicaid managed care, and are beyond the scope of this regulation. We direct interested parties to review the Medicaid managed care final rule, once published, for issues related to Medicaid managed care. Again, subpart K only applies and relates to separate child health programs.

Comment: One commenter requested that HCFA clarify whether a State that has existing laws relating to consumer protections is able to choose its Medicaid procedures instead. A different commenter suggested that the proposed regulations could be read to suggest that HCFA anticipates that States will use both the Medicaid procedures and procedures applicable to commercial health plans. However, this commenter noted that many States do not have the same grievance rules for Medicaid and for commercial health plans, so it may be impossible for managed care entities to meet both sets of requirements. This second commenter assumed that HCFA intended that the use of Medicaid procedures and procedures applicable to commercial health plans would be alternatives, and recommended that HCFA clarify this issue.

Response: As noted above, the use of Medicaid procedures may be efficient for States, but those procedures are not required. State laws applicable to commercial plans may or may not apply to a separate child health program, depending on the provisions of the State law. We expect that States that decide to adopt Medicaid procedures for the review process in their separate child health program will thereby be meeting State law requirements applicable to commercial health plans. However, this rule only establishes core elements and minimum standards for reviews; it does not require States to adopt Medicaid review procedures.

Comment: A few commenters proposed giving States three options to comply with requirements for grievance and appeals procedures: (1) processes that comply with the State grievance and appeal procedures currently in effect for health insurance issuers; (2) the Medicaid rules, systems and procedures; or (3) the Health Carrier External Review Model Act as developed by the National Association of Insurance Commissioners (NAIC).

Response: We appreciate the suggestion on possible models. However, rather than mandating a specific, detailed model that States must follow, we elected instead to establish core elements and minimum standards that reflect the most important aspects of these and other models of patient protection, but give States flexibility over the design of their review process. States can elect to use any model as long as that model addresses each of the core elements and meets or exceeds the minimum requirements set forth by this regulation.

Comment: One commenter supported internal review by the contractor and external review by an independent agency (or the State agency) for appeals related to eligibility, premiums and benefits. Another commenter questioned HCFA's requirement for external and internal review.

Response: We appreciate the support expressed by one of these commenters and acknowledge the diverging opinions on the value of internal and external reviews. In this final regulation, we address external review only, and only with regard to adverse health services matters. Under § 457.1130(b) of this final regulation, we require that a State ensure that an enrollee has the opportunity for external review of a decision by the State or its contractor to delay, deny, reduce, suspend, or terminate health services in whole or in

part, including a determination about the type or level of services; or for failure to approve, furnish, or provide payment for health services in a timely manner. Under § 457.1150(b) we require that States must provide enrollees with the opportunity for an independent, external review that is conducted either by the State or a contractor other than the contractor responsible for the matter subject to external review. States retain the flexibility to determine whether, how, and when to require internal review of these decisions and other kinds of decisions and actions. As for decisions relating to eligibility and disenrollment for failure to pay cost sharing, as described below, a review process that meets core elements outlined in § 457.1140, and applicable standards of §§ 457.1150–1180, will meet the standards set by these regulations. We note that under §§ 457.1150(a), we require that a review of an eligibility or enrollment matter as described in § 457.1130(a), must be conducted by a person or entity who has not been directly involved in the matter under review. This could be a State agency or an independent contractor employed by the State to assist with making eligibility determinations. The State may decide to use the same review process for reviews of eligibility and health services or different process at its discretion.

Comment: One commenter believed that the grievance and appeal system must be designed to provide enrollees with a single point of entry so that, regardless of the subject matter, enrollees file their grievances or appeals with a single State entity. The entity would then be responsible for assigning it to the appropriate reviewing authority.

Response: We recognize the importance of easy and clear access to the review process. In § 457.110(b)(6), we require States to make available to potential applicants, and to provide to applicants and enrollees information on the review process. We also require States to describe the core elements of their review process in their State plans, in part to assure that the public has input into the design of the review process. A single point of entry may be an efficient way to manage the process, particularly if the State decides that different entities will be responsible for reviewing health services and eligibility decisions. However, a single point of entry for the review process is not required by this final regulation.

Comment: One commenter expressed their view that the rules lack sufficient clarity and specificity to ensure that consumers will be accorded adequate due process protections in a State that does not adopt the Medicaid procedures. Accordingly, in this commenter's view, HCFA should outline the basic requirements that must be addressed by a State if it does not choose the Medicaid system. At a minimum, this commenter suggested that these requirements should specify: (1) the content of the written notice; (2) circumstances for continued benefits; (3) processing of grievances and fair hearings including exhaustion requirements; (4) the enrollees' rights and responsibilities during the grievance and fair hearing process; (5) standards for conduct of the hearing; and (6) time frames for expedited and final resolution of grievances and appeals.

Several commenters underscored the need for due process protections in title XXI because of the lack of entitlement to benefits under the program and recommended requiring the Medicaid procedures. One commenter suggested that families need full access to an impartial review process, timely and adequate notices, opportunities to review records and evidence and examine witnesses, the right to represent themselves or to bring a representative, the right to receive a decision promptly, and the right to prompt corrective action. According to this commenter, referencing State laws without applying specific standards will be inadequate to assure equitable treatment of children because some of the laws are loose and vague on matters such as the time period within which a grievance must be resolved, who must hear the appeal, and what notice must be provided.

Another commenter considered it inappropriate to allow States with separate child health programs to use less stringent appeal procedures than required under Medicaid. In the commenter's opinion, SCHIP benefits are targeted at low-income children who, like Medicaid eligibles and recipients, have limited resources. The commenter also noted that while SCHIP is not an entitlement, constitutional due process considerations may apply and require that recipients be afforded minimal protections. If this is the case, the commenter noted that HCFA's current proposed rule may not meet those standards.

Response: We agree with these commenters about the need to set forth minimum standards for procedural protection for States with separate child health programs and provide these protections in §§ 457.1120 through 457.1190 of the final regulation. We adopted many of the commenters' suggestions in these sections of the final regulation, consistent with basic principles of due process. We did not elect to issue requirements for exhaustion of an internal review process, opting instead to require external review of health services matters as described in § 457.1130 and setting maximum time frames for the completion of external review (and internal, if available) in § 457.1160(b). It is within each State's discretion whether and in what conditions internal review will be available. The requirement is that the external review be implemented within 90 days (taking into account the medical needs of the patient). If a State chooses to establish internal review, internal and external review must be completed within that time frame.

We also left to the State's discretion enrollee responsibilities during the review process, although the regulations do set forth basic enrollee rights in § 457.1140. Many of the other protections suggested by the commenters have been addressed throughout §§ 457.1120–457.1180. In these sections, we identify basic procedural protections that are common to most review procedures and that must be provided in the context of separate child health programs. However, in the interest of preserving State flexibility, we left many of the particular design elements related to implementing the protections to the State's discretion.

Comment: One commenter noted that clarification is needed with regard to which types of decisions are subject to which grievance and appeals processes.

Response: We acknowledge the need for clarification about the scope of the requirements relating to review processes and provide it in the final regulation at § 457.1130.

Comment: One commenter noted inequity in the fact that Medicaid expansion programs receive 75 percent FMAP for grievance and appeal activities while separate child health programs are required to pay for these activities within the 10 percent limit for administrative expenditures.

Response: As the commenter indicated, section 2105(c)(2) of the Act places a limit on administrative expenditures. The costs of a review process are subject to the enhanced matching rate under SCHIP and may or may not be considered administrative costs that fall under the 10 percent administrative cap, depending on the nature of the expenditure and the method by which it is paid. While there is no cap on administrative expenditures within Medicaid, such

expenditures consume far less than 10 percent of Medicaid spending. To the extent that a State relies on preexisting review mechanisms, such as those that may be operating under the State's insurance laws, the State's employee health plan or it's Medicaid program, further efficiencies may be realized.

Comment: Several commenters noted the need to include grievance or appeal protections for providers who contract with SCHIP managed care entities or with SCHIP programs on a fee-for-service basis. In the opinion of these commenters, such protections are necessary because many of these ''safety net'' providers cannot afford to have payments withheld, delayed or denied without an expedited process to challenge the actions of the managed care entity or SCHIP program. One State did not support the requirement that providers be given a notice of appeal.

Response: We agree that States need to adopt procedures to address these concerns, but did not include in the proposed regulation or incorporate in this final regulation a requirement that States adopt procedural protections for providers involved in disputes with a State or a contractor. Providers and their advocates may work at the State level to obtain such protections, which States have the flexibility to provide.

Comment: Several commenters recommended that the regulation require that bilingual workers and linguistically appropriate materials used in application assistance, including information relating to grievances and appeals, be made available to ensure that all applicants, including those with limited English proficiency and persons with disabilities (parents and guardians with disabilities) are given notice and understand their rights concerning eligibility. Commenters recommended that the preamble explain the title VI mandate requiring linguistic access to services and give examples of how States and contracted entities can comply. Two commenters asked that both the preamble and regulations make it clear that failure to provide linguistically and culturally appropriate notices and services is grounds for filing a grievance or appeal.

Response: We addressed these comments in subpart A along with other comments on § 457.110 and § 457.130.

Comment: One commenter on § 457.365 noted that the grievance and appeal provisions depend almost entirely on the ability of families to know about and comprehend the nature of the rights available. According to this commenter, organizations upon which families rely for information should be utilized in a family-friendly manner.

Response: In § 457.110 we set forth requirements regarding the availability of accurate, easily understood, linguistically appropriate information for potential applicants, applicants, and enrollees, including information about the review process. We also encourage organizations working with enrollees to provide appropriate assistance to enrollees' families in accessing and navigating the review processes in the State. Additionally, under § 457.1140(d)(1), we require that States provide applicants and enrollees with the opportunity to represent themselves or have representatives of their choosing in the review process.

- State plan requirement § 457.1120 (proposed § 457.985(b)).

Proposed § 457.985(b) required States to establish and maintain written procedures for addressing grievances and appeals. We received many comments to subpart A noting the need for more routinized public input into the development of the State plan. In order to ensure public input into the development of the grievance and appeal procedures and ensure that each State addresses the core elements as it designs its procedures, the final regulations require a State to describe its review process in its State plan, pursuant to § 457.1120. We believe that the combination of State flexibility, minimum Federal standards, and public input will produce systems that provide necessary and appropriate procedural protections without imposing a ''one size fits all'' approach.

- Matters Subject to Review § 457.1130 (proposed §§ 457.361(c), 457.365, 457.495, 457.565, 457.970(d), 457.985(a)).

Eligibility and Enrollment Matters

In § 457.361(c), we proposed to require that States provide an applicant whose eligibility is denied or an enrollee whose enrollment is terminated with an explanation of the right to request a hearing. In proposed § 457.985(a)(1) and (2), we proposed to require that States give applicants and enrollees written notice of their right to file grievances and appeals in cases where the State takes action to deny, suspend, or terminate eligibility, or to disenroll for failure to pay cost sharing. Section 457.365 of the proposed regulation provides that a State must provide enrollees in separate child health programs with an opportunity to file grievances and appeals for denial, suspension or termination of eligibility in accordance with § 457.985. Likewise, § 457.565 of the proposed regulation provided that a State must provide enrollees in separate child health programs with the right to file grievances and appeals as specified in § 457.985 for disenrollment from the program for failure to pay cost sharing. In § 457.970(d), we proposed that a State may terminate the eligibility of an applicant or enrollee for ''good cause'' other than failure to continue to meet the requirements for eligibility. We also provided that enrollees terminated for good cause must be given a notice of the termination decision that sets forth the reasons for termination and provides a reasonable opportunity to appeal the termination decision.

Comment: One commenter indicated that since title XXI is not an entitlement, and therefore children are not entitled to receive services, States should not be required to establish a grievance procedure for children terminated for good cause.

Response: As provided by § 457.1130(a), States must provide enrollees in a separate child health program with an opportunity for a review of a termination of eligibility. The opportunity for a review is an important component of a fair and efficient system that should apply regardless of whether a State believes that it terminated coverage for good cause. Indeed, in such a situation, the purpose of the review would be to allow the enrollee an opportunity to address whether there was good cause to terminate eligibility. Reviews serve an important purpose regardless of whether the coverage provided is considered to be an entitlement. In this final regulation, we removed proposed § 457.970(d) (concerning ''good cause'') because we found it unnecessary and the comments suggested it was potentially confusing. States have the flexibility to identify any number of reasons for terminating an enrollees's eligibility that are consistent with this regulation.

Comment: A few commenters believed that denials, suspensions, and terminations of eligibility should be reviewed under a different process than the internal and external review process set out in § 457.985(b). Several commenters also questioned the appropriateness of utilizing the envisioned grievance and appeals system for decisions regarding failure to pay cost sharing and noted that disenrollment for failure to pay cost sharing should be reviewed under a different process than that set out in § 457.985. One commenter suggested that HCFA require States to use their Medicaid grievance and fair hearing process for eligibility and disenrollment determinations rather than deferring to

internal appeals or State-specific insurance practices.

Response: We agree with the comment that internal and external review consistent with State insurance law may not be the appropriate form of review for eligibility and enrollment matters, but we leave this matter to State discretion, as long as the minimum review requirements are met. A State may use the same process for reviewing eligibility and enrollment decisions as it uses to review health services decisions, or it may use different processes as long as the requirements pertaining to each type of review are met.

Comment: One commenter suggested that HCFA permit applicants and enrollees to file grievances and appeals on the grounds that eligibility determinations were limited or delayed.

Response: We agree that an enrollee should be given the opportunity for a review to address the failure to make a timely eligibility determination. Section § 457.1130(a) requires a review to address such a situation. As for the case of a limitation of eligibility, we believe that denials, reduction, or terminations of eligibility encompass and therefore require an opportunity for review of a decision to limit eligibility.

Comment: One commenter believed that HCFA should modify its regulations to allow reasonable exceptions to grievance requirements, such as when disenrollment or suspension of services results from a State exceeding its allotment.

Response: Under § 457.1130(c), we provide an exception and do not require a State to provide an opportunity for review of an adverse eligibility, enrollment, or health services matter if the sole basis for the decision is a provision in the State plan or in Federal or State law that requires an automatic change in eligibility, enrollment, or a change in coverage under the health benefits package that affects all applicants or enrollees or a group of applicants or enrollees without regard to their individual circumstances. If a State stopped enrolling new applicants because it had spent all of its allotted funds, this would likely be a situation where applicants would not need to be granted a review of the denial of their application. Whether a review would be required would depend on whether the denial was automatic and applied broadly. For example, if a State with limited funds amended its approved State plan to enroll only new applicants with special health care needs, an opportunity for review would be required to provide denied applicants an opportunity to establish that they met the State's enrollment criteria. However, if a State exceeds its allotment and no longer wishes to operate its State plan as approved, the State could either keep the plan in place and, pursuant to the State plan, suspend operation of the program until the beginning of the next Federal fiscal year when additional funding becomes available, or request withdrawal of its State plan by submitting a State plan amendment to HCFA as described in §§ 457.60 and 457.170. Under each of these scenarios, the State would no longer be approving any new applications and as such, reviews of application denials or suspensions would not be subject to the review requirements.

Health Services Matters

In § 457.985(a)(3), we proposed to require the State to provide the right to file grievances and appeals in cases where the State or its contractors take action to ''reduce or deny services provided for in the benefit package.'' In addition, proposed § 457.495 required States to provide enrollees in a separate child health program the right to file grievances or appeals for reduction or denial of services as specified in § 457.985.

We note that the range of health services-related matters required to be subject to review under the final rule is more narrow than the range of matters included within the definition of grievance in the proposed rule.

Comment: Several commenters agreed with the inclusion of § 457.985 in the proposed rule but encouraged modification of the provision to include the right to file a grievance or appeal for the *termination* of services as well as for reduction or denial of services *in whole or in part.*

Response: We agree with this comment, and § 457.1130(b)(1) of the final rule reflects that States must ensure that an enrollee has an opportunity for external review of matters related to delay, denial, reduction, suspension, or termination of health services, in whole or in part, including a determination about the type or level of services.

Comment: A commenter suggested that HCFA should permit applicants and enrollees to file grievances and appeals on the grounds that requests for covered services were limited or delayed.

Response: We agree with the comment, and in § 457.1130(b)(2), we require States to ensure an enrollee has an opportunity for external review of a failure to approve, furnish, or provide payment for health services in a timely manner.

Comment: One commenter noted that the system of review to an independent body should resemble the Medicaid system to the extent possible, in order to ease the burden on providers and to provide continuity for families who move between programs.

Response: We recognize the importance of easing the burden on providers and on families who move between a separate child health program and Medicaid. However, we decided not to require that the external review for separate child health programs mirror the external review process required under Medicaid and to take a more flexible approach consistent with title XXI. We note that some States have chosen to adopt the Medicaid model for reviews in order to have a consistent system of review for their child health programs.

Comment: One commenter indicated that States should provide a timely appeals process that includes direct discussion between the reviewing panel, the patient's physician and the relevant specialists and, if appropriate, an external review by an independent panel of pediatricians experienced in the treatment of the patient's illness.

Response: We agree with the need for a timely process. Under § 457.1140(b), review standards must be timely in accordance with the time frames set forth under § 457.1160. However, under this final regulation, we have not prescribed the type of communication that must be allowed between the enrollee's physician and any review panel. The State has the leeway to require consultation with the enrollee's provider and/or with independent physicians, within the framework of the minimum standards established by these rules.

Comment: One commenter believed that § 457.985(d) should be deleted because the term ''complaint'' is not defined and it is not clear what type of problem constitutes a complaint that would end up outside the grievance and appeals processes. The commenter noted that it is also unclear who would be responsible for making such a determination, and what would happen should the plan decide that a consumer's grievance is really only a ''complaint,'' or vice versa. In this commenter's view, the regulation should not sanction the development or utilization of ''complaint'' systems that fall outside of the grievance and appeals process.

Response: We have deleted proposed § 457.985(d) from the regulation text because we agree that its provisions were unclear. Under the final regulation, we decided only to require

external review of the types of matters described in § 457.1130(b) and to leave States and their contractors the flexibility, within the confines of applicable law, to design review procedures to address any decisions or actions not required to be subject to review under the final regulation.

• Core Elements of Review § 457.1140

Comment: One commenter asserted that HCFA should specify the basic components of a fair hearing, that the State agency responsible for administering the separate child health program, rather than a managed care plan, should retain responsibility for eligibility and enrollment appeals, and that the preamble should encourage States to use the Medicaid fair hearing process for appeals of this kind. According to this commenter, a fair hearing requires the following components: (1) The right to an impartial hearing officer; (2) the right to review records that will be used at the hearing; (3) the right to review evidence and examine witnesses; (4) the right to represent oneself or be assisted by another; and (5) the right to obtain a timely written decision with an explanation of the reasons for the decision. One commenter specifically questioned the rationale for external review of eligibility decisions because those decisions do not require the medical judgement necessary in benefit denials.

One commenter argued that HCFA should adopt minimum standards for States that opt not to use their Medicaid fair hearing processes to ensure that: (1) Appeals and determinations are timely; (2) decisions are made by an impartial hearing officer or person; (3) hearings are held at reasonable times and places; and (4) enrollees have a right to: (a) Timely review their files and other applicable information necessary to prepare for the hearing; (b) be represented or represent oneself; and (c) present testimony and evidence.

Response: While we agree that a State agency review, such as the Medicaid hearing process, may be more appropriate for eligibility and enrollment matters than an internal and external review process developed under an insurance model for health services matters, we determined it was not appropriate to require a State agency review or the Medicaid process for separate child health programs. Instead, these final regulations establish a set of core elements that each State must address when it designates its review process.

Section § 457.1140 incorporates certain suggestions of commenters and requires that States, in conducting a review, ensure that: (a) Reviews are conducted by an impartial person or entity in accordance with § 457.1150; (b) review decisions are timely in accordance with § 457.1160; (c) review decisions are written; and (d) applicants and enrollees have an opportunity to: (1) Represent themselves or have representatives of their choosing in the review process; (2) review their files and other applicable information relevant to the review of the decision; (3) fully participate in the review process, whether the review is conducted in person or in writing, including by presenting supplemental information during the review process; and (4) receive continued enrollment in accordance with § 457.1170.

Comment: Two commenters noted that § 457.361(c) establishes that notices of eligibility decisions must include information about the right of applicants to request a ''hearing.'' Proposed § 457.365, on the other hand, requires States to provide enrollees in separate child health programs with an opportunity to file ''grievances and appeals'' for denial, suspension, or termination of eligibility. These commenters expressed that the multiple reviews suggested by both these provisions of the proposed rule have the potential to create unnecessary administrative expenses for the State and to confuse consumers.

One of these commenters agreed that an applicant should receive an explanation, preferably in writing, if an application is denied. This notice is particularly important when the State uses a variety of ''helpers,'' such as community organizations or other program staff, to assist in the enrollment process. In such situations, the commenter believed that opportunities for misinformation or miscommunication arise. For Medicaid programs, the commenter noted the word ''hearing'' is used to mean the entire State fair hearing process, which is a formal and often lengthy procedure. For separate child health programs, however, a much simpler process, such as review by a senior staff member, is appropriate according to this commenter, given that there is no individual entitlement to benefits under title XXI. This commenter therefore recommended that § 457.361(c) be amended to make it clear that separate child health programs need not employ the Medicaid hearings process and that the State should provide an opportunity for review of such decisions that need not take the form of a hearing.

Response: We recognize that we may have created confusion in using different terminology in §§ 457.361(c) and 457.365. We therefore clarified the review process that will be applicable to adverse eligibility matters in § 457.1140 of the final regulation.

We appreciate the commenter's concern that certain enrollee protections may create an additional administrative expense for some States. However, on balance, the importance of ensuring an enrollee's basic right to a fair and efficient decision regarding eligibility for health benefits coverage justifies the administrative expenses that may be incurred. We note, furthermore, that these final regulations accord States broad flexibility to design review processes that operate efficiently without undue administrative costs. We also appreciate the support for the requirement that notice must be provided in writing.

As for the concerns about the mechanics of the review process, States with separate child health programs do not have to use the Medicaid fair hearing process as the mechanism for review of adverse eligibility and enrollment matters. While an opportunity for review of such matters is required, we left it to the States' discretion to develop the details of the review process for their separate programs, provided the process meets the minimum guidelines set forth in §§ 457.1140, 457.1150(a), 457.1160(a), 457.1170, and 457.1180.

Comment: One commenter asked that HCFA clarify what kinds of procedures will be necessary if a State does not elect to use its Medicaid program or does not have existing State law. One commenter expressed their view that the language of proposed § 457.985 could be interpreted to mean that States without existing State laws requiring internal and external review procedures need not establish any procedures for children enrolled in SCHIP. One commenter stated their view that a choice between Medicaid and State insurance practices is appropriate for issues other than eligibility and disenrollment determinations.

Response: We agree with the comment that our proposed rule could leave children in some States without access to a review process. Since State law varies and some States do not have applicable State laws, in order to assure some minimum standard of protections for all children, we elected to adopt in § 457.1140 minimum standards for conducting reviews of matters identified in § 457.1130. In addition, under §§ 457.1130(b) and 457.1150(b) of this final regulation, a State is required to ensure that enrollees have the opportunity for an external review of certain health services matters,

regardless of whether external review is required under existing State law. Internal reviews are not required by these regulations.

• Impartial Review § 457.1150 (proposed § 457.985(b)).

We proposed under § 457.985(d) that States must establish and maintain written procedures for addressing grievances and appeal requests, including processes for internal review by the contractor and external review by an independent entity or the State agency. We proposed that these procedures must comply with State-specific grievance and appeal requirements currently in effect for health insurance issuers (as defined in section 2791(b) of the Public Health Service Act) in the State.

Comment: One commenter recommended the language at § 457.985(b) be amended to read ''* * * process for internal review by the contractor and independent external review by the State agency * * *.'' This commenter noted it has established a strong independent review process through the State insurance agency. The commenter said that the term ''independent entity'' when used to describe an external review can be interpreted to mean an organization separate from the health plan, but chosen by the plan to do the reviews. The commenter noted that such an arrangement is a clear conflict of interest and indicated that the independence of reviewers can be best assured if the review goes through a neutral State agency. The commenter did not support the NAIC's Health Carrier External Review Model Act.

Response: We appreciate the concern related to the independence of external reviews and have made some modifications to clarify and emphasize the need for an impartial review. To afford States the greatest flexibility in how they implement their external review process, we did not change the language to allow only for external review by a State agency. Consistent with applicable State law, States may choose the entity that will provide external review.

However, under § 457.1150(b), with respect to an external review of health services matters, we did specify that the external review must be independent and conducted by the State or a contractor other than the contractor responsible for the matter subject to external review. To the extent that a State relies on a contractor to conduct such reviews, we expect that States will closely monitor the review process to assure that enrollees are in fact receiving an independent review of their case. We also encourage community organizations and advocates to work closely with families to assist them in navigating the process and to assist the State in identifying issues related to impartiality or conflicts of interest if they arise. We would also like to note that in the review of eligibility and enrollment matters, we require under § 457.1150(a) that a review must be conducted by an impartial person or entity who has not been directly involved in the matter under review.

Comment: One commenter expressed the view that the automatic placement of adverse decisions on the docket of a State fair hearing system is critical to ensuring that the rights of enrollees are fully vindicated, given that the State hearing system is the first time the enrollees receive an independent review. This commenter believed the burden placed on the fair hearing system would not outweigh the Constitutional deficiency of not requiring an automatic filing for a fair hearing after an adverse decision by a non-impartial decision maker. This commenter said that due process concerns are significant, and that enrollees may not truly comprehend that they have a right to an external review despite the best efforts at notice on the part of a State/contractor and assuming they understood the notice of their rights. The commenter believed that automatic referral would reduce these problems, improve public perception about health care decisions given the review by an impartial decision maker, and improve the overall quality of care by encouraging correct treatment decisions at the outset.

The commenter noted that the number of cases proceeding through the State fair hearing process, even with automatic referral, may not be substantial or costly. According to the commenter, in Medicare where automatic referral occurs, the cost is generally less than $300 per case. In 1997, automatic referral resulted in only 1.65 cases per 1000 managed care enrolles. Yet, this commenter stated, access to an outside impartial review is clearly significant for enrollees. The commenter pointed to a Kaiser Family Foundation study on State external review laws that found almost 50 percent of cases considered through an external appeals review overturned the managed care organization's initial decisions. The commenter noted that while States have financial concerns in maintaining a streamlined external review process, such concerns should not overrule an enrollee's right to due process.

Response: As noted above, States do not need to use the State fair hearing process as the independent external review process required under §§ 457.1130(b) and 457.1150(b). External review can be done either by a State agency or a contractor other than the contractor responsible for the matter subject to external review. While we appreciate the commenter's concerns, we elected not to require States with separate child health programs to ensure the automatic referral of adverse decisions to external review. We did, however, adopt minimum procedural protections related to the right to an independent external review in certain situations, consistent with the requirements of due process.

We acknowledge the important information contained within the study cited by the commenter relating to the minimal administrative cost of automatic referral. Given the low cost of such a process, and the added protections and accountability it can provide in some circumstances, we encourage States to consider this option carefully when establishing their review process.

• Timeframes § 457.1160 (proposed §§ 457.361(c), 457.985(b) and 457.995(g)(2)).

In proposed § 457.985(b) and § 457.995(g), respectively, we required that ''resolution of grievances and appeal requests will be completed within a reasonable amount of time'' and that ''grievances and appeals must be conducted and resolved in a timely manner that is consistent with the standard health insurance practices in the State in accordance with § 457.985.'' In proposed § 457.361(c), we provided that ''the State must send each applicant a written notice of the decision on the application and, if eligibility is denied or terminated, the specific reason or reasons for the action and an explanation of the right to request a hearing within a reasonable time.''

Comment: Several commenters noted that the regulation should require that grievances and appeals be decided in a timely fashion. Several commenters asserted that if HCFA decides to maintain its proposed policy on grievances and appeals, strict minimal timelines should be incorporated to ensure that grievances and appeals are conducted in an expedited manner. A different commenter, representing providers, noted that it saw no reason why providers should not be expected to respond within seven days to a request for treatment. That commenter noted that if a State/contractor denied such a request, an enrollee would not receive any new benefits until the final

resolution of the grievance process. A State/contractor could request an extension if it could show the extension would be in the enrollee's best interest. The commenter also believed that HCFA should establish minimum requirements for an expedited procedure to meet the needs of enrollees with severe medical conditions.

This commenter also suggested a requirement of 14 days for a response to a standard grievance. Two commenters acknowledged that suggested time frames are different from the 30 day time frames in Medicare+Choice and Medicaid managed care, but argued that SCHIP enrollees do not have the opportunity to get services elsewhere while they are waiting for the appeal to be resolved. One commenter also noted that when Medicaid and SCHIP individuals are denied treatment, they often have no other recourse except the proposed grievance process. They recommended that HCFA reduce the standard resolution time frame in Medicaid managed care from 30 to 14 days. A different commenter recommended providing for an accelerated process where there is an initial denial of services that poses the risk of serious medical harm.

Several commenters recommended HCFA define maximum time frames, and one commenter recommended HCFA define a ''reasonable'' time period and indicate what maximum time frame would still meet the ''reasonable'' requirement. This second commenter also believed that a lengthy grievance process might be held to violate an enrollee's due process rights. The commenter recommended a maximum time frame of fourteen days for responding to a standard grievance, which may be to review a provider's decision not to provide requested items or services, or to review a provider's decision to deny, suspend, or terminate eligibility, reduce or deny benefits, or disenroll the enrollee for failure to pay cost sharing. The commenter noted that, in many cases, the State/contractor will have an established policy and will not need the full fourteen days. This commenter also noted that even in cases which involve an assessment of an individual's condition, fourteen days is ample time. The commenter advocated that States be allowed to set a time frame of less than fourteen days. The commenter noted that a State/subcontractor does not necessarily save money by delaying resolution of a grievance, because the State remains financially responsible for the care and may have to reimburse the family for expenses incurred prior to enrollment. In certain cases, it might cost the State/subcontractor more to delay treatment because the treatment ultimately required might cost more than the initial requested treatment.

Response: As reflected in the proposed regulation, we agree that a review process should be completed in a timely fashion and, as reflected in the final regulation, that there is a need for minimum timeliness standards. As in the proposed regulation, in § 457.340(c) of this final regulation, we prescribed maximum time frames for eligibility determinations. In this final regulation, we also separately address the timeliness of review of eligibility and enrollment matters, and the timeliness of review of adverse health services matters. Under § 457.1130(a), a State must ensure that an applicant or enrollee has an opportunity for review of a: (1) denial of eligibility; (2) failure to make a timely determination of eligibility; or (3) suspension or termination of enrollment, including disenrollment for failure to pay cost sharing. Under § 457.1160(a), the State must complete the review of the matters described in § 457.1130(a) within a reasonable amount of time. In order to ensure that delays in the review process do not cause a gap in coverage, under § 457.1170, States are required to provide an opportunity for the continuation of enrollment pending the completion of review of a suspension or termination of enrollment, including a decision to disenroll for failure to pay cost sharing. We also require the State to consider the need for expedited review when there is an immediate need for health services. Under § 457.1120 we require States to describe these time frames in their State plans.

In light of concern about the time frames for review of health services matters, we specified a time standard for the resolution of external reviews (and any internal review if available), including expedited time frames, in § 457.1160(b). Health services matters subject to review include: (1) delay, denial, reduction, suspension, or termination of health services, in whole or in part, including a determination about the type or level of services; or (2) failure to approve, furnish, or provide payment for health services in a timely manner. Reviews must be completed in accordance with the medical needs of the patient. Under the standard time frame, a State must ensure that external review of a decision as described in § 457.1150(b) is completed within 90 calendar days of the date an enrollee initially requests external review (or an internal review if available) of the decision. Under the expedited time frame, a State must ensure that internal review (if available), or external review as required by § 457.1150(b), is completed within 72 hours of the time an enrollee initially requests a review if the enrollee's physician determines that operating under the standard time frame could seriously jeopardize the enrollee's life or health or ability to attain, maintain or regain maximum function. If the enrollee has access to internal and external review, then each level of review must be completed within 72 hours (for a possible total of 144 hours). The State must provide an extension to the 72-hour period of up to 14 days if the enrollee requests such an extension. This provision for an expedited time frame reflects our agreement with the comments calling for an accelerated process if the passage of the standard time allowed for the process poses serious harm to the enrollee.

Comment: One commenter recommended that in order to ensure an enrollee's rights to obtain timely medical care, both the internal grievance process and the State fair hearing process should conclude within 90 days. They noted that current State fair hearing regulations require a State to complete the fair hearing within 90 days from the request for the hearing.

This commenter also stated the proposed regulations did not provide guidance on what happens if a State/contractor fails to meet its grievance and appeals procedures and recommended HCFA establish minimum standards to address noncompliance. The commenter said that even with standard health insurance practices, there is no guarantee that a State/contractor will comply in a timely fashion. The commenter recommended the approach of the Medicare+Choice regulations that provide that an managed care organization's failure to meet initial determination and reconsideration time frames is automatically considered an adverse decision that is referred to the next level of review. This commenter advocated that HCFA adopt this policy in the SCHIP regulations as well. The commenter believed this position, coupled with minimum time frames, would best protect enrollees' rights without causing undue hardships on providers.

This commenter also recommended that HCFA should grant States the authority to impose monetary fines upon participating contractors for failure to meet time frames as a means to enforce compliance. The commenter recommended amending § 457.935 to include language requiring States that contract with participating contractors to impose sanctions if the State determines that a participating

contractor fails to provide medically necessary services that the participating contractor is required to provide, or fails to meet specified time frames.

Response: Under § 457.1160(b)(1), we defined the standard time frame for the review of a health services matter. A State must ensure that external review, as described in § 457.1150(b), is completed within 90 calendar days of the date an enrollee requests external review (or internal review if available). We expect that an enrollee will be provided notice of the outcome of the review within the 90-day time frame. As described above, the final regulations provide an opportunity for expedited review, under § 457.1160(b)(2).

We do not see a need to create further compliance standards or enforcement mechanisms beyond those that have been already implemented pursuant to section 2106(d)(2) of the Act. This provision requires States to comply with the requirements under title XXI and allows HCFA to withhold funds from States in the case of substantial noncompliance with such requirements. It is within the State's discretion to determine whether to include in contracts monetary fines for failure to meet time frames as a means to enforce compliance with required time frames. States are, of course, required to administer their programs in accordance with the law and their State plans. At a minimum, therefore, States are responsible for monitoring the conduct of their contractors and ensuring that their conduct fully complies with these regulations and the State plan.

Comment: One commenter noted that the regulations do not make clear the relationship between the internal and external review processes. In most instances, State law requires exhaustion of the internal review process (as does the NAIC model) before a consumer can move to the external review. However, a number of States also include timelines and exceptions (for example, when the harm has already occurred) to ensure that this does not impede the process unnecessarily, and the commenter recommended that HCFA do the same. Another commenter expressed that HCFA should prohibit States from requiring exhaustion of internal plan processes. If HCFA does not prohibit such a requirement, according to this commenter, it must include adequate safeguards so that plans do not benefit from delay at the enrollee's expense. Specifically, HCFA should require that States set strict timetables for review and determination, assure aid continuing pending a determination, and provide for expedited review when the failure to authorize a required level of treatment or to provide or continue a service jeopardizes the enrollee's health.

Another commenter noted that some States may require an enrollee to exhaust a plan's internal grievance procedures before allowing access to the State fair hearing process and believed these State practices may violate enrollee's due process rights. The commenter requested that we ensure that enrollees not be required to exhaust internal grievance procedures before accessing the State fair hearing process. The commenter was concerned that the internal grievance process does not provide impartial review. They noted that even under the proposed Medicaid managed care regulations, the individual conducting the internal review, while not familiar with the case file, is employed by the plan provider. According to this commenter, this individual has an inherent pecuniary interest to resolve the grievance in favor of the State/contractor. Because the enrollee is effectively denied benefits until the process is complete, States/contractors have little incentive to resolve the grievances quickly. The commenter argued that if the enrollee is forced to exhaust the internal grievance process, the enrollee would be deprived of due process. The commenter recommended HCFA amend § 457.985(b) to permit the enrollee to request a State fair hearing on a grievance at any time.

Response: It should be noted that the State fair hearing process is the process for external review under Medicaid managed care. While States have the option to use the Medicaid fair hearing process to satisfy the requirement for external review under this regulation, we do not require this process for separate child health programs. We also left to States the discretion to decide whether plans should be required to conduct an internal review and whether, if they do so, they should require exhaustion of internal plan processes before an enrollee could pursue an external review. Nonetheless, we believe it is important for enrollees to have certain minimum procedural protections consistent with due process and have therefore adopted minimum requirements and time frames for reviews. Under §§ 457.1130(b) and 457.1150(b), States must provide enrollees access to an external review of certain health services matters. Pursuant to § 457.1150(b), review decisions must be independent and made by the State or a contractor other than the contractor responsible for the matter subject to external review. While a State may require an enrollee to request and pursue an internal review, any procedures developed by the State or its contractors relating to internal review cannot interfere with the enrollee's right to complete the external review within 90 days from the date a review (either internal or external) is requested.

- Continuation of Enrollment § 457.1170 (Proposed § 457.985(c)).

We received a number of comments urging us to require continuation of enrollment pending completion of the review.

Comment: Several commenters were particularly concerned that children receiving benefits under separate child health programs may be as poor as those who receive Medicaid in other States, and believed that States should therefore be required to continue assistance at pre-termination levels until an impartial review of a child's case is completed. Multiple commenters argued that even though the SCHIP statute does not include the same entitlement as Medicaid, constitutional due process may require minimal protections that are not included in the proposed rule. A few commenters underscored the need for due process protections in title XXI because of the lack of entitlement to benefits under the program and recommended the Medicaid procedures. Other commenters echoed the specific suggestion that there be circumstances in which benefits continue for current recipients pending appeal.

One commenter specifically recommended that continuation of services pending appeal should occur in circumstances where termination or reduction of services poses serious medical harm and to provide for an accelerated process where there is an initial denial of services that pose such harm. Two commenters noted that continuation of benefits is especially important for enrollees terminated for failure to pay cost sharing or other financial contributions, which do not relate to an enrollee's actual eligibility for benefits. These commenters recommended that HCFA require that enrollees must affirmatively request termination of benefits. One commenter recommended the language at § 457.985 be amended by adding: ''Unless an enrollee affirmatively requests that items or services not be continued, the State/contractor must continue the enrollee's benefits until the issuance of the final grievance decision or State fair hearing decision.''

Response: We appreciate the commenters' concerns about the need to protect children enrolled in separate child health programs who have very limited incomes and whose families have little or no ability to pay for costly but necessary health services, and we

have adopted provisions related to continuation of enrollment, as described below.

Section § 457.1170 requires States to ensure the opportunity for continuation of enrollment pending review of termination or suspension of enrollment, including a decision to disenroll for failure to pay cost sharing. A State may limit the time period during which such coverage is provided by arranging for a prompt review of the eligibility or enrollment matter. However, not all such matters are subject to the continuation of coverage requirement; under § 457.1130(c), a State is not required to provide an opportunity for review of such a matter if the sole basis for the decision is a provision in the State plan or in Federal or State law requiring an automatic change in eligibility, enrollment, or a change in coverage under the health benefits package that affects all applicants or enrollees or a group of applicants or enrollees without regard to their individual circumstances. Therefore, if the situation is such that the State is not required to provide an opportunity for review according to this regulation, then the State does not have to provide the opportunity for continuation of enrollment. We also note that the costs of providing continued benefits are not administrative costs subject to the 10 percent cap, regardless of the outcome of the review. With respect to disenrollment due to failure to pay cost sharing, we have added a provision in § 457.570(b) to ensure that the disenrollment process afford an enrollee the opportunity to show that the enrollee's family income has declined prior to disenrollment for nonpayment of cost-sharing charges. Finally, we note that services need not be continued pending a review of a health services matter, although, as described above, expedited review processes must be available when the physician or provider determines that the enrollee's life or health or ability to function will be jeopardized.

• Notice § 457.1180 (proposed §§ 457.361(c), 457.902, 457.985(a), and 457.995(g)).

In the preamble to the proposed regulation at § 457.985, we stated that a State should make available to families of targeted low-income children information about complaint, grievance, and fair hearing procedures. We proposed to require that the State and its ''participating providers'' give applicants and enrollees written notice of their right to file grievances and appeals. In proposed § 457.361(c), we required that ''the State must send each applicant a written notice of the decision on the application and, if eligibility is denied or terminated, the specific reasons or reasons for the action and an explanation of the right to request a hearing within a reasonable amount of time.''

Comment: A commenter on § 457.340 and § 457.361 expressed strong support for the inclusion of rules setting minimum standards for procedural fairness, including the basic due process protections of opportunity to apply without delay, assistance in completing applications, required notices, and timely eligibility decisions. This commenter noted that notice is a basic due process right required by the U.S. Constitution under well-settled law whenever a citizen is denied a public benefit, and that the rules should specify that notice must be timely. The commenter also recommended that for current recipients, notice of an adverse action should be in advance of the action. In the commenter's view, the notice should inform people of the right to be accompanied by a representative as well as the right to appeal.

Another commenter on § 457.340 suggested that rules should specify that notice of denial or adverse action must be timely and in advance of adverse action for current benefits, with benefits continuing through an appeal process, should an appeal be initiated. In this commenter's view, notice should be required to be timely and include information regarding the right to appeal and to be accompanied to the hearing by a representative.

Response: We appreciate the support for these standards, and the effort to establish rules that are consistent with due process requirements. We agree that notice should be timely and have added this to the language at § 457.1180. As in the proposed regulation, the final regulation sets forth maximum time frames for eligibility determinations in § 457.340(c). Additionally, in the case of redetermination of eligibility, under § 457.340(d), the regulations require that in the case of a suspension or termination of eligibility, the State must provide sufficient and timely notice to enable the child's parent or caretaker to take any appropriate actions that may be required to ensure ongoing coverage. For example, if continued enrollment pending a review is allowed when a review is requested before enrollment is scheduled to end, notice of the action and the opportunity for review must be provided to the family with enough advance notice to allow the family to request the review and to keep their child enrolled pending review. Under § 457.1160(a), a State must complete review of an eligibility or enrollment matter within a reasonable amount of time. In setting time frames, the State must consider the need for expedited decisions when there is an immediate need for health services. Additionally, under § 457.1140(d)(2) we require that applicants and enrollees have a right to timely review of their files and other applicable information relevant to the review of the decision. Under this final regulation, however, while States have discretion to determine the precise timing of the notices in light of their own administrative needs, the notice of the outcome of the review must be delivered within the prescribed overall time frames for review.

We addressed the issue of notice in § 457.1180, in which we required States to ensure that applicants and enrollees are provided timely written notice of any determinations required to be subject to review under § 457.1130 that includes the reasons for the determination; an explanation of applicable rights to review of that determination, the standard and expedited time frames for review, and the manner in which a review can be requested; and the circumstances under which enrollment may continue pending review. Section § 457.340(d) cross references the notice requirements of § 457.1180. Under § 457.1140(d)(1) States must ensure that applicants and enrollees have an opportunity to represent themselves or have representatives of their choosing in the review process. As for continuation of enrollment, the regulations require States under § 457.1170 to continue enrollment pending the completion of a review of a suspension or termination of enrollment including a decision to disenroll for failure to pay cost sharing.

Comment: One commenter requested clarification on the relationship of § 457.361(c) to the requirement in § 457.360(c). This commenter expressed a belief that every family should be notified of the status of each child's application and whether: (1) the application for enrollment in the separate child health program has been approved; (2) the application has been referred to Medicaid; or (3) the child had been found ineligible for both programs.

Response: The State must provide written notice of any determination of eligibility under §§ 457.340(d) and 457.1180. So, if the State determines that an applicant is ineligible for coverage under its separate child health program, the State must provide written notice of that determination. If the application is a joint Medicaid/SCHIP application, a State would then need to

comply with Medicaid requirements in providing notice about an applicants eligibility for Medicaid. In the case of termination or suspension of eligibility, under § 457.340(d), the regulations require that the State must provide sufficient notice to enable the child's parent or caretaker to take any appropriate actions that may be required to ensure ongoing coverage.

Comment: One commenter suggested that HCFA limit requirements that providers furnish notice to enrollees. According to this commenter, some States permit treating providers and managed care plans to provide SCHIP applications and perform direct marketing activities, but some do not. In this commenter's view, providers in States that do not allow such involvement would have no opportunity to provide applicants with notices. This commenter also suggested that HCFA not require treating providers who serve SCHIP enrollees under a managed care contract to provide notice to enrollees. This commenter suggested that this would be more appropriately done by the managed care plan in the member information materials. Yet another commenter strongly supported the language in § 457.985(a) requiring that participating providers, in addition to States, provide applicants and enrollees written notice of their right to file grievances. This commenter argued that it is important that applicants and enrollees have access to information about their grievance and appeal rights at the points of direct contact—which is most often the provider.

Response: In § 457.1180, we specified the general content of the notice but left States the flexibility to determine who should provide the notice. We do not consider general statements of procedure in initial member information materials sufficient notice of the review process available for a particular determination.

Comment: One commenter noted that enrollees should be informed of their right to appeal any adverse decision to an independent body.

Response: We agree with the need for enrollee notification. Section 457.1180 requires timely notice of determinations subject to the review process specified in this regulation, including matters subject to external review by an independent entity.

• Application of Review Procedures where States Offer Premium Assistance for Group Health Plans § 457.1190.

We note that under this final rule we use the term ''premium assistance program'' instead of ''employer-sponsored insurance model'' to describe a situation where a State pays part or all of the premiums for an enrollee or enrollees' group health insurance coverage or coverage under a group health plan. Our responses to comments referring to ''employer-sponsored insurance models'' reflect this change in terminology.

Comment: One commenter noted that for coverage provided under a premium assistance program, the State does not contract for services and is not in a position to dictate compliance with requirements included in § 457.985.

Response: We acknowledge that States' SCHIP programs do not have direct authority over group health plans that may be providing coverage under premium assistance programs. At the same time, there is no basis for providing children fewer procedural protections because they may be enrolled in a premium assistance program under SCHIP. In order to balance these concerns, the regulations provide States flexibility so that they may offer premium assistance through plans that do not meet the review standards set out in these regulations, as long as families are not required to enroll their children in these plans. Under § 457.1190, a State that has a premium assistance program through which it provides coverage under a group health plan that does not meet the requirements of §§ 457.1130(b), 457.1140, 457.1150(b), 457.1160(b), and 457.1180 must give applicants and enrollees the option to obtain health benefits coverage through its direct coverage plan. The State must provide this option at initial enrollment and at each redetermination of eligibility.

Comment: One State expressed concern that the level of detail of the CBRR provisions in the proposed regulation inhibits States from developing effective premium payment systems for premium assistance programs. Another commenter noted that under premium assistance programs, there is no contractual mechanism through which to enforce requirements, given that the employer, not the State, contracts with the health plan. This commenter said that requiring States to apply these requirements under such a model will mean that employer plans will never qualify for premium assistance. This commenter assumed that HCFA did not intend these requirements to apply to premium assistance programs, and recommended that HCFA clarify its position.

Response: While we appreciate the commenters' concern, States must comply with the requirements of this regulation regardless of whether coverage is provided through a group health plan. Under title XXI, the standards and protections apply to all children receiving SCHIP coverage, including children receiving SCHIP-funded coverage through group health plans. We do recognize that States do not have direct contractual relationships with premium assistance programs and accounted for this constraint in § 457.1190.

K. Expanded Coverage of Children Under Medicaid and Medicaid Coordination

The proposed regulations discussed in this subsection are changes to Medicaid regulations found in parts 433 and 435. These rules apply to Medicaid only.

Section 2101 of the Act requires that States coordinate child health assistance under title XXI with other sources of health benefits coverage for children. Section 2102(b)(3)(B) of the Act requires that children found through the SCHIP screening process to be potentially eligible for Medicaid under the State's Medicaid plan shall be enrolled for such assistance.

Section 4911 of the BBA, amended by section 162 of the DC Appropriations Act, Public Law 105–100, enacted on November 19, 1997, established a new optional categorically-needy eligibility group known as ''optional targeted low-income children.'' The law provides for an enhanced Federal matching rate for Medicaid services provided to children eligible under this group. The BBA also provides for States to receive this enhanced Federal matching rate for services to children who meet the definition of ''optional targeted low-income children'' and whom the State covers by expanding an existing Medicaid eligibility group (for example, poverty-related children). ''SCHIP'' itself is not a new or separate Medicaid eligibility group. A State that implements a Medicaid expansion program under SCHIP, may expand eligibility to the new optional Medicaid eligibility group just mentioned, expand eligibility to optional targeted low-income children through expanding an existing Medicaid eligibility group, or implement a combination of the two options. We note that Medicaid expansion programs are subject to all the rules and requirements set forth in title XIX of the Act and its implementing regulations, and the State Medicaid plan. Section 4912 of the BBA added a new section 1920A to the Act to allow States to provide Medicaid services to children during a period of presumptive eligibility.

In addition to modifications to the proposed regulations made in response

to the comments discussed below, we have amended part 436 of this subchapter to reflect the changes made by the BBA to eligibility for Medicaid in Guam, Puerto Rico and the Virgin Islands. The changes made to part 436 by these regulations mirror those made to part 435, governing Medicaid eligibility in the States, District of Columbia, the Northern Mariana Islands and American Samoa. Specifically, new § 436.3 corresponds to new § 435.4; modifications to §§ 436.229, 436.1001 and 436.1002 correspond to the modifications made to §§ 435.229, 435.1001 and 435.1002; and new §§ 436.1100–1102 correspond to new §§ 435.1100–1102. Our failure to amend part 436 in the proposed rules was an oversight. There are no distinctions in policy or requirements with respect to the regulations pertaining to the States, District of Columbia, the Northern Mariana Islands and American Samoa versus those pertaining to Guam, Puerto Rico and the Virgin Islands. And any changes made to the proposed rules pertaining to expanded coverage of children under Medicaid and Medicaid coordination in these final regulations are also reflected in the amendments to part 436. We received a number of general comments on this subpart and one comment relating to the screen and enroll requirements set forth in subpart C which is relevant to this section. We will address these comments below.

1. General Comments

Comment: With respect to the screen and enrollment requirements of section 2102(b)(3)(B) of the Act, two commenters recommended that the regulations require that, even if a separate application for a separate child health program (as opposed to a joint application with Medicaid) is used, the application form and any supporting verification must be transmitted to the appropriate Medicaid office for processing without further action by the applicant to initiate a Medicaid application. One commenter recommended that if an applicant for a separate child health program, who has been determined potentially eligible for Medicaid, is to be required to take any additional steps in order to apply for Medicaid, the Medicaid agency must inform the family of the action required.

Response: The obligations of the State agency or contractor responsible for determining eligibility for a separate child health program with respect to the requirement that children screened potentially eligible for Medicaid be enrolled in that program are discussed in the preamble to subpart C and are set forth in § 457.350 of the final regulations.

We have added a new § 431.636 to clarify the obligations of the State Medicaid agency with respect to the screen-and-enroll requirement. Specifically, we have added this section to require that State Medicaid agencies adopt procedures to complete the Medicaid application process for, and facilitate the enrollment of, children for whom the Medicaid application and enrollment process has been initiated pursuant to § 457.350(h)(2) in subpart C of these regulations. Such procedures shall ensure (1) that the Medicaid application is processed in accordance with the regulations governing eligibility for Medicaid in the States and District of Columbia, 42 CFR part 435 or the regulations governing Medicaid eligibility in Guam, Puerto Rico and the Virgin Islands, 42 CFR part 436, as appropriate; and (2) that the applicant is not required to provide any information or documentation that has been provided to the State agency or contractor responsible for determining eligibility under the State's separate child health program and forwarded by such agency or contractor to the Medicaid agency on behalf of the child pursuant to § 457.350(h)(2) of this subchapter.

When a State Medicaid agency receives an application—either a joint SCHIP-Medicaid application or separate Medicaid application—for a child screened potentially eligible for Medicaid, the application must be processed in accordance with title XIX, Medicaid regulations, and the State plan. If the Medicaid agency has all the information it needs to process the Medicaid application, no further follow-up is needed until the State is ready to make a final eligibility determination. If additional information is needed, the agency must contact the family and explain what is needed to complete the Medicaid application process.

If a separate application is used, the State Medicaid agency should promptly follow up with the family as soon as it receives information about the child. If the family has not already completed a Medicaid application, the Medicaid agency should provide the family with an appropriate application and inform the family about any additional steps that must be taken or additional information which must be provided in order to complete the Medicaid application process.

Comment: We received a number of comments urging HCFA to seek statutory changes expressly authorizing more flexibility for States. The suggested changes include allowing States more flexibility under presumptive eligibility and a longer period of presumptive eligibility, and giving States the option of establishing their own filing unit rules by eliminating the prohibition on deeming income from anyone other than from a parent to a child or a spouse to a spouse.

Response: We will take these suggestions into consideration in developing future legislative proposals.

Comment: One commenter also suggested that States be allowed to ''outsource'' (privatize) Medicaid eligibility determinations.

Response: We have previously considered requests by States to privatize Medicaid eligibility determinations. Medicaid policy requires that most activities included in the eligibility determination process be performed by employees of a public agency. Therefore, we do not have the discretion to allow States to ''out source'' Medicaid eligibility determinations.

Comment: One commenter indicated that the regulations should clarify that, if a State chooses to provide continuous eligibility under section 1902(e) of the Social Security Act, as added by section 4731 of the BBA, it must provide continuous eligibility for all children who are eligible for Medicaid.

Response: These regulations do not address changes made by the BBA that are not directly related to title XXI. A separate Notice of Proposed Rulemaking will be published addressing other changes made by the BBA to the Medicaid program.

Comment: One commenter noted that, for new eligibility groups, States often have no eligibility determination experience and may be reluctant to ease the documentation and verification requirements for fear of increasing the error rate under the Medicaid eligibility quality control (MEQC). Two organizations supported waiving MEQC errors for new eligibility groups created by PRWORA, which we explained in the preamble to the proposed rule we would be willing to do. One State asked if the MEQC waiver of errors extended to the section 1931 group or to child-only groups.

Response: Section 1903(u) of the Act, which provides the statutory basis for MEQC, does not give HCFA the authority to grant a grace period for eligibility errors. However, the statute does provide that a State can request a waiver of a Federal financial disallowance relating to eligibility errors on the basis that it made a good faith effort to meet the 3-percent error rate limit. Implementing regulations at 42 CFR 431.865 include sudden and

unanticipated workload changes that result from changes in Federal law as an example of circumstances under which HCFA may find that a State made a good faith effort. Under this authority, we have offered in the past to waive errors in cases of pregnant women and infants that occurred during the first 6 months in which States were implementing a new Federal law mandating coverage of these groups (the Medicare Catastrophic Coverage Act of 1988). Our intent in offering this waiver was to encourage States to expand coverage to pregnant women and infants without the concern of fiscal penalties. It also allowed States time to develop the experience necessary to accurately determine Medicaid eligibility for these new groups.

We recognize that the sweeping changes in law brought by welfare reform and title XXI presented similar opportunities as well as many challenges to States. The PRWORA of 1996 established a new eligibility category for families with children, which is not linked to welfare. The BBA of 1997 established a new coverage group for children and established an enhanced match rate to encourage expanded coverage of children under this new group or other existing Medicaid groups. HCFA has encouraged States to take advantage of the title XXI funds to expand coverage for children, and we have encouraged States to simplify their enrollment procedures to reduce barriers to participation for all Medicaid-eligible children and their families. As we explained in the preamble to the proposed rule we would waive MEQC eligibility errors attributable to the coverage of these new and expanded groups of children and families. Our intent is to give States the opportunity to gain experience in making accurate eligibility determinations for these newly covered children without relying on lengthy applications or requiring excessive eligibility verification requirements due to State concern with fiscal penalties.

Although we are making MEQC waivers available, States are unlikely to face MEQC fiscal penalties. States have maintained a national error rate below 2-percent for over ten years. In addition, welfare reform implementation problems have resulted in eligible children and families being denied or terminated from Medicaid rather than ineligible children and families being enrolled in Medicaid. MEQC errors arise when a State makes erroneous payments. There are likely very few cases in which such erroneous payments have been made due to section 1931 implementation.

Finally, we have encouraged States to develop alternative MEQC programs because this option can be a particularly effective means of focusing on error-prone areas. Thirty-one States are currently operating alternative MEQC programs either as pilots or as part of a section 1115 waiver (most since 1994). For the duration of the pilot or section 1115 waiver, the error rates for these States are frozen at below 3 percent, and the States are not subject to disallowances.

In terms of the scope of the waiver, we agree with the comment that any waiver should apply to the section 1931 group as well as other groups pertaining to children. Therefore, we have determined that we should grant a MEQC waiver for eligibility errors directly attributable to the implementation of: (1) coverage for children and families determined eligible after October 1, 1996 for Medicaid under section 1931 or section 1925 of the Act; (2) coverage for children determined eligible after October 1, 1997 for Medicaid under the optional group of targeted low-income children under age 19 (or reasonable groups of these children) who are otherwise ineligible for Medicaid, have a family income below a certain State-specified level and have no health insurance (see section 1902(a)(10)(A)(ii) of the Act); and (3) coverage of children determined or redetermined eligible for Medicaid after October 1, 1997 whose disabled status is protected under section 4913 of the BBA. This waiver does not apply to children covered under separate child health programs because the MEQC process does not apply to such programs.

We are limiting the waivers to one year beginning with the publication date of this final rule rather than the first year of implementation of the legislation as we did previously with new coverage of pregnant women and infants. In recent months, we have learned that many States still need to adapt their systems to assure that children eligible for Medicaid under section 1931 receive Medicaid. Thus, at this point, limiting the waivers to one year after implementation of the statute would not accomplish the intended purpose. Since many States are still expanding coverage to children and are adopting new approaches to simplify their eligibility and redetermination procedures, waivers effective for one year following the promulgation of these regulations should enable States to finish updating their systems to ensure effective implementation of section 1931 eligibility without incurring financial penalties as they do so. The incidence of erroneous Medicaid denials and terminations should diminish as States gain experience, and that MEQC waivers should encourage States to move quickly to make the changes necessary to determine eligibility consistent with the requirements of the law.

Because the regulations currently provide the basis for waiver requests and the good faith waiver process is administrative in nature, it is not necessary to amend regulations at 42 CFR 431.865 to include this specific waiver exclusion. In the unlikely event that a State experiences an error rate above 3 percent over the next year, we will provide that State with instructions for applying for a good faith waiver.

Comment: One commenter expressed strong support for the conclusion that all Medicaid rules, including those related to EPSDT, apply to Medicaid expansion programs.

Response: We appreciate the support. A State that expands eligibility for children under Medicaid must apply all the title XIX rules to the expansion population including children for whom the State receives enhanced FMAP at the title XXI rate.

2. Disallowance of Federal Financial Participation for Erroneous State Payments (§ 431.865)

We proposed to amend § 431.865(b)to exclude from the definition of ''erroneous payment'' payments made for care and services provided to children during a period of presumptive eligibility. We received no comments on this section and are implementing it as proposed. We are, however, also making a technical amendment to the definition of erroneous payment in § 431.865(b). Specifically, we are changing the word ''in'' in paragraph (1) to ''if'' so that the definition reads: ''Erroneous payments means the Medicaid payment that was made for an individual or family under review who—(1) Was ineligible for the review month or, if full month coverage is not provided, at the time services were received.'' The use of ''in'' instead of ''if'' clearly was a typographical error.

3. Rates of FFP for Program Services (§ 433.10)

We proposed to add a new paragraph (c)(4) to state that the FFP for services provided to uninsured children under an SCHIP Medicaid expansion program would be the enhanced FMAP established by SCHIP. We received no comments on this section and are implementing it as proposed.

4. Enhanced FMAP Rate for Children (§ 433.11)

Section 4911 the BBA, as amended by section 162 of Public Law 105–100, authorized an increase in the Federal medical assistance percentage (FMAP) used to determine the Federal share of State expenditures for services provided to certain children. Federal financial participation for these children will be paid at the enhanced FMAP rate determined in accordance with § 457.622, provided that certain conditions are met. The State's allotment under title XXI will be reduced by payments made at this enhanced FMAP, consistent with § 457.616.

Under proposed § 433.11(b) in order to be eligible to receive Federal payments at the enhanced FMAP, a State must:

(1) Not adopt income and resource standards and methodologies for determining a child's eligibility under the Medicaid State plan that are more restrictive than those applied under the State plan in effect on June 1, 1997;

(2) Have sufficient funds available under the State's title XXI allotment to cover the payments involved; and

(3) Maintain a valid method of identifying services eligible for the enhanced FMAP.

Under § 457.606, the State must also have an approved State plan in effect. For purposes of determining whether an income or resource standard or methodology is more restrictive than the standard or methodology under the State plan in effect on June 1, 1997, we proposed to compare it to the standard or methodology that was actually being applied under the plan on June 1, 1997. For purposes of this section, a pending Medicaid State plan amendment that would establish a more restrictive standard or methodology, but that has an effective date later than June 1, 1997, would not be considered ''in effect'' on June 1, 1997, regardless of when it was submitted. However, while States that adopt more restrictive income or resource standards or methodologies than those in effect on June 1, 1997 would not be eligible for enhanced FMAP, the proposed rule provided that if a State drops an optional eligibility group entirely, the prohibition against receiving enhanced FMAP does not apply.

In § 433.11, we proposed that the enhanced FMAP would be used to determine the Federal share of State expenditures for services provided to three categories of children. The first category for whom the enhanced FMAP would be available in the proposed rule was the new group of ''optional targeted low-income children'' described in proposed § 435.229. Under this category, the State would expand eligibility to a new group of children.

Under the second category the State would cover children who meet the definition of ''optional targeted low-income child'' by expanding coverage under existing Medicaid groups. Thus, a State would not need to adopt the new eligibility group of optional targeted low-income children in order to receive the enhanced match. As long as the newly-covered children under an expanded Medicaid group met the definition of targeted low-income child, including the requirements that they be uninsured and not eligible for Medicaid under the State plan in effect on March 31, 1997, the State could receive the enhanced match for them. (Note that the State could claim the regular FMAP for children covered by an expansion, who do not meet the definition of optional targeted low-income children because they are covered by private insurance.) These first two categories of children are reflected in proposed § 433.11(a)(1), which implements sections 1905(u)(2)(C) and 1902(a)(10)(A)(ii)(XIV) of the Act.

The third category for whom the State may receive the enhanced FMAP consists of children born before October 1, 1983 who would not be eligible for Medicaid under the policies in the Medicaid State plan in effect on March 31, 1997, but to whom the State subsequently extends eligibility by using an earlier birth date in defining eligibility for the group of poverty-level-related children described in section 1902(l)(1)(D) of the Act. The enhanced FMAP is available for services to children in this third category even if they have creditable health insurance, as defined at 45 CFR 146.113. We note that, as the statutory phase-in of poverty-level-related children under age 19 proceeds, the numbers of children in this third category will diminish; by October 1, 2002, all the children in this category will be included in the mandatory group of children described in section 1902(l)(1)(D) of the Act, and State spending for services to them will be matchable at the State's regular FMAP.

Concerning the second category above, it is unlikely that Congress intended to provide enhanced FMAP for services provided to children who, although not eligible under the policies in effect in the Medicaid State plan in effect on March 31, 1997, became eligible after that date due solely to a Federal statutory change or an already scheduled periodic cost-of-living increase. These types of changes are inherent in the State plan policies in effect on March 31, 1997. Enhanced FMAP will be available only when children are made eligible due to a change in State policy, which expands eligibility to cover previously ineligible children.

Federal payments made at the enhanced FMAP rate reduce the title XXI appropriation in accordance with section 2104(d) of the Act. Thus, HCFA must apply such payments against a State's title XXI allotment until that allotment is exhausted. After the title XXI allotment is exhausted, expenditures will be matched at the State's regular FMAP rate.

Comment: Three commenters objected to our proposal to allow a State to receive enhanced FMAP if the State drops an optional eligibility group that was covered on March 31, 1997 because the maintenance of effort provision in the statute was intended to prevent States from dropping Medicaid coverage in order to put children in a separate child health program. The commenters argued that our proposal is contrary to the statutory intent.

Response: We appreciate the commenters' concern. However, while the maintenance of effort provisions of the statute explicitly speak to more restrictive income and resource standards and methodologies, they do not reference other conditions of eligibility or other State actions, such as dropping optional eligibility groups.

Prior to the enactment of SCHIP, the overwhelming majority of children under 19 who were eligible for Medicaid under an optional category received coverage under the States' medically needy programs. By that time, children previously covered under other optional groups largely had been subsumed by the mandatory poverty-related eligibility groups. Given the further recent expansion of eligibility under the poverty-related groups and through the use of less restrictive income and resource standards and methodologies permitted under section 1931 of the Act, the number of children in these other groups has further diminished. Most of the children who remain covered under an optional group—other than those in a medically needy group—fall into the optional categorically needy group of children eligible under section 1902(a)(10)(A)(ii)(I) of the Act, often referred to as ''Ribicoff children.''

Under section 1902(a)(10)(C)(ii)(I) of the Act, States cannot drop only children under 19 from their medically needy programs. It is highly unlikely that a State would drop its entire

medically needy program in order to place a few children in SCHIP. Since the number of children in other optional eligibility groups is very small, there is little financial incentive for States to drop any of these groups either. The only reason a State might potentially drop one of its optional groups would be to cover the children under another, broader group. Such simplifications likely will promote enrollment of children and should not be discouraged.

In this context, two additional points are pertinent to understanding our decision. First, under the proposed regulation, States that eliminate an optional eligibility category will not be able to receive the enhanced FMAP for any children who would have been eligible for Medicaid under the eligibility standards for the dropped group in effect on March 31, 1997. Thus, the proposed regulations do not permit States to transfer any children from coverage under an optional Medicaid group to a stand-alone SCHIP program or to receive enhanced FMAP for such children under a Medicaid expansion. States simply would not be precluded from receiving the enhanced match for other children in its SCHIP program, which is what would happen if a State reduced coverage under a mandatory category.

Second, all Ribicoff children under age 19 will be subsumed by the mandatory poverty-level group by October 1, 2002, so any savings generated from eliminating this group, which, as discussed above would be nominal, would also be short-lived.

Accordingly, there is little incentive for States to eliminate any non-medically needy eligibility categories under Medicaid. In the highly unlikely event that a State nonetheless chose to do so, the number of children who would be affected would be minimal. The small number of potentially (but unlikely to be) affected children does not justify restricting States' ability to simplify their Medicaid programs in this regard.

Comment: One commenter requested that we add ''with or without creditable insurance'' to § 433.11(a)(2), to make it clear that the enhanced FMAP is available for children born before October 1, 1983 who would be described in section 1902(l)(1)(D) of the Act (the poverty-level children's group) if they had been born on or after that date and would not qualify for medical assistance under the State plan in effect on March 31, 1997, even if they have creditable health coverage.

Response: We have added ''with or without group health coverage or other health insurance coverage'' to § 433.11(a)(2) to clarify this point.

5. Optional Targeted Low-Income Children (§ 435.229)

Section 4911 of the BBA amended the Social Security Act by adding a new section 1902(a)(10)(A)(ii)(XIV) to establish an optional categorically-needy group of children referred to as ''optional targeted low-income children,'' and described in section 1905(u)(2)(C) of the Act. Section 1905(u)(2)(C), as added by section 4911 of the BBA, was subsequently revised by section 162 of Public Law 105–100 and, in the process, ''(C)'' was changed to ''(B)''. In an apparent oversight, no conforming change was made to section 1902(a)(10)(A)(ii)(XIV) of the Act to refer to section 1905(u)(2)(B), rather than to 1905(u)(2)(C). Since it appears that this was simply a drafting error, we consider the reference to 1905(u)(2)(C) in this section to be a reference to 1905(u)(2)(B).

Section 1905(u)(2)(B) defines an optional targeted low-income child as a child who meets the definition of a targeted low-income child in section 2110(b)(1) of title XXI of the Act and who would not qualify for Medicaid under the Medicaid State plan in effect on March 31, 1997. Because only a child under 19 can qualify as a targeted low-income child under section 2110(b)(1) of the Act (see section 2110(c) of the Act), to be covered as an optional targeted low-income child under Medicaid, an individual also must be under 19 (even though individuals between 19 and 21 can qualify for Medicaid under other eligibility groups).

The very specific cross reference in section 1905(u)(2)(B), to section 2110(b)(1), for the definition of an optional targeted low-income child indicates that the Medicaid definition of ''optional targeted low-income child'' is based only on section 2110(b)(1). Thus, the definition of ''targeted low-income child'' for Medicaid does not include the exclusions described in section 2110(b)(2) that apply to the definition of ''optional targeted low-income child'' for separate child health programs under title XXI. Specifically, the following groups of children are excluded from eligibility for a separate child health program under title XXI, but are not excluded from eligibility for Medicaid: (1) children who are inmates of public institutions and patients in institutions for mental diseases (IMD); and (2) children who are eligible for health benefits coverage under a State health benefits plan on the basis of a family member's employment with a public agency in the State.

Under existing Medicaid eligibility rules, there is no eligibility exclusion for children who are inmates of a public institution, patients in an IMD, or children eligible for health benefits coverage under a State health benefits plan on the basis of a family member's employment with a public agency in the State, although restrictions on Federal financial participation (FFP) apply under some circumstances. Specifically, no FFP is available under Medicaid for services provided to inmates of public institutions or patients in an IMD. We note that under Medicaid, if, under section 1905(a)(16) of the Act, a State elects to cover inpatient psychiatric services for individuals under age 21, FFP is available for services furnished to children in psychiatric facilities for individuals under age 21 that meet certain standards and conditions (see § 441.150ff).

Turning to the proposed rule, the definition of optional targeted low-income child at section 1905(u)(2)(B) of the Act excludes children who would have been eligible for medical assistance under the State plan in effect on March 31, 1997 on any basis, thus including those who would have been eligible under a State's medically needy group. This exclusion was set forth in proposed § 435.229(a)(2). We explained in the preamble to the proposed rule that we would interpret section 1905(u)(2)(B) to exclude children who would have been eligible as medically needy based on their current financial status without a ''spend-down,'' an amount that can be spent on medical care before the child can become eligible. However, children who would have been eligible for Medicaid under the State plan in effect on March 31, 1997 only after paying a spend down would not be excluded, because they would not have been eligible for Medicaid until the spend-down had been met.

We explained in the preamble for proposed § 435.229 that the regular Medicaid financial methodologies that govern eligibility of children in a State, that is, the income and resource methodologies under the State's AFDC plan in effect on July 16, 1996, must also be used to determine whether a child is eligible under the new group of optional targeted low-income children. However, a State may use the authority of section 1902(r)(2) of the Act to adopt less restrictive methods of determining countable income and resources for this group.

States that choose to cover a group of optional targeted low-income children also must apply uniform income and

resource eligibility standards for the group throughout the State. States also are required to provide all services covered under the plan, including EPSDT services, to optional targeted low-income children. Indeed, as we explained in the preamble to the proposed rule, States must apply all regular Medicaid rules. We thought it worth emphasizing that this includes Medicaid rules pertaining to immigration status.

States are not required to provide coverage to all children who meet the definition of an optional targeted low-income child. As with the existing Medicaid rules, eligibility under the optional group can be limited to a reasonable group or reasonable groups of such children. However, this option, reflected in proposed § 435.229(b)(2), does not allow States to limit a group by geographic location because of the requirement in section 1902(a)(1) of the Act that a State plan be in effect in all political subdivisions of the State. Also, as explained in the preamble to the proposed rule, we do not consider it reasonable to limit a group by age other than by those age groups specified by Congress in section 1905(a)(1) and referenced in section 1902(a)(10)(A)(ii). We believe that if Congress had intended to allow other uses of age to establish categories of eligibility, the statute would not have specified any age groups. We note that, in the case of the group of optional targeted low-income children, a State does not have the option to cover a reasonable category of children under age 21 or 20, because for purposes of defining ''targeted low-income child'' for title XXI programs and ''optional targeted low-income child'' for Medicaid expansion programs, ''child'' is defined in section 2110(c)(1) of the Act as a child under age 19. (This age limitation applies to all optional targeted low-income children, not only those in the optional group.)

Section 2110(b)(1)(B) refers to the Medicaid applicable income level, which, under 2110(b)(4), explicitly recognizes potentially different levels based upon the age of a child. The income standard for the optional categorically-needy group of optional targeted low-income children may be different for infants, children under age 6, and children between ages 6 and 18 (that is, under age 19) if the State's Medicaid applicable income levels for these age groups differ.

We did not propose to require or allow States to apply eligibility-related private health insurance substitution provisions, such as periods of uninsurance, to the ''optional targeted low-income children'' group because such eligibility conditions are inconsistent with the entitlement nature of Medicaid and are therefore not permitted by the Medicaid statute in the absence of a section 1115 waiver.

Finally, we explained in the preamble to the proposed rule that States are obligated to continue to provide services to eligible optional targeted low-income children after its title XXI allotment is exhausted, unless the Medicaid State plan is amended to drop the group of optional targeted low-income children. Once the title XXI allotment is exhausted, Medicaid matching funds are available for these children at the regular matching rate rather than the enhanced rate.

Comment: Two commenters requested that the Medicaid regulations include a definition of optional targeted low-income child because they found the cross-reference to the title XXI regulations is confusing. They also noted that some provisions in title XXI, such as permitting States to limit eligibility by geographic region, do not apply in Medicaid.

Response: We accept the commenters' request to clarify the definition of optional targeted low-income child in the Medicaid regulations, rather than cross-reference § 457.310(a). In proposed § 435.229(a), the cross-reference to § 457.310(a) resulted in the inclusion of some provisions of the definition of targeted low-income child that only apply to separate child health programs. Therefore, we have removed the cross-reference in § 435.229 to § 457.310(a) and added a Medicaid-specific definition of optional targeted low-income child to § 435.4 (for the States, the District of Columbia, the Northern Mariana Islands, and American Samoa) and to § 436.3 (for Guam, Puerto Rico, and the Virgin Islands). The definition of optional targeted low-income child applies to the optional categorically needy group of optional targeted low-income children under § 435.229 and § 436.229 for whom the enhanced FMAP is available.

Specifically, §§ 435.4 and 436.3 include the following children in the definition of ''optional targeted low-income child'': (1) children who have family income at or below 200 percent of the Federal poverty line for a family of the size involved; (2) children who reside in a State which does not have a Medicaid applicable income level, as that term is defined in § 457.10; or (3) children who reside in a State that has a Medicaid applicable income level and has a family income that exceeds the Medicaid applicable income level for the age of such child, but not by more than 50 percentage points; or (4) children whose income does not exceed the effective income level specified for such child to be eligible for medical assistance under the policies of the State plan under title XIX on June 1, 1997. As noted, we have revised the definition to clarify that an optional targeted low-income child that resides in a State that has a Medicaid applicable income level may have family income that exceeds the Medicaid applicable income level, but does not exceed the effective income level that has been specified under the policies of the State plan under title XIX on June 1, 1997. This provision effectively allows children who became eligible for Medicaid as a result of an expansion after March 31, 1997 but before June 1, 1997 may be considered optional targeted low-income children. It also means that children who were below the Medicaid applicable income level, but were not Medicaid eligible due to financial reasons that were not related to income (for example, due to an assets test) can be covered by SCHIP.

Furthermore, the definition in § 435.4 and § 436.3 requires that an optional targeted low-income child must not be: (1) Eligible for Medicaid under the policies of the State plan in effect on March 31, 1997; or (2) covered under a group health plan or under health insurance coverage unless the health insurance coverage program is offered by the State, has been in operation since before July 1, 1997, and the State receives no Federal funds for the program's operation. A child would not be considered covered under a group health plan if the child did not have reasonable geographic access to care under that plan. These criteria mirror the provisions of proposed § 457.310, except those that apply only to separate title XXI child health programs.

Comment: Three commenters indicated that children who were covered by section 1115 demonstration projects with a limited benefit package should not be considered to have been recipients of Medicaid, and therefore should not be excluded from the definition of optional targeted low-income children. They urged HCFA to provide a regulatory clarification so that children eligible under a section 1115 demonstration project that only provided a limited range of services would be eligible for enhanced matching under the definition of an ''optional targeted low-income child.''

Response: We agree with the commenters and have therefore revised the definition of the term ''Medicaid applicable income level'' at § 457.10, to address their concerns. Specifically, in § 457.10 we clarify that, for purposes of the definition of ''Medicaid applicable

income level,'' the term ''policies of the State plan'' includes policies under most section 1115(a) Statewide demonstration projects; however, the term does not include section 1115(a) demonstrations that granted coverage to a new group of eligibles but which did not provide inpatient hospital coverage, or which limited eligibility both by allowing only children who were previously enrolled in Medicaid to qualify and imposing premiums as a condition of participation in the demonstration. This exception does not apply to waivers that extended the time period or conditions under which an individual could receive transitional medical assistance.

The exclusion of children eligible for medical assistance under the State plan in effect as of March 31, 1997 was intended to ensure that States did not transfer coverage of low-income children who would have been eligible under their Medicaid program at the regular Federal matching rate to the enhanced matching rate established by SCHIP. However, this provision does not specifically address the treatment of children who could have been covered under a section 1115 demonstration project in effect on March 31, 1997.

Our understanding is that the provision was not intended to preclude States from claiming enhanced matching funds for expanded coverage to children whose income is below the demonstration project eligibility thresholds in place as of March 31, 1997, if those programs did not offer comprehensive coverage or limited eligibility to individuals who were previously enrolled in Medicaid and imposed premiums as a condition of participation. Demonstrations that had these types of restrictions are significantly more limited in scope (either in coverage or eligibility) than ''traditional'' Medicaid programs. Our experience with SCHIP and our increased understanding of how this provision is affecting States' ability to expand coverage have led us to agree with the commenters that an overly broad interpretation of the exclusion contained in section 1905(u)(2)(B) of the Act would be contrary to the intent of the statute. Furthermore, because enrollment in these types of demonstrations is relatively small, any supplantation of State dollars would be minimal. Therefore, we have clarified this provision in the final rule.

Comment: Several commenters supported the proposal that EPSDT policies apply to optional targeted low-income children. One of these commenters also agreed that there should not be a required period of uninsurance for these children and encouraged HCFA to explicitly prohibit such a requirement.

Response: EPSDT applies to this group of children because they are in a Medicaid group and entitled to all benefits and protections provided to children under Medicaid law and regulations. With respect to periods of uninsurance, we have not included the prohibition against requiring a period of uninsurance in the regulation text for this provision since periods of uninsurance are already prohibited by the Medicaid statute and regulations. We believe that this prohibition is inherent in the entitlement nature of Medicaid. States may not impose conditions of eligibility other than those specifically allowed by statute, regulation, or waiver. We will work with States that have such policies in place to assure that the requirements of the statute are met.

6. Furnishing a Social Security Number (§ 435.910)

Section 1137(a)(1) of the Act requires applicants and recipients of Medicaid to furnish the State with their social security number(s) as a condition of eligibility. While the United States Supreme Court in *Bowen v. Roy*, 476 U.S. 693 (1986) upheld this requirement, it did so in a plurality decision in which some of the Justices held that the challenge was moot because the claimant had obtained a social security number. As a result, that decision did not foreclose someone else with religious objections to applying for a social security number from challenging the constitutionality of section 1137(a)(1) of the Act. The Religious Freedom Restoration Act of 1993 also raised questions about the requirements of section 1137(a)(1) of the Act in cases involving religious objections.

Consequently, in 1995 HCFA announced a policy that permits States to obtain or assign alternative identifiers to eligible individuals who object to obtaining an SSN on religious grounds. This policy was adopted in order to enable States to administer Medicaid in the most efficient manner possible. In § 435.910 of the proposed rule we attempted to accommodate the purpose of section 1137(a)(1) with the Constitution's protection of freedom of religion and the dictates of the 1993 Act by permitting alternative identifiers.

We received no comments on this section. However, we wish to clarify that the statute requires an SSN of applicants and recipients only. States may request but may not require other individuals in the household to provide their SSN's. For example, if application is made on behalf of a child and the parent is not applying, the State may request the parent's SSN but must note that the SSN is not required and may not deny the child's eligibility if the parent does not provide his/her own SSN.

7. FFP for Services and FFP for Administration (§ 435.1001 and § 435.1002)

Section 1920A of the Act allows States to provide services to children under age 19 during a period of presumptive eligibility. The implementation of this provision is discussed below. In accordance with this new option, we proposed to amend § 435.1001 to provide FFP for necessary administrative costs incurred by States in determining presumptive eligibility for children and providing services to presumptively eligible children. In § 435.1002 we proposed to provide FFP for services covered under a State's plan which are furnished to children during a period of presumptive eligibility. We received no comments on either of these sections and are implementing them as proposed.

8. Exemption From the Limitation on FFP for Categorically Needy, Medically Needy, and Qualified Medicare Beneficiaries (§ 435.1007)

Section 162 of Public Law 105–100 amended 1903(f)(4) of the Act to add the optional group of optional targeted low-income children and other children for whom enhanced FMAP is available to the list of those who are exempt from the limitations on FFP found in section 1903(f). All previous citations in section 1903(f) were references to Medicaid eligibility groups, whereas this new provision adds not an eligibility group per se, but rather children on whose behalf enhanced FMAP is available.

With certain exceptions, section 1903(f) limits FFP to families whose income does not exceed 133⅓ percent of the amount that ordinarily would have been paid to a family of the same size without any income or resources, in the form of money payments under the Aid to Families with Dependent Children program. This provision effectively limits the use of the authority under section 1902(r)(2) to expand eligibility through the use of less restrictive income and resource methodologies for those groups that are not exempt from the limitation.

However, section 162 of Public Law 105–100 could result in extending the exemption from the FFP limitation to children other than (1) children in the optional eligibility group of optional

targeted low-income children or (2) children in other groups already exempt from the FFP limitation. If this were to occur, a conflict with the comparability requirements of section 1902(a)(17) and § 435.601(d)(4) of the Medicaid regulations could arise. If, for example, a State sought to use more liberal income methodologies for counting income in determining the medically-needy eligibility of optional targeted low-income children than used for counting income in determining the medically-needy eligibility of other children, the comparability requirements would be violated.

Because the exemption from the FFP limit did not override the comparability requirement of the Medicaid statute, we proposed to continue to apply the FFP limitations described in § 435.1007 to all children who are covered as medically-needy and to any optional categorically-needy group which is subject to the FFP limit. States may use more liberal methodologies under section 1902(r)(2) of the Act for the optional categorically-needy group composed exclusively of optional targeted low-income children without reference to the FFP limitations of section 1903(f). We received no comments on this section and have adopted this portion of the rule as proposed.

9. Presumptive Eligibility for Children (Part 435, Subpart L)

Section 4912 of the BBA added a new section 1920A to the Act to allow States to provide services to children under age 19 during a period of presumptive eligibility, prior to a formal determination of Medicaid eligibility. We set forth the basis and scope of subpart L in proposed § 435.1100.

Under section 1920A of the Act, only a ''qualified entity'' can determine whether a child is presumptively eligible for Medicaid on the basis of preliminary information about the child's family income. In accordance with section 1920A(b)(3)(A) of the Act, we define a qualified entity in § 457.1101 as an entity that is determined by the agency to be capable of making determinations of presumptive eligibility for children and that— (1) furnishes health care items and services covered under the approved Medicaid State plan and is eligible to receive payments under the approved plan; (2) is authorized to determine eligibility of a child to participate in a Head Start program under the Head Start Act; (3) is authorized to determine eligibility of a child to receive child care services for which financial assistance is provided under the Child Care and Development Block Grant Act of 1990; or (4) is authorized to determine eligibility of an infant or child to receive assistance under the special nutrition program for women, infants, and children (WIC) under section 17 of the Child Nutrition Act of 1966. In addition, the Benefits Improvement and Protection Act of 2000 (BIPA) (P.L. expanded this list of qualified entities to include an entity that (5) is an elementary or secondary school, as defined in section 14101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 8801); (6) is an elementary or secondary school operated or supported by the Bureau of Indian Affairs; (7) is a State or Tribal child support enforcement agency; (8) is an organization that is providing emergency food and shelter under a grant under the Stewart B. McKinney Homeless Assistance Act; (9) is a State or Tribal office or entity involved in enrollment in the program under Part A of title IV, title XIX, or title XXI; or (10) is an entity that determines eligibility for any assistance or benefits provided under any program of public or assisted housing that receives Federal funds, including the program under section 8 or any other section of the United States Housing Act of 1937 (42 U.S.C. 1437 *et seq.*) or under the Native American Housing Assistance and Self Determination Act of 1996 (25 U.S.C. 4101 *et seq.*); or (11) any other entity the State so deems, as approved by the Secretary.

Finally, section 1920A(b)(3)(B) also authorizes the Secretary to issue regulations further limiting those entities that may become qualified entities. We note that, although State agency staff can receive and process applications for regular Medicaid, they cannot make presumptive eligibility determinations unless they themselves meet the definition of a ''qualified entity'' under § 457.1101.

We note that the date that the completed regular Medicaid application form is received by the Medicaid State agency is the Medicaid filing date for Medicaid eligibility, unless State agency staff are located on site at the qualified entity, in which case the Medicaid filing date is the date that the onsite State agency staff person receives the completed form. Alternatively, the State can opt to consider the date the determination of presumptive eligibility is made as the Medicaid application date.

In accordance with section 1920A(b)(2), we also proposed in § 435.1101 that the period of presumptive eligibility begins on the day that a qualified entity makes a determination that a child is presumptively eligible. The child would then have until the last calendar day of the following month to file a regular Medicaid application with the Medicaid agency. If the child does not file a regular Medicaid application on time, presumptive eligibility ends on that last day. If the child files an application for regular Medicaid, presumptive eligibility ends on the date that a determination is made on the regular Medicaid application.

Finally, proposed § 435.1101 defined ''applicable income level'' as the highest eligibility income standard established under the State plan which is most likely to be used in determining the Medicaid eligibility of the child for the age involved. We note that there may be different applicable income levels for children in different age groups. For example, the standards for presumptive eligibility might be 133 percent of the Federal poverty level (FPL) for children under 6 and 100 percent FPL for children age 6 through 19, if these were the highest standards applicable to children of the specified ages under a State's Medicaid plan.

We proposed in § 435.1102(a) to provide limited flexibility to States in calculating income for purposes of determining presumptive eligibility. We also explained in the preamble to the proposed rule that under § 435.1102(a) we would allow States to require that qualified entities request and use general information other than information about income, as long as the information can be obtained through the applicant's statements and is requested in a fair and nondiscriminatory manner. With respect to income, in States that adopt the most conservative approach to presumptive eligibility, the qualified entity would use gross family income. The qualified entity would compare gross family income to the applicable income level, as defined in § 435.1101.

For States wishing to adopt a more liberal approach, however, we specifically proposed to allow States to require that qualified entities apply simple income disregards, such as the general $90 earned income disregard. However, as explained in the preamble we did not propose to allow States to require that qualified entities deduct the costs of incurred medical expenses in order to reduce income to the allowed income level. We solicited comments on whether States should be allowed to require that qualified entities make certain adjustments to gross income and ways that these adjustments could be limited.

Proposed §§ 435.1102(b)(1) and (b)(2) implement the provisions of section

1920A(b)(1) of the Act. Section 435.1102(b)(1) requires that States provide qualified entities with regular Medicaid application forms (defined in proposed § 435.1101) as well as information on how to assist parents, guardians, and other persons in completing and filing such forms. At a minimum, we proposed that States must furnish qualified entities with the applications used to apply for Medicaid under the poverty-related groups described in section 1902(l)(1) of the Act.

Proposed § 435.1102(b)(2) requires States to establish procedures to ensure qualified entities—(1) notify the Medicaid agency that a child is presumptively eligible within 5 working days; and (2) provide written information to parents and custodians of children determined to be presumptively eligible, explaining that a regular Medicaid application must be filed by the last day of the following month in order for the child to continue to receive services after that date and that if an application is timely filed on the child's behalf, the child will remain presumptively eligible until a determination of the child's eligibility for regular Medicaid has been made; and (3) provide written information to parents and custodians of children determined not to be presumptively eligible of the reason for the determination and that the child has a right to apply to regular Medicaid.

While we are requiring such notification, we are considering presumptive eligibility to be a special status, distinct from regular Medicaid eligibility. Therefore, we did not propose to apply to a decision on presumptive eligibility the notification requirements, found in §§ 435.911 and § 435.912 and part 431, subpart E, that a State must meet when it makes a decision on a regular Medicaid application. Nor did we propose to grant rights to appeal a denial or termination of services under a presumptive eligibility decision because a determination of presumptive eligibility is not considered to be a determination of Medicaid eligibility. If a regular Medicaid application is filed on the child's behalf and is denied, the child would have the right to appeal that denial.

Because presumptive eligibility is a special status, we considered whether States should be required to provide all services to presumptively eligible children or whether they should be permitted to limit the services provided. In § 457.1102(b)(3), we proposed to require that States provide all services covered under the State plan, including EPSDT, to presumptively eligible children.

Although section 1920A places no restrictions on the number of periods of presumptive eligibility for a child, it undermines the intent of the provision to provide a child with an unrestricted number of periods. Therefore, we proposed in § 435.1102(c) to allow States to establish reasonable methods of limiting the number of periods of presumptive eligibility that can be authorized for a child in a given time frame. We solicited comments on what would constitute a reasonable limitations and whether specific limitations on the number of periods of presumptive eligibility should be imposed by regulation.

Existing regulations at § 435.914 permit States to provide Medicaid for an entire month when the individual is eligible for Medicaid under the plan at any time during the month. However, as explained in the preamble to the NPRM, because a determination of presumptive eligibility is not, by definition, a determination of Medicaid eligibility, but simply a decision of temporary eligibility based on a special status, and because section 1920A(b)(2) of the Act expressly defines the period of presumptive eligibility, we did not propose to permit States to provide full-month periods of presumptive eligibility.

Section 4912 of the BBA provides that, for purposes of Federal financial participation, services that are covered under the plan, furnished by a provider that is eligible for payment under the plan, and furnished to a child during a period of presumptive eligibility, will be treated as expenditures for medical assistance under the State plan. This provision is reflected in proposed § 435.1001. We note that in the event that a child determined to be presumptively eligible is not found eligible for Medicaid after a final eligibility determination, the services provided during the presumptive eligibility period that otherwise meet the requirements for payment will be covered. See § 447.88 and § 457.616 for a discussion of the options for claiming FFP payment related to presumptive eligibility.

Comment: We received one comment that the regulations should clarify that a State can provide a joint SCHIP/Medicaid application or a shortened Medicaid application used for pregnant women and children as well as a ''regular Medicaid application.''

Response: We agree that a qualified entity may provide parents and caretakers with either a shortened application that is used to establish eligibility for pregnant women and children under the poverty-level-related groups described in section 1902(l) of the Act or a joint application for a separate child health program and Medicaid that is used to establish eligibility of children. We have revised the definition of ''application form'' in § 435.1101 to include the joint SCHIP/Medicaid application for a Medicaid and a separate child health program.

We would like to clarify that, under Federal law, no application form for presumptive eligibility itself is required. Thus, qualified entities can make presumptive-eligibility determinations based strictly on oral information. (The qualified entity would need to record the pertinent information, but the parent or caretaker (or other responsible adult) would not themselves need to complete an application.) This would not preclude qualified entities from assisting families in completing and filing the regular Medicaid application to the extent permitted under law, and we strongly encourage them to do so.

Alternatively, a State may choose to use a written application for presumptive eligibility, although it cannot require the parent or caretaker to provide information other than the information on income necessary to make the determination.

We encourage States that choose to use a written application, particularly those with simplified Medicaid application forms, to use the same form for presumptive eligibility as that used for regular Medicaid, as this will eliminate the need for the child's family to complete two forms. The parent or caretaker can be encouraged to complete the application and assisted in doing so. But, again, so long as pertinent information on income is provided, presumptive eligibility in a State that has elected this option cannot be denied because the full application is not completed.

In either event, of course, the State must provide qualified entities with information on how to assist families in completing and filing the application and ensure that they give presumptive-eligibility applicants a Medicaid application form. We also strongly encourage States, in turn, to encourage qualified entities to provide such assistance to the extent permitted under Medicaid law and regulations.

Comment: One commenter specifically supported the requirement that presumptive eligibility must be provided Statewide and one commenter specifically objected to this requirement. A third commenter objected to requiring each qualified entity to conduct Statewide

presumptive eligibility outreach and determination.

Response: We have considered the commenters' suggestions and have retained proposed § 435.1102(b)(4) related to Statewide availability of presumptive eligibility. Section 1920A(b)(3)(C) provides States with the authority to limit the classes of entities that may become qualified entities; and therefore may limit the population that have the opportunity to become presumptively eligible. For example, States could designate WIC agencies to make determinations of presumptive eligibility only for the clients who have applied for or are receiving WIC, but all of the WIC agencies across the State would be required to offer presumptive eligibility. Therefore, a State could effectively limit the availability of presumptive eligibility by designating particular qualified entity to offer it.

Comment: One commenter noted that schools would not be able to do determinations of presumptive eligibility for pre-schooled, home-schooled, drop-outs or graduates.

Response: Although schools are not likely to be in regular contact with children falling into one of these groups, and as a practical matter may not be in a position to make presumptive eligibility decisions for them, schools that are Medicaid providers would not be precluded from determining the eligibility of a child simply because the child did not attend the school. Thus, schools would also be authorized to determine the presumptive eligibility of the children identified by the commenter.

Comment: We received one comment concerning verification of information used to determine presumptive eligibility. The recommendation was that the regulations specifically require that ''self-attestation'' be used for determinations of presumptive eligibility if income disregards are used and that in other cases, HCFA encourage States to allow applicants to attest to information required for a determination of presumptive eligibility without providing documentation.

Response: We have revised § 435.1102 to make it clear that an estimate of income is to be used for purposes of presumptive eligibility determinations even when a State has chosen to apply simple disregards. The statute provides that determinations of presumptive eligibility are based on ''preliminary information'' and we do not believe that requiring documentation is consistent with the intent that the process be simple for both the applicant and the provider and result in immediate eligibility. Therefore, an applicant's self-attestation as to income is all that would be required to establish the amount of income for presumptive eligibility determinations, regardless of whether income disregards are used or not. This is consistent with the proposed rules pertaining to presumptive eligibility for pregnant women, published March 23, 1994 (59 FR 13666).

Comment: One commenter specifically supported allowing only simple disregards in determinations of presumptive eligibility. Another commented that States should be free to decide whether to use gross or net income for determinations of presumptive eligibility.

Response: We appreciate the support and agree in part with the second commenter. States are free to use only gross income. States may also apply simple disregards to gross income such as a general earned income disregard. However, it would not be consistent with statutory intent to allow States to require that qualified entities apply complicated income disregards or make complicated determinations. Therefore, we have not revised proposed § 457.1102(a) in this final regulation.

Comment: Three commenters expressed support for requiring that, in proposed § 457.1102(b)(3), presumptive eligibility include EPSDT services. One of these commenters urged that the preamble discuss the steps that States should take to assure that EPSDT services are provided.

Response: We are not including any specific EPSDT guidance in this regulation. The regular Medicaid policies which pertain to EPSDT, including policies about providing information about EPSDT services to families and generally informing families about the benefits of preventive health, would apply when a child is found presumptively eligible for Medicaid.

Comment: We received several comments concerning written notices provided to the family and the responsibilities of qualified entities. One comment was that it would be difficult for schools to issue the notice of presumptive eligibility and the temporary enrollment card and the State should be allowed to do this instead. Another was that it would be difficult for schools to send a written notice to those found not to be presumptively eligible and might result in the family's confusion and anger. One comment was that, generally, HCFA should encourage States to develop procedures that are not burdensome to providers, provide adequate training and provider relations, and keep the provider apprized of the status of the application so that, if not completed at the time of any follow-up visit, the provider can encourage the family to complete the process, as necessary.

Response: Our understanding is that the intent of the legislation is to minimize the burden placed on qualified entities, including schools and other providers. However, the statute specifically requires that the qualified entity inform the family that an application for Medicaid must be filed by the end of the following month. It is also clear that qualified entities are expected to provide Medicaid applications and assistance in completing and filing such applications. We certainly encourage States to simplify the presumptive eligibility process to the greatest extent allowed under the law. It is not unnecessarily burdensome for the qualified entity to provide written notices to those found presumptively eligible or ineligible, as these notices could be pre-printed notices provided by the State.

Although we have not required it, it would not be unnecessarily burdensome for a State to require a qualified entity to provide a temporary enrollment card to enable the child to access services during the period of presumptive eligibility particularly when the qualified entity itself does not provide medical services. We also encourage States to keep qualified entities apprized of the status of the child's application if the entity is willing to follow up with families whose application has not been completed.

Comment: One commenter suggested that § 435.1102(b)(2)(iii) should be amended to require that qualified entities tell individuals who are not found presumptively eligible for Medicaid that they may file for coverage under a separate child health program as well as Medicaid and provide applications for both programs as well as information on how to complete and file them.

Response: We have not required that qualified entities provide information about a separate child health program. However, we encourage States to do this as part of their outreach programs and coordination efforts. In addition, as noted above, we have amended § 435.1101 to make it clear that the application provided by a qualified entity may be a joint Medicaid/SCHIP application.

Comment: One commenter urged HCFA to encourage States to simplify the enrollment process and provide prompt, easy-to-understand information to the family about the eligibility determination process and any remaining steps that the family must

take. Another expressed concern that States are not required to send a notice at the end of a presumptive-eligibility period, which would alert families who sent in a Medicaid application that was never received.

Response: HCFA has encouraged States to simplify both the eligibility requirements and the enrollment procedures to the greatest extent possible and will continue to do so. We also encourage States to make all information provided to families understandable and will provide technical assistance in this area. We encourage States to notify families that the child's presumptive eligibility will be terminated and that no Medicaid application has been received. We also encourage States to establish other procedures to follow-up with families of presumptively-eligible children early on in the presumptive-eligibility period. However, requiring States to do so is beyond the intent of the statute, and could discourage some States from adopting presumptive eligibility for children at all. We will not mandate that States institute such procedures.

Comment: We received several comments in response to our specific request related to limitations on the number of periods of presumptive eligibility available to a child. One commenter believed that no more than one period of presumptive eligibility within 24 months would be reasonable, but recommended that States be allowed to set their own standards. Another commenter agreed it would be unreasonable to provide unlimited periods of presumptive eligibility, but believed that it would be reasonable to allow only one period per lifetime. A third recommended that there be no lifetime limit on the number of periods, but a limit on the number of periods within a specific time-frame (for example, one period of presumptive eligibility within a twelve-month period). A final commenter believed that it would be difficult for providers, who are considered qualified entities, to track the number of presumptive-eligibility any child has enjoyed.

Response: We have decided to require that States adopt reasonable standards regarding the number of periods of presumptive eligibility that will be authorized for a child within a given period of time. Under some circumstances, more frequent or numerous periods of presumptive eligibility may be justified and individual circumstances may be taken into account. We are not requiring that States establish a specific maximum number of periods for specific time frames in this final regulation. We realize that the circumstances that result in a need for an additional period of presumptive eligibility will vary greatly from case to case. In addition, States may wish to have some experience before setting up a standard that qualified entities must follow. We expect States to monitor the use of presumptive eligibility to determine whether there is a need for specific limitations on the number of periods of presumptive eligibility to which a child is entitled.

We appreciate the support for our position that it would be unreasonable to provide unlimited periods of presumptive eligibility. However, if a State decides to establish set limits, we do not agree that one period of presumptive eligibility in a lifetime is reasonable given the changes in a child's circumstances that may occur over time. It would be reasonable, however, to limit the periods of presumptive eligibility to one per twelve or twenty-four month period, as suggested. Furthermore, it would be reasonable to connect limitations on presumptive eligibility to the length of time during which a child is not covered by Medicaid. For example, a State could prohibit an additional period of presumptive eligibility until the child had been disenrolled from Medicaid for a certain period of time. In response to the last commenter, after a State has established how it will restrict the number of periods of presumptive eligibility, we expect that the State will develop procedures for assuring that the restrictions are applied without unduly burdening the qualified entities, including providers.

L. Medicaid Disproportionate Share Hospital (DSH) Expenditures

Section 4911 of the BBA amended section 1905(b) of the Act to require that for expenditures under section 1905(u)(2)(A)(that is, medical assistance for optional targeted low-income children) or section 1905(u)(3) (that is, medical assistance for children referred to as ''Waxman children''), the Federal medical assistance percentage is equal to the *enhanced* FMAP described in section 2105(b)of the Act unless the State has exhausted its title XXI allotment, in which case the State's regular FMAP would apply. In other words, under the statute, States that provide health insurance coverage to children as an expansion of their Medicaid programs may receive an enhanced match for services provided to the Medicaid expansion population.

Under the authority of section 1902(a)(13)(A)(iv) of the Act, States are required to take into account the situation of hospitals that serve a disproportionate number of low-income patients with special needs when developing rates for Medicaid inpatient hospital services. Medicaid disproportionate share hospital (DSH) expenditures thus are payments made for hospital services rendered to Medicaid-eligible patients. Depending on the State's DSH methodology, some of the payments may be directly identifiable as expenditures for services for a child in a SCHIP-related Medicaid expansion program. HCFA concluded in the proposed rule that those identifiable payments must qualify for the enhanced FMAP.

We further proposed § 433.11 which set forth provisions regarding the enhanced FMAP rate available for State DSH expenditures related to services provided to children under an expansion to the State's current Medicaid program. However, based on the statutory changes included in the ''Medicare, Medicaid, and CHIP Balanced Budget Refinement Act of 1999,'' this section is being deleted. Specifically, H.R. 3426 incorporated changes to section 1905(b) (42 U.S.C. 1396d(b)) by inserting the phrase ''other than expenditures under section 1923,'' after ''with respect to expenditures.'' By inserting this phrase, the statute specifically excludes Medicaid DSH expenditures from qualifying for enhanced FMAP.

III. Provisions of the Final Rule

In this final rule, we are adopting the provisions as set forth in the November 8, 1999 proposed rule with the following substantive revisions:

A. Part 431—State Organization and General Administration

We added a new § 431.636 to provide for coordination of Medicaid with the State Children's Health Insurance Program. This section provides that the State must adopt procedures to facilitate the Medicaid application process for, and the enrollment of children for whom the Medicaid application and enrollment process has been initiated.

B. Part 433—State Fiscal Administration

We removed proposed paragaph § 433.11(b)(3) regarding enhanced FMAP for disporportionate share hospital expenditures provided to certain children.

C. Part 435—Eligibility in the States, District of Columbia, the Northern Mariana Islands, and American Samoa

- We added a definition of optional targeted low-income child at § 435.4.

• We revised § 435.229 to refer to optional targeted low-income children as defined at § 435.4.

• We revised § 435.910(h)(3) to provide that a State may use the Medicaid identification number established by the State to the same extent as an SSN is used for purposes described in paragraph (b)(3) of this section.

• At § 435.1101 we replaced the term ''applicable income level'' with the term ''presumptive income level.'' The definition for this term remains the same.

• We revised the requirement at proposed paragraph § 435.1102(b)(4) to provide that agencies that elect to provide services to children during a period of presumptive eligibility must allow determinations of presumptive eligibility to be made by qualified entities on a Statewide basis.

D. Part 436—Eligibility in Guam, Puerto Rico, and the Virgin Islands

In the proposed rule, we inadvertently omitted certain revisions to part 436. The following revisions parallel the changes made to part 435:

• We added a definition of optional targeted low-income children at § 436.3.

• We added a new § 436.229, regarding provision of Medicaid to optional targeted low-income children.

• We revised paragraph (a) of § 436.1001, regarding FFP for administration.

• We added a new paragraph (c) to § 436.1002, regarding FFP for services.

• We added a new subpart L, Option for Coverage of Special Groups.

E. Part 457—Allotments and Grants to States

• We replaced the term ''Children's Health Insurance Program'' with the term ''State Children's Health Insurance Program'' throughout the regulation.

• We replaced the term ''beneficiary'' with the term ''applicant'' or ''enrollee'' throughout the regulation.

Subpart A—Introduction; State Plans for State Child Health Insurance Programs and Outreach Strategies

Section 457.10

• We added definitions for the following terms: ''applicant'', ''cost sharing'', ''enrollee'', ''enrollment cap'', ''health care services'', ''health insurance coverage'', ''health insurance issuer'', ''health services initiatives'', ''joint application'', ''optional targeted low-income child'', and ''premium assistance program''.

• For the following terms, we eliminated the cross reference and set forth the full text of the definition at § 457.10: ''contractor'', ''emergency medical condition'', ''emergency services'', ''health benefits coverage'', ''managed care entity'', ''post-stabilization services''.

• We revised the definition of American Indian/Alaska Native (AI/AN) by removing the provision that descendants in the first or second degree of members of Federally recognized tribes are considered AI/AN.

• We removed the definitions of ''contractor'', ''cost-effectiveness'', ''employment with a public agency'', ''grievance'', ''legal obligation'', ''post-stabilization services'', ''premium assistance for employer sponsored group health plans'', and ''State program integrity unit''.

Section 457.40

• We revised paragraph (c) to require that the State must identify, in the State plan or State plan amendment, by position or title, the State officials who are responsible for program administration and financial oversight.

Section 457.60

• We revised proposed paragraph (a)(1) (now paragraph (a)) to provide that a State must amend its State plan whenever necessary to reflect changes in Federal law, regulations, policy interpretations, or court decisions that affect provisions in the approved State plan.

• We revised proposed paragraph (a)(2) (now paragraph (b)) to provide that a State must amend its State plan whenever necessary to reflect changes in State law, organization, policy, or operation of the program that affect the following program elements: Eligibility, including enrollment caps and disenrollment policies; procedures to prevent substitution of private coverage, including exemptions or exceptions to periods of uninsurance; the type of health benefits coverage offered; addition or deletion of specific categories of benefits offered under the plan; basic delivery system approach; cost-sharing; screen and enroll procedures, and other Medicaid coordination procedures, review procedures, and other comparable required program elements.

• We revised proposed paragraph (a)(3) (now paragraph (c)) to provide that a State must amend its State plan to reflect changes in the source of the State share of funding, except for changes in the type of non-health care related revenues used to generate general revenue.

Section 457.65

• We added a new paragraph (d) to set forth requirements for amendments relating to enrollment procedures.

• We redesignated proposed paragraphs (d) and (e) as paragraphs (e) and (f), respectively.

• We removed proposed paragraph (d)(2), as this provision has been incorporated into § 457.60(c).

• We added a new paragraph (f)(2) to provide that an approved State plan continues in effect unless a State withdraws its plan in accordance with § 457.170(b).

Section 457.70

• We removed proposed paragraph (c)(1)(vi), which provided that Medicaid expansion programs must meet the requirements of subpart H of this final rule.

Section 457.80

• We revised paragraph (c) to provide that the State plan must include a description of procedures the State uses to accomplish coordination of SCHIP with other public and private health insurance programs, sources of health benefits coverage for children, and relevant child health programs, such as title V, that provide health care services for low-income children.

Section 457.90

• We added a new paragraph (b)(3) to provide that outreach strategies may include application assistance, including opportunities to apply for child health assistance under the plan through community-based organizations and in combination with other benefits and services available to children.

Section 457.110

• We revised paragraph (a) to provide that the State must make linguistically appropriate information available to families.

• We revised paragraphs (a) and (b) to provide that the State must ensure that information is made available to applicants, and enrollees.

• We revised paragraph (b) to provide that States must have a mechanism in place to ensure that applicant and enrollees are provided specific information in a timely manner.

Section 457.120

• We added a new paragraph (c) to require that the State plan include a description of the method the State uses to ensure interaction of Indian Tribes and organizations on the implementation of procedures regarding provision of child health assistance to AI/AN children.

Section 457.125

• We revised paragraph (a) by removing language regarding consultation with Indian tribes, which has been incorporated into § 457.120(c).

Section 457.140

• We revised the introductory text of this section to provide that a State plan or State plan amendment must include a 1-year budget.

Section 457.170

• We revised this section to provide more specific rules regarding withdrawal of proposed State plans or plan amendments and withdrawal of approved State plans.

Section 457.190

• We moved the provisions of § 457.190 to new § 457.203.

Subpart C—State Plan Requirements: Eligibility, Screening, Applications and Enrollment

Section 457.301

• We removed our proposed definition of ''employment with a public agency''.

• We added a definition of the term ''joint application''.

Section 457.305

• We revised paragraph (a) to provide that the State plan must include a description of the methodologies used by the State to calculate eligibility under the financial need standard.

• We added a new paragraph (b) to clarify that the State plan must describe the State's policies governing enrollment and disenrollment, including enrollment caps, and processes for instituting waiting lists, deciding which children will be given priority for enrollment, and informing individuals of their status on a waiting list.

Section 457.310

• We revised the financial need standard for a targeted low-income child at paragraph (b)(1).

• We revised paragraph (b)(2)(ii) to provide that a child would not be considered covered under a group health plan if the child did not have reasonable geographic access to care under that plan.

• We revised paragraph (c)(1)(ii) to clarify our policy concerning contributions toward the cost of dependent coverage.

Section 457.320

• We revised paragraph (b)(3) to specifically prohibit discrimination on the basis of diagnosis.

• We revised paragraph (c) to permit States to accept self-declaration of citizenship, provided that the State has implemented effective, fair, and nondiscriminatory procedures for ensuring the integrity of their application process with respect to self-declaration of citizenship.

• We revised paragraph (a)(7) and added a new paragraph (d) to address eligibility standards related to residency.

• We revised paragraph (a)(10) and added a new paragraph (e) regarding duration of eligibility.

Section 457.340

• We removed proposed § 457.340 and renamed this section, ''Application for and enrollment in a separate child health program.'' This section sets forth provisions regarding application assistance, notice of rights and responsibilities, timely determinations of eligibility, notice of decisions concerning eligibility, and effective date of eligibility.

Section 457.350

• We have revised this section for consistent use of the terms ''found eligible'' and ''potentially eligible''.

• We removed the provisions of proposed paragraph (b) regarding screening with joint applications.

• We redesignated proposed paragraph (c) as paragraph (b) and proposed paragraph (d) as paragraph (c)

• We revised paragraph (b) (proposed paragraph (c)) to require that a State must use screening procedures to identify, at a minimum, any applicant or enrollee who is potentially eligible for Medicaid under one of the poverty level related groups described in section 1902(l) of the Act, section 1931 of the Act, or a Medicaid demonstration project approved under section 1115 of the Act, applying whichever standard and corresponding methodology generally results in a higher income eligibility level for the age group of the child being screened.

• We added a new paragraph (d) to provide that if a State applies a resource test and a child has been determined potentially income eligible for Medicaid, the State must also screen for Medicaid eligibility by comparing the family's resources to the appropriate Medicaid standard.

• We have clarified the provisions of paragraph (e) (now paragraph (f)) regarding children found potentially eligible for Medicaid.

• We added new paragraphs (g) and (h) to specify requirements regarding informed application decisions and waiting lists, enrollment caps and closed enrollment.

Section 457.353

• We added a new section, ''Evaluation of screening process and provisional enrollment.'' This section sets forth requirements regarding monitoring and evaluations of the screen and enroll process, provisional enrollment during the screening process, and expenditures for coverage during a period of provisional enrollment.

Section 457.360

• We removed this section.

Section 457.365

• We removed the provisions of proposed § 457.365, regarding grievances and appeals, and incorporated them into new subpart K.

Section 457.380 (proposed § 457.970)

• We moved the provisions of proposed § 457.970 to new § 457.380.

• We removed the provision at proposed § 457.970(d) that the State may terminate the eligibility of an applicant or beneficiary for ''good cause.''

Subpart D—Coverage and Benefits: General Provisions

Section 457.402

• We revised § 457.402(a) to list surgical services separately at paragraph (a)(4).

• We moved the definitions of ''emergency medical condition,'' ''emergency services,'' and ''health benefits coverage,'' which were set forth at proposed paragraphs (b), (c), and (e) respectively, to § 457.10.

Section 457.410

• We revised paragraph (b)(1) to provide that the State must obtain coverage for well-baby and well-child care services as defined by the State.

• We revised paragraph (b)(2) to provide that the State must obtain coverage for age-appropriate immunizations.

Section 457.430

• We revised § 457.430 by clarifying that benchmark-equivalent health benefits coverage must meet the requirements of § 457.410(b) and by removing proposed paragraph (b)(4) regarding well-baby and well-child care and immunizations.

Section 457.440

• We revised paragraph (b)(2) to clarify that a State must submit an actuarial report when it amends its existing State-based coverage.

Section 457.450

• We revised paragraph (a) to provide that Secretary-approved coverage may include coverage that is the same as the coverage provided to children under the Medicaid State plan.

Section 457.490

• We revised § 457.490(a) to provide that the State must describe the methods of delivery of child health assistance including the methods for assuring the delivery of the insurance products and the delivery of health care services covered by such products to the enrollees, including any variations.

Section 457.495

• We removed the provisions of proposed § 457.495 regarding grievances and appeals and incorporated them into new subpart K.

• We moved the provisions of proposed § 457.735 to § 457.495, and renamed the section, ''State assurance of access to care and procedures to assure quality and appropriateness of care''.

Subpart E—State Plan Requirements: Beneficiary Financial Responsibilities

Section 457.500

• We added a new paragraph (a)(1) to add section 2101(a) of the Act to the statutory authority for this subpart.

• We revised paragraph (c) to remove the provision that, with respect to a mandatory cost-sharing waiver for AI/AN children, subpart E applies to a Medicaid expansion program.

Section 457.505

• We added a new paragraph (c) to § 457.505 to provide that the State plan must include a description of the State's disenrollment protections as required under § 457.570.

Section 457.510

• We revised paragraph (d) to provide that when a State imposes premiums, enrollment fees, or similar fees, the State plan must describe the consequences for an enrollee or applicant who does not pay a charge and the disenrollment protections adopted by the State.

Section 457.515

• We revised paragraph (d) to provide that the State plan must describe the consequences for an enrollee who does not pay a charge and the disenrollment protections adopted by the State.

• We removed the statement from paragraph (e) the a methodology that primarily relies on a refund is not an acceptable methodology.

Section 457.520

• We revised § 457.520(b) to provide that for the purposes of cost sharing, well-baby and well-child care services include routine examinations as recommended by the AAP's ''Guidelines for Health Supervision III'', or as described in ''Bright Futures: Guidelines for Health and Supervision of Infants, Children and Adolescents,'' Laboratory tests associated with the well-baby and well-child routine physical examinations, and immunizations as recommended and updated by ACIP.

Section 457.525

• We redesignated proposed paragraph (a)(4) as paragraph (a)(5) and revised this paragraph to provide that the public schedule must include information about consequences for an applicant or an enrollee who does not pay a charge including disenrollment protections.

• We added a new paragraph (a)(4) to provide that the public schedule must include information on mechanisms for making payments for required charges.

• We revised paragraph (b)(1) to require States to provide the public schedule to SCHIP enrollees at the time of reenrollment after a redetermination of eligibility, and when cost-sharing charges and cumulative cost-sharing maximums are revised.

Section 457.535

States may not impose premiums, deductibles, coinsurance, copayments or any other cost-sharing charges on children who are American Indians and Alaska Natives, as defined in § 457.10.

Section 457.540

• We redesignated proposed paragraphs 457.550(a) and (b) as paragraphs 457.540(d) and (e).

• We redesignated proposed paragraph (e) as paragraph (f).

Section 457.545

• We removed the provisions of this section.

Section 457.550

• We eliminated this section and incorporated its contents into other sections of this subpart.

• We redesignated paragraphs (a) and (b) as § 457.540(d) and (e).

• We redesignated paragraph (c) as § 457.555(e).

Section 457.555

• We revised § 457.555(b) to indicate that cost sharing may not exceed 50 percent of the payment the State would make under the Medicaid fee-for-service system for the first day of care in the institution.

• We added a new paragraph (c) to provide that any copayment that the State imposes on services provided by an institution to treat an emergency medical condition may not exceed $5.00.

• We redesignated proposed paragraph (c) as paragraph (d).

• We removed proposed paragraph (d) regarding emergency room services provided outside and enrollee's managed care network.

Section 457.560

• We reorganized this section for clarity.

Section 457.565

• We eliminated this section, as it has been incorporated into new subpart K.

Section 457.570

• We added the requirement, at paragraph (b), that the disenrollment process must afford the enrollee's family the opportunity to show that his or her income has declined prior to disenrollment for nonpayment of cost-sharing and charges, and in the event that such a showing indicates that the enrollee may have become eligible for Medicaid or for a lower level of cost sharing, the State must facilitate enrolling the child in Medicaid or adjust the child's cost-sharing category as appropriate.

• We added the requirement, at paragraph (c), that the State must provide the enrollee with an opportunity for an impartial review to address disenrollment from the program.

Subpart G—Strategic Planning

Section 457.710

• We added a new paragraph (e) to provide that the State's strategic objectives, performance goals and performance measures must include a common core of national performance goals and measures consistent with the data collection, standard methodology, and verification requirements, as developed by the Secretary.

Section 457.735

• We moved the provisions of proposed § 457.735 to § 457.495.

Section 457.740

• We revised paragraph (a) to provide that Territories are exempt from the definition of ''State'' for purposes of quarterly reporting.

• We redesignated proposed paragraph (a)(2) as paragraph (a)(3) and added an new paragraph (a)(2) to

provide that the quarterly reports must include data on a ''point-in-time'' enrollment count as of the last day of each quarter of the Federal fiscal year.

• We added a new paragraph (a)(3)(ii) to provide that the quarterly report must include data on the number of children enrolled in Medicaid by gender, race, and ethnicity.

Section 457.750

• We revised paragraph (b)(1) to provide that in the annual report, the State must include information related to a core set of national performance goals and measures as developed by the Secretary.

• We added a new paragraph (b)(7) to provide that the annual report must include data regarding the primary language of SCHIP enrollees.

• We added a new paragraph (b)(8) to provide that the annual report must describe the State's current income standards and methodologies for its Medicaid expansion program and separate child health program as appropriate.

• We revised paragraph (c) to set forth requirements regarding the State's annual estimate of changes in the number of uninsured children in the State.

Section 457.760

• We removed this section.

Subpart H—Substitution of Coverage

Section 457.810

• We added introductory text to paragraph (a).

• We revised paragraph (a)(1) to provide that an enrollee must not have had coverage under a group health plan for a period of at least 6 months prior to enrollment in a premium assistance program. A State may not require a minimum period without coverage under a group health plan that exceeds 12 months.

• We revised paragraph(a)(2) to specify the circumstances in which States may permit reasonable exceptions to the requirement for a minimum period without coverage under a group health plan.

• We removed proposed paragraph (a)(3), which specified that a newborn is not required to have a period without insurance as a condition of eligibility for payment for employer-sponsored group health coverage.

• We added a new paragraph (a)(3) to require that the requirement for a minimum period without coverage under a group health plan does not apply to a child who, within the previous 6 months, has received coverage under a group health plan through Medicaid under section 1906 of the Act.

• We added a new paragraph (a)(4) to specify that the Secretary may revise the 6-month waiting period requirement at her discretion.

• We revised paragraph (b) to provide that for health benefits coverage obtained through premium assistance for group health plans, the employee who is eligible for the coverage must apply for the full premium contribution available from the employer.

• We also removed paragraph (b)(1), which included the minimum 60 percent employer contribution requirement.

Subpart I—Program Integrity

Section 457.902

• We added a definition of the term ''actuarilly sound principles''.

• We moved the definition of ''managed care entity'' to § 457.10.

• We eliminated the definitions of ''contractor'', ''grievance'' and ''State program integrity unit''.

Section 457.920

• We removed this section.

Section 457.940

• We revised paragraph (b)(2) to provide that a State must provide child health assistance in an effective and efficient manner by using payment rates based on public or private payment rates for comparable services for comparable populations, consistent with principles of actuarial soundness.

Section 457.950

• We revised paragraph (a)(3) to provide that a State must ensure that its contract with an MCE provides access for the State, HCFA, and the HHS Office of the Inspector General to enrollee health claims data and payment data.

• We redesignated proposed paragraph (b)(2) as paragraph (b)(3).

• We added a new paragraph (b)(2) to provide that a State that makes payments to fee-for-service entities under a separate child health program must ensure that fee-for-service entities understand that payment and satisfaction of the claims will be from Federal and State funds, and that any false claims may be prosecuted under applicable Federal or State laws.

Section 457.955

• We added a new paragraph (b)(2) to provide that States must ensure that MCEs are prohibited from conducting any unsolicited personal contact with a potential enrollee by an employee or agent of a managed care entity for the purpose of influencing the individual to enroll with the entity.

Section 457.970

• We removed this section and incorporated its provisions into § 457.380.

Section 457.975

• We removed this section.

Section 457.985

• We removed this section and incorporated its provisions into new subpart K.

sbull; We added a new § 457.985, Integrity of professional advice to enrollees.

Section 457.990

• We removed this section and incorporated its provisions into new subpart K.

Section 457.995

• We removed this section and incorporated its provisions into new subpart K.

Subpart J—Allowable Waivers: General Provisions

Section 457.1000

• We revised paragraph (c) to provide that this subpart applies to a Medicaid expansion program when the State claims administrative costs under title XXI and seeks a waiver of limitations on such claims for use of a community-based health delivery system. This subpart does not apply to demonstrations requested under section 1115 of the Act.

Section 457.1003

• We added a new § 457.1003 to provide that HCFA will review the waivers in this subpart as State plan amendments under the same timeframes for State plan amendments specified in subpart A.

Section 457.1005

• We revised § 457.1005(c) to provide that an approved waiver for cost-effective coverage through a community-based health delivery system remains in effect for no more than 3 years.

Section 457.1015

• We removed the requirement at paragraph (b)(2) regarding demonstrating cost-effectiveness through comparison with a child-only health benefits package.

Subpart K—Applicant and Enrollee Protections

• We relocated certain provisions involving applicant and enrollee

protections to this new subpart K, ''Applicant and Enrollee Protections.'' Specifically, we moved to this subpart proposed § 457.985, which set forth requirements relating to grievances and appeals, and proposed § 457.990, which set forth requirements for privacy protections.

• We added the following sections in response to public comment: § 457.1140, Core elements of review; § 457.1170, Continuation of Benefits; and § 457.1190, Premium assistance for group health plans.

• The following table shows the disposition of the sections set forth in the proposed rule that have been incorporated into subpart K.

Proposed regulations	Final regulations
Definitions—Contractor.	
457.902	Deleted.
Definitions—Grievance.	
457.902	Deleted.
Denial, Suspension, or Termination of Eligibility	Revised 457.1130(a).
457.365	Revised 457.1130(b).
Reduction or Denial of Services	Revised 457.1130(a).
457.495	Revised 457.1180.
Disenrollment for Failure to Pay Cost Sharing	Revised 457.1130(a) and 457.1180.
	Revised 457.1130(a) and 457.1180.
457.565	Revised 457.1130(b) and 457.1180.
Enrollees Rights to File Grievances and Appeals	Revised 457.1120, 1150(b), and 457.1160.
	Deleted.
	Deleted.
457.985(a)	Deleted.
	Deleted.
457.985(a)(1)	Deleted.
	Revised 457.985, Cross Reference 457.110(b)(5).
457.985(a)(2)	Revised 457.985, Cross Reference 457.110(b)(5).
457.985(a)(3)	Revised 457.1110(b).
	Revised 457.1110.
457.985(b)	Revised 457.1110(a) and (d).
	Revised 457.1110(a) and (d).
457.985(c)	Revised 457.1110(a).
	Revised 457.1110(a).
457.985(c)(1)	Revised 457.1110(c) and (e).
	Revised 457.1110(a).
457.985(c)(2)	Deleted.
	Deleted.
457.985(d)	Deleted.
457.985(e)	Revised 457.1110(e).
457.985(e)(1)	Revised 457.1120 and 457.1180, Cross Reference 457.110(b)(6).
	Revised 457.1130(a).
457.985(e)(2)	Revised 457.1130(b).
Privacy Protections	Revised 457.1130(a)(3).
	Revised 457.1160.
457.990(a).	

F. Technical Corrections

In this final rule we are making the following technical corrections to subpart B, General Administration, and subpart F, Payments to States, of part 457. These subparts were published in final on May 24, 2000 (65 FR 33616).

Subpart B—General Administration—Reviews and Audits; Withholding for Failure To Comply; Deferral and Disallowance of Claims; Reduction of Federal Medical Payments

• We moved the provisions of proposed § 457.190 regarding administrative and judicial review to new § 457.203, as we believe these provisions are more appropriately located in subpart B.

• We revised § 457.204(d)(2) to clarify the meaning of the term ''corrective action.''

• We revised § 457.208(a) to cross refer to the provisions of new § 457.203.

• We removed § 457.234, State plan requirements, as these provisions duplicate § 457.50.

Subpart F—Payments to States

• We removed § 457.624, Limitations of certain payments for certain expenditures, as paragraphs (a) and (b) of this section duplicate the provisions of §§ 457.475 and 457.1010, respectively.

IV. Regulatory Impact Analysis

A. Impact Statement

Section 804(2) of title 5, United States Code (as added by section 251 of Public Law 104–121), specifies that a ''major rule'' is any rule that the Office of Management and Budget finds is likely to result in—

• An annual effect on the economy of $100 million or more;

• A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or

• Significant adverse effects on competition, employment, investment productivity, innovation, or on the ability of United States based enterprises to compete with foreign based enterprises in domestic and export markets.

This final rule does not establish the SCHIP allotment amounts. However, it provides for the implementation and administration of the SCHIP program, and as such, is an economically significant, major rule.

We have examined the impacts of this final rule as required by Executive Order 12866, the Unfunded Mandate Reform Act of 1995 (Pub. L. 104–4), and the Regulatory Flexibility Act (RFA) (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulations are

necessary, to select regulatory approaches that maximize net benefits (including potential economic environments, public health and safety, other advantages, distributive impacts, and equity).

The Unfunded Mandates Reform Act of 1995 requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year. Because participation in the SCHIP program on the part of States is voluntary, any payments and expenditures States make or incur on behalf of the program that are not reimbursed by the Federal government are made voluntarily. These regulations implement narrowly defined statutory language and would not create an unfunded mandate on States, tribal or local governments.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any final rule that may have a significant impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. With the exception of hospitals located in certain rural counties adjacent to urban areas, 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 50 beds.

In addition, for purposes of the RFA, we prepare a regulatory flexibility analysis unless we certify that a rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, non-profit organizations, and governmental agencies. Most hospitals and other providers and suppliers are small entities, either by non-profit status or by having revenues of $5 million or less annually. Individuals and State agencies are not included in the definition of small entity. As discussed in detail below, this final rule will have a beneficial impact, if any, on health care providers.

Therefore, we are not preparing an analysis for section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant impact on a substantial number of small entities or on the operations of a substantial number of small rural hospitals.

B. Cost Benefit Analysis

This analysis addresses a wide range of costs and benefits of this rule. Whenever possible, we express impact quantitatively. In cases where quantitative approaches are not feasible, we present our best examination of determinable costs, benefits, and associated issues. This final regulation would implement all programmatic provisions of the State Children's Health Insurance Program (SCHIP) including provisions regarding State plan requirements, benefits, eligibility, and program integrity, which are specified in title XXI of the Act. This final regulation would have a beneficial impact in that it would allow States to expand the provision of health benefits coverage to uninsured, low-income children who previously had limited access to health care.

SCHIP is the largest single expansion of health insurance coverage for children since the creation of Medicaid in 1965. SCHIP was designed to reach children from working families with incomes too high to qualify for Medicaid, but too low to afford private health insurance. As discussed in detail below, this initiative set aside $40 billion over ten years for States to provide new health coverage for millions of children. To date, plans prepared by all 50 States, 5 U.S. territories, and the District of Columbia have been approved. We estimate that States enrolled at least 3 million children in fiscal year 2000. The implementation of SCHIP has significantly reduced the number of uninsured children nationwide. Previously uninsured children now have access to a range of health care services including well baby and well child care, immunizations, and emergency services. In addition to the obvious benefit of providing access to health care coverage for millions of children, as discussed in detail below, SCHIP will also have a beneficial impact on the private sector.

1. Disbursement of Federal Funds

Budget authority for title XXI is specified in section 2104(a) of the Act with additional funding authorized in Pub. L. 105–100. The total national amount of Federal funding available for allotment to the 50 States, the District of Columbia, and the Commonwealths and Territories for the life of SCHIP, is established as follows:

TOTAL AMOUNT OF ALLOTMENTS

Fiscal year	Amount
1998	$4,295,000,000
1999	4,275,000,000
2000	4,275,000,000
2001	4,275,000,000
2002	3,150,000,000
2003	3,150,000,000
2004	3,150,000,000
2005	4,050,000,000
2006	4,050,000,000
2007	5,000,000,000

Under Public Law 105–277, an additional $32 million was appropriated for allotment only to the Commonwealths and Territories, and only for FY 1999. In addition, we note that there was an additional allocation of $20 million in FY 1998, which increases the FY 1998 total allotment amount to $4.295 billion. Also, for each of the first five years, $60 million of the allotment must be used for the special diabetes programs.

Section 702 of the Balanced Budget Refinement Act of 1999 (Pub. L. 106–113, BBRA) appropriated an additional $249 million for Territories. In addition, section 703(c) of the BBRA requires that the Secretary conduct an independent evaluation of 10 States with approved child health plans and appropriates $10 million for FY 2000 for this purpose. The additional allotments for Territories are established as follows:

INCREASED ALLOTMENTS FOR TERRITORIES

Fiscal Year	Amount
2000	$34,200,000
2001	34,200,000
2002	25,200,000
2003	25,200,000
2004	25,200,000
2005	32,400,000
2006	32,400,000
2007	40,000,000

We note that the Federal spending levels for the SCHIP program are based entirely on the spending and allocation formulas contained in the statute. The Secretary has no discretion over these spending levels and initial allotments of funds allocated to States. Both direct program and administrative costs are covered by the allotments.

2. Impact on States

SCHIP is a State-Federal program under which funds go directly to States, which have great flexibility in designing their programs. Specifically, within broad Federal guidelines, each State determines the design of its program, eligible groups, benefit packages,

payment levels for coverage and administrative and operating procedures. As such, it is difficult to quantify the economic impact on States beyond the obvious benefit of additional funding provided at an ''enhanced'' matching rate as compared to the matching rates for the Medicaid program. As stated above, the total Federal payments available to States are specified in the statute and are allocated according to a statutory formula based on the number of uninsured, low-income children for each State, and a geographic adjustment factor. For qualifying expenditures, States will receive an enhanced Federal matching rate equal to its current FMAP increased by 30 percent of the difference between its regular matching rate and 100 percent, except that the enhanced match cannot exceed 85 percent.

The following chart depicts estimated outlays for the SCHIP program. These estimates differ from the allotments referred to above in that the allotments allow the money to be spent over a period of three years.

FISCAL YEAR OUTLAYS

[In billions]

	1999	2000	2001	2002	2003
Federal share	0.6	1.3	1.9	2.5	3.0
State share	0.2	0.6	0.8	1.1	1.3
Total	0.8	1.9	2.7	3.6	4.3

Note: These estimates are based on State and Federal budget projections and have been included in the President's FY 2001 budget. Outlay estimates do not include costs for Medicaid expansion programs but only for separate child health programs.

Because the final rule largely confirms the provisions in the proposed rule, which were based on previously released guidance, most States' programs are already in compliance with these Federal requirements. In addition, this final rule includes a balance of provisions that provide additional flexibility for States with further clarification of the intent of the statute. Therefore, coupled with the fact that States are working with a limited amount of funds, we do not anticipate that the publication of this rule will have a significant or unexpected impact on States.

3. Impact on the Private Sector

We note that due to the flexibility that States have in designing and implementing their SCHIP programs it is not possible to determine the impact on individual providers groups of providers, insurers, health plans, or employers. However, we anticipate that the SCHIP program will benefit the private sector in a number of ways. The program may have a positive impact on a number of small entities given that SCHIP funding will filter down to health care providers and health plans that cover the SCHIP population. Health plans that provide insurance coverage under the SCHIP program will benefit to the extent that children are generally a lower-risk population. That is, children tend to use fewer high-cost health care services than older segments of the population. Thus, by providing health insurance coverage for preventive care such as well-baby and well-child care and immunizations, SCHIP may benefit health insurers by reducing the need to provide more costly health care services for serious illnesses. Additionally, because SCHIP provides health insurance coverage to children who were previously uninsured, health care providers will no longer have to absorb the cost of uncompensated care for these children. The private sector may also benefit from SCHIP to the extent that children and families with health insurance coverage are more likely to use health care services. Thus, health care providers are likely to experience an increase in demand for their services. Small businesses that are unable to afford private health insurance for their employees will benefit to the extent that the employees, or their children qualify for SCHIP. However, because States have largely been operating their SCHIP programs in accordance with the proposed rule since the beginning of their programs, we do not anticipate the final rule will have a significant impact on the private sector, with the exception of the potential for additional program expansions.

4. Impact on Beneficiaries

The main goal of SCHIP is to provide health insurance coverage for children in families that are not eligible for Medicaid, but do not earn enough to afford private health insurance. SCHIP will allow a large number of children who were previously uninsured to have access to health insurance and the opportunity to receive health care services on a regular basis.

Subpart E of this final rule sets forth provisions regarding the costs that beneficiaries may incur (cost sharing) under SCHIP. In accordance with the statute, we set forth provisions concerning general cost sharing protection for lower income children and American Indians/Alaska Natives, cost sharing for children from families with certain income levels, and cumulative cost-sharing maximums. Section 457.555 sets forth maximum allowable cost sharing charges on targeted low-income children in families with income from 101 to 150 percent of the FPL. This section specifies maximum copayment amounts that may be imposed under fee-for-service delivery systems and managed care organizations. Additionally, regarding cumulative cost sharing maximums, § 457.560 provides that cost sharing for children with family income above 150 percent of the Federal poverty level may not exceed 5 percent of total family income for the year. For children with family income at or below 150 percent of the Federal poverty level, cost sharing may not exceed 2.5 percent of total family income for the year.

We note that due to State flexibility in establishing cost-sharing amounts below the maximums and differing utilization patterns among beneficiaries, it is difficult to quantify the amount of cost sharing that families incur to participate in SCHIP. However, in light of the number of children enrolled in SCHIP, we believe that for most beneficiaries, the benefit of access to health insurance coverage outweighs the costs associated with participation in the program.

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

We received the following comment on the impact analysis:

Comment: Several commenters believe that the regulation is administratively burdensome. Specifically, commenters asserted that the administrative funding for SCHIP is insufficient to effectively operate a State plan under the proposed regulations. The proposed rule fails to adequately acknowledge that State budgets for outreach and administrative activities are limited to 10 percent of total expenditures. Commenters believe this method of computing the administrative cap places States in a difficult position because in order to increase enrollment (and consequently the State's total expenditures), States must incur expenditures for outreach. Commenters recommended that we exclude outreach expenditures from the 10 percent cap.

Commenters also noted that the proposed regulations create additional administrative burdens that do not improve services and may force States to revise programs at additional costs to States. They indicated that for Medicaid expansion programs, Federally required systems changes are matched at 90 percent with no cap. However, the proposed regulations do not offer a similar provision for separate child

health programs required to make changes to existing systems. Additionally, separate child health programs are required to absorb these costs within the limited 10 percent administrative cap.

Commenters strongly recommended that we carefully consider the administrative feasibility and the cost of the proposed regulations for SCHIP eligibles and their families, States and MCEs. Commenters argued that the burden of high administrative costs will be particularly difficult for health plans to bear because per enrollee revenues are comparatively small under SCHIP. The commenters suggested that we evaluate carefully the costs and benefits of administrative requirements to avoid threatening the economic viability of SCHIP programs. The participation of private health plans can offer significant advantages in providing attractive plans for beneficiaries, organizing provider networks, controlling costs and delivering innovations from the employer-based market. However, the low cap on administrative expenses has served to deter some private plans from participating in SCHIP programs. Some private health plans have found it difficult to forecast the financial risk associated with covering children under this program and are concerned that they cannot provide for adequate reserves under the cap.

Response: Under section 2105(c)(2)(A) of the Act, States may receive funds at the enhanced FMAP for administrative expenditures, outreach, health services initiatives, and certain other child health assistance, only up to a ''10 Percent Limit.'' The ''10 Percent Limit'' found in the statute specifies that the ''total computable'' amount of these expenditures (the combined total State and Federal share of benefit and administrative expenditures) for which FFP may be claimed cannot exceed 10 percent of the sum of the total computable expenditures made under section 2105(a) of the Act and the total computable expenditures based on the enhanced match made under sections 1905(u)(2) and (u)(3) of the Act.

It is important to note that States may mitigate the effect of little or no program expenditures on the calculation of the 10 percent limit in one fiscal year by delaying the claiming of administrative expenditures until a subsequent fiscal year. In that case, the delayed administrative expenditures could be applied against the subsequent year's 10 percent limit, which may be calculated using presumably higher program expenditures. This should prove helpful to States now that their programs are up and running and the original start up costs are diminishing. In addition, as States gain more experience operating their programs, administrative costs should fall below the 10 percent cap on administrative expenditures.

In response to the comment that some health plans have found it difficult to foresee the risk associated with covering children under this program, we have no requirement for plan administrative costs. These costs are subject to negotiations between the individual health plan and the State in a risk based capitated arrangement.

V. Federalism

Under Executive Order 13132, we are required to adhere to certain criteria regarding Federalism in developing regulations. Title XXI authorizes grants to States that initiate or expand health insurance programs for low-income, uninsured children. A State Children's Health Insurance Program (SCHIP) under title XXI is jointly financed by the Federal and State governments and is administered by the States. Within broad Federal guidelines, each State determines the design of its program, eligible groups, benefit packages, payment levels for coverage and administrative and operating procedures. States have great flexibility in designing programs to best meet the needs of their beneficiaries. HCFA works closely with the States during the State plan and State plan amendment approval process to ensure that we reach a mutually agreeable decision.

Federal payments under title XXI to States are based on State expenditures under approved plans that could be effective on or after October 1, 1997. The short time frame between the enactment of the Balanced Budget Act (BBA) (August 5, 1997) and the availability of the funding for States required the Department to begin reviewing SCHIP plans submitted by States and Territories at the same time as it was issuing guidance to States on how to operate the SCHIP programs. The Department worked closely with States to disseminate as much information as possible, as quickly as possible, so States could begin to implement their new programs expeditiously.

To be more specific, the Department began issuing guidance to States within one month of enactment of the BBA. We provided information on each State's allotment through two **Federal Register** notices published on September 12, 1997 (62 FR 48098) and February 8, 1999 (64 FR 6102). We developed a model application template to assist State's in applying for title XXI funds. We provided over 100 answers to frequently asked questions. We issued policy guidance through a series of 23 letters to State health officials. All of this information is currently available on our website located on the Internet at *http://www.hcfa.gov.* We have also provided technical assistance to all States in development of SCHIP applications.

On November 8, 1999 we published in the **Federal Register** a proposed rule that set forth all programmatic provisions for SCHIP (64 FR 60882). We received 109 timely comments on the proposed rule. Interested parties that commented included States, enrollee advocate organizations, individuals, and provider organizations. The comments received varied widely and were often very detailed. We received a significant number of comments on the following areas: State plan issues, such as when an amendment to an existing plan is needed; the exemption to cost sharing for American Indian/Alaska Native children; eligibility ''screen and enroll'' requirements; Medicaid coordination issues; eligibility simplification options such as presumptive eligibility; the definition of a targeted low-income child; substitution of private coverage; data collection on race, ethnicity, gender and primary language; grievance and appeal procedures; and premium assistance for employer-sponsored coverage. In this final rule we provide detailed responses to all issues raised by the commenters.

The final programmatic regulation incorporates much of the guidance that already has been issued to States. As the final regulation builds upon previously released guidance, most of the regulation represents policies that have been in operation for some time and are a result of the consultation process that is required as part of the implementation of SCHIP; specifically, the State plan approval process. In developing the interpretative policies set forth in this final rule, we also listened to the concerns of States through processes other than the State plan process as well, by attending conferences and meeting with various groups representing State and public interests. We consulted with State and local officials in the course of the design and review stages of State proposals, and many of the policies found in the proposed and this final rule are a direct result of these discussions and negotiations with the States. To the extent consistent with the objectives of the statute, to obtain substantial health care coverage for uninsured low-income children in an effective an efficient manner, we have endeavored to preserve State options in implementing

their programs. As we continue to implement the program, we have identified a number of areas in which we further elaborate on previous guidance or implement new policies. A summary of key issues is set forth at section II.A.1 of the preamble to this final rule.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to provide a 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. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comments on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;
- The accuracy of the agency's estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comment on each of these issues for the information collection requirement discussed below. The following sections of this document contain information collection requirements:

Section 457.50—State Plan

In summary, § 457.50 requires a State to submit a child health plan to HCFA for approval. The child health plan is a comprehensive written statement submitted by the State describing the purpose, nature, and scope of its Child Health Insurance Program and giving assurance that it will be administered in conformity with the specific requirements of title XIX (as appropriate), title XXI, and the regulations in this chapter. The State plan contains all information necessary for HCFA to determine whether the plan can be approved to serve as a basis for Federal financial participation in the State program.

The burden associated with this requirement is the time and effort for a State to prepare and submit its child health plan to HCFA for approval. These collection requirements are currently approved by OMB under OMB1 0938–0707.

Section 457.60—Amendments

In summary, § 457.60 requires a State to submit to HCFA for approval an amendment to its approved State plan, whenever necessary, to reflect any changes in; (1) Federal law, regulations, policy interpretations, or court decisions, (2) State law, organization, policy or operation of the program, or (3) the source of the State share of funding.

The burden associated with this requirement is the time and effort for a State to prepare and submit any necessary amendments to its State plan to HCFA for approval. Based upon HCFA's previous experiences with State plan amendments we estimate that on average, it will take a State 80 hours to complete and submit an amendment. We estimate that 10 States/territories will submit an amendment on an annual basis for a total burden of 800 hours.

Section 457.70—Program Options

In summary, § 457.70 requires a State that elects to obtain health benefits coverage through its Medicaid plan to submit an amendment to the State's Medicaid State plan as appropriate, demonstrating that it meets specified requirements in subparts A, B, C, F, G and J of part 457 and the applicable Medicaid regulations.

The burden associated with this requirement is the time and effort for a State to prepare and submit the necessary amendment to its Medicaid State plan to HCFA for approval. Based upon HCFA's previous experiences with State Plan amendments we estimate that on average, it will take a State 2 hours to complete and submit an amendment for HCFA approval. We estimate that 28 States/territories will submit an amendment for a total one-time burden of 56 hours.

Section 457.350—Eligibility Screening

In summary, § 457.350 requires a State that chooses to screen for Medicaid eligibility under the poverty level related groups described in 1902(l) of the Act, to provide written notification to the family if the child is found not to be Medicaid eligible.

The burden associated with this requirement is the time and effort for a State to prepare and provide written notification to the family if the child is found not to be Medicaid eligible. The average burden upon the State to prepare the notice is a one time burden estimated to be 10 hours and that it will take 3 minutes for the State to provide and the family to read the information. We estimate that on average, that each State will be required to provide 1 million notices on an annual basis for a total annual burden of 50,000 hours, per State. Therefore, the total estimated burden is calculated to be 2,700,000 hours on an annual basis.

Section 457.360—Facilitating Medicaid Enrollment

In summary § 457.360(c) requires a State to provide full and complete information, in writing to the family (that meets the requirements of (c)(1) through (c)(2) of this section), to ensure that a decision by the family not to apply for Medicaid or not to complete the Medicaid application process represents an informed decision.

The burden associated with this requirement is the time and effort for a State to prepare and provide written notice to the family to ensure that a decision by the family not to apply for Medicaid or not to complete the Medicaid application process represents an informed decision. The average burden upon the State to disseminate a standard notice to the family is estimated to be 3 minutes. We estimate that on average, each State will be required to provide 1 million notices on an annual basis for a total annual burden of 50,000 hours, per State. Therefore, the total estimated burden is calculated to be 2,700,000 hours on an annual basis.

Section 457.361—Application for and Enrollment in CHIP

In summary, § 457.361(b) requires a State to inform applicants, at the time of application, in writing and orally if appropriate, about the eligibility requirements and their rights under the program.

The burden associated with this requirement is the time and effort for a State to inform each applicant in writing and orally if appropriate, about the eligibility requirements and their rights and obligations under the program. We estimate the average burden upon the State to disseminate a standard notice to the family is estimated to be 3 minutes. We estimate that on average, each State will be required to provide 1 million notices on an annual basis for a total annual burden of 50,000 hours, per State. Therefore, the total estimated burden is calculated to be 2,700,000 hours on an annual basis.

In summary, § 457.361(c) requires a State to send each applicant a written notice of the agency's decision on the application and, if eligibility is denied or terminated in accordance with § 457.1170(b) (that is, the specific reason or reasons for the action and an

explanation of the right to request a hearing within a reasonable time).

The burden associated with this requirement is the time and effort for a State to prepare and provide written notice to each applicant of the agency's decision on the application, and if eligibility is denied or terminated, the specific reason or reasons for the action and an explanation of the right to request a hearing within a reasonable time. We estimate that on average, it will take each State 3 minutes to prepare each notice and that each State will be required to provide 1 million notices on an annual basis for a total annual burden of 50,000 hours, per State. Therefore, the total estimated burden is calculated to be 2,700,000 hours on an annual basis.

Section 457.431—Actuarial Report for Benchmark-Equivalent Coverage

In summary, § 457.431 requires a State that wants to obtain approval for benchmark-equivalent benefits coverage described under § 457.430 to submit to HCFA an actuarial report that: (1) Compares the actuarial value of coverage of the benchmark package to the State-designed benchmark-equivalent benefit package; (2) demonstrates through an actuarial analysis of the benchmark-equivalent package that coverage requirements under § 457.430 are met; and (3) meets the requirements of § 457.431(b).

The burden associated with this requirement is the time and effort for a State that wants to obtain approval for benchmark-equivalent benefits coverage described under § 457.430 to prepare and submit its actuarial report to HCFA for approval. We estimate that, on average, it will take a State 40 hours to prepare and submit a report for HCFA approval. We estimate that 6 States/territories will submit a plan for a total burden of 240 hours.

Section 457.440—Existing State-Based Comprehensive Coverage

Under paragraph (b) of this section, a State may modify an existing comprehensive State-based coverage program described in paragraph (a) of the section if, among other items, the State submits an actuarial report when it amends its existing coverage.

The burden associated with this requirement is the time and effort for a State needs to prepare an actuarial report. There are only three States that would have this option; we do not anticipate that more than one of them would modify its program in a given year. It would take that State an average of 40 hours to prepare the report.

Section 457.525—Public Schedule

In summary, § 457.525(b) requires a State to make the public schedule required under paragraph (a) available to:

(1) SCHIP enrollees, at the time of enrollment and reenrollment after a redetermination of eligibility, and when cost-sharing charges and cumulative cost-sharing maximums are revised.

(2) SCHIP applicants, at the time of application.

(3) All SCHIP participating providers.

(4) The general public.

The burden associated with this requirement is the time and effort for a State to prepare and make available its public schedule available to these four groups. We estimate that on average, it will take each State/Territory 120 minutes to prepare its public schedule and 3 minutes to disseminate no more than 20,000 copies of its schedule on an annual basis for a total annual burden of 1000 hours, per State/Territory. Therefore, the total estimated burden is calculated to be 54,000 hours on an annual basis.

Section 457.570—Disenrollment Protections

Under paragraph (a) of this section, a State must give enrollees reasonable written notice of and an opportunity to pay past due premiums, copayments, coinsurance, deductibles or similar fees prior to disenrollment.

The burden associated with this requirement is the time and effort for a State to prepare a standardized notice and to fill out and give the enrollees the notice. We estimate that it will take each State four hours to create a notice, for a national burden of 216 hours. We anticipate that it will take no longer than 10 minutes per enrollee to fill out the notice and give it to the enrollee; we estimate that approximately five per cent of enrollees will be given notices. If there are 2.6 million children enrolled, as projected, the burden nationally will be 21,700 hours of burden [(2.6 million $\times$ 5 percent $\times$ 10 minutes) $\div$ 60].

Section 457.740—State Expenditure and Statistical Reports.

In summary, § 457.740 requires a State to submit a report to the Secretary that contains quarterly program expenditures and statistical data, no later than 30 days after the end of each quarter of the federal fiscal year. The burden associated with this requirement is the time and effort for a State to prepare and submit its report to the Secretary. These collection requirements are currently approved by under OMB approval number OMB# 0938–0731, with a current expiration date of 1/31/2002.

In addition § 457.740 requires a State to submit an annual report, thirty days after the end of the Federal fiscal year, of an unduplicated count for the Federal fiscal year of children who are enrolled in the title XIX Medicaid program, and the separate child health and Medicaid-expansion programs, as appropriate, by age, service delivery, and income categories described in paragraphs (a) and (b) of this section.

The burden associated with this requirement is the time and effort for a State to prepare and submit its annual report to the Secretary. We estimate that on average, it will take a State 40 hours to complete and submit their report. We estimate that 54 States/territories will submit a plan for a total burden of 2160 hours.

Section 457.750—Annual Report

In summary, § 457.750 requires a State to submit a report to the Secretary by January 1 following the end of each federal fiscal year, on the results of the State's assessment of operation of the State child health plan.

The burden associated with this requirement is the time and effort for a State to prepare and submit its annual report on the results of the State's assessment of operation of the State child health plan. We estimate that on average, it will take a State 40 hours to complete and submit their report. We estimate that 54 States/territories will submit a plan for a total burden of 2160 hours.

Section 457.810—Premium Assistance for Employer-Sponsored Group Health Plans: Required Protections Against Substitution

In summary, § 457.810(d) requires a State that uses title XXI funds to provide premium subsidies under employer-sponsored group health plans to collect information to evaluate the amount of substitution that occurs as a result of the subsidies and the effect of subsidies on access to coverage.

The burden associated with this requirement is the time and effort for a State to collect the necessary data to evaluate the amount of substitution that occurs as a result of the subsidies and the effect of subsidies on access to coverage. We estimate that on average, it will take a State 20 hours to collect the necessary data for their evaluation. We estimate that 54 States/territories will submit a plan for a total burden of 1,080 hours.

Section 457.940—Procurement Standards

Under paragraph (a), a State must submit to HCFA a written assurance that title XXI services will be provided in an effective and efficient manner. The burden associated with this requirement is the time and effort for a State to write this assurance. We believe that the time involved will be minimal and assign one hour per State for this requirement.

Section 457.950—Contract and Payment Requirements Including Certification of Payment-Related Information

This section, in paragraph (b), requires a State that makes payments to fee-for-service entities under a separate child health program to—

(1) Establish procedures to certify and attest that information on claim forms is truthful, accurate, and complete.

(2) Ensure that fee-for-service entities understand that payment and satisfaction of the claims will be from federal and State funds, and that any false claims may be prosecuted under applicable federal or State laws.

(3) Require, as a condition of participation, that fee-for-service entities provide the State, HCFA and/or the HHS Office of the Inspector General with access to enrollee health claims data, claims payment data and related records.

The burden associated with this requirement is the time and effort for a State to establish procedures. It is also the time and effort required for a fee-for-service entity to certify and attest that information on claim forms is truthful, accurate, and complete and to provide access to the required data to the State, HCFA and/or the HHS Office of the Inspector General. Depending on the situation, we estimate that the time required to complete such a certification would be 8 hours per certification, per year. Therefore, 8 hours × 51 States and Territories for a total burden of 408 hours per year.

Section 457.965—Documentation

In summary, § 457.965 requires a State to include in each applicant's record facts to support the State's determination of the applicant's eligibility for CHIP. While this requirement is subject to the PRA, we believe that the burden associated with this requirement is exempt from the PRA as defined in 5 CFR 1320(b)(3), because this requirement would be imposed in the absence of a Federal requirement.

Section 457.985—Integrity of Professional Advice to Enrollees

Under this section, the State must guarantee, in all contracts for coverage and services, beneficiary access to information, in accordance with §§ 422.208 and 422.210(a) and (b), related to limitations on physician incentives or compensation arrangements that have the effect of reducing or limiting services and information requirements respectively.

The burden associated with this requirement is the time and effort for a State to include this guarantee in its contract(s) and for its contractor(s) to give beneficiaries access. We estimate that it will take a token hour for each State to comply with this requirement. We estimate that it will take each contractor 1 hour to include this assurance in its contracts, however the number of contractors that will be affected cannot be known, as States have flexibility to use contractors as they deem appropriate.

Section 457.1005—Waiver for Cost-Effective Coverage Through a Community-Based Health Delivery System

In summary, § 457.1005 requires a State requesting a waiver for cost-effective coverage through a community-based health delivery system, to submit documentation to HCFA that demonstrates that they meet the requirements of § 457.1005(b)(1) and (b)(2).

The burden associated with this requirement is the time and effort for a State that wants to obtain a waiver to prepare and submit the necessary documentation to HCFA that demonstrates that they meet the requirements of § 457.1005.

We estimate that on average, it will take a State 24 hours to prepare and submit a waiver request for HCFA approval. We estimate that 10 States/territories will submit a request for a total burden of 240 hours.

Section 457.1015—Cost Effectiveness

In summary, § 457.1015 requires a State to report to HCFA in its annual report the amount it spent on family coverage and the number of children it covered. While this requirement is subject to the PRA, the burden associated with this requirement is captured in § 457.750 (Annual report).

Section 457.1180—Notice

Under this section, a State must provide enrollees and applicants timely written notice of any determinations required to be subject to review under § 457.1130, a notice that includes the reasons for the determination; an explanation of applicable rights to review of that determination, the standard and expedited time frames for review, and the manner in which a review can be requested; and the circumstances under which benefits may continue pending review.

The burden associated with this requirement is the time and effort for a State to prepare and give out the notice. We estimate that it will take each State four hours (216 hours nationally) to develop a standardized form into which enrollee-specific information may be inserted and a half hour per enrollee to prepare and give out the notice. We estimate that approximately 10 percent of enrollees will receive a notice under this provision, or 130,000 hours nationally [(2.6 million × 30 minutes × 10 percent) ÷ 60 minutes].

We have submitted a copy of this final rule to OMB for its review of the information collection requirements in §§ 457.50, 457.60, 457.70, 457.350, 457.360, 457.361, 457.431, 457.440, 457.525, 457.740, 457.750, 457.760, 457.810, 457.940, 457.965, 457.985, 457.1005, 457.1015, and 457.1140. These requirements are not effective until they have been approved by OMB.

If you have any comments on any of these information collection and record keeping requirements, please mail the original and 3 copies directly to the following: Health Care Financing Administration, Office of Information Services, Standards and Security Group, Division of HCFA Enterprise Standards, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850. Attn: Julie Brown HCFA–2006–P.

And, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, HCFA Medicaid Desk Officer.

List of Subjects

42 CFR Part 431

Grant programs-health, Health facilities, Medicaid, Privacy, Reporting and record keeping requirements.

42 CFR Part 433

Administrative practice and procedure, Child support, Claims, Grant programs-health, Medicaid, Reporting and record keeping requirements.

42 CFR Part 435

Aid to Families with Dependent Children, Grant programs-health, Medicaid, Reporting and record keeping requirements, Supplemental Security Income (SSI), Wages.

42 CFR Part 436

Aid to Families with Dependent Children, Grant programs-health, Guam, Medicaid, Puerto Rico, Supplemental Security Income (SSI), Virgin Islands.

42 CFR Part 457

Administrative practice and procedure, Grant programs-health, Children's Health Insurance Program, Reporting and record keeping requirements.

42 CFR chapter IV is amended as set forth below:

A. Part 431 is amended as follows:

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

1. The authority citation for part 431 continues to read as follows:

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

2. A new § 431.636 is added to read as follows:

§ 431.636 Coordination of Medicaid with the State Children's Health Insurance Program (SCHIP).

(a) *Statutory basis.* This section implements—

(1) Section 2102(b)(3)(B) of the Act, which provides that children who apply for coverage under a separate child health plan under title XXI, but are found to be eligible for medical assistance under the State Medicaid plan, must be enrolled in the State Medicaid plan; and

(2) Section 2102(c)(2) of the Act, which requires coordination between a State child health program and other public health insurance programs.

(b) *Obligations of State Medicaid Agency.* The State Medicaid agency must adopt procedures to facilitate the Medicaid application process for, and the enrollment of children for whom the Medicaid application and enrollment process has been initiated in accordance with § 457.350(f) of this chapter. The procedures must ensure that—

(1) The applicant is not required to provide information or documentation that has been provided to the State agency responsible for determining eligibility under a separate child health program under title XXI and forwarded by such agency to the Medicaid agency on behalf of the child in accordance with § 457.350(f) of this chapter;

(2) Eligibility is determined in a timely manner in accordance with § 435.911 of this chapter;

(3) The Medicaid agency promptly notifies the State agency responsible for determining eligibility under a separate child health program when a child who was screened as potentially eligible for Medicaid is determined ineligible or eligible for Medicaid; and

(4) The Medicaid agency adopts a process that facilitates enrollment in a State child health program when a child is determined ineligible for Medicaid at initial application or redetermination.

3. In § 431.865(b), the definition of ''erroneous payments'' is revised to read as follows:

§ 431.865 Disallowance of Federal financial participation for erroneous State payments (for annual assessment periods ending after July 1, 1990).

* * * * *

(b) * * *

Erroneous payments means the Medicaid payment that was made for an individual or family under review who—

(1) Was ineligible for the review month or, if full month coverage is not provided, at the time services were received;

(2) Was ineligible to receive a service provided during the review month; or

(3) Had not properly met enrollee liability requirements prior to receiving Medicaid services.

(4) The term does not include payments made for care and services covered under the State plan and furnished to children during a presumptive eligibility period as described in § 435.1102 of this chapter.

* * * * *

B. Part 433 is amended as follows:

PART 433—STATE FISCAL ADMINISTRATION

1. The authority citation for part 433 is revised to read as follows:

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

2. In § 433.10, the heading of paragraph (c) is republished and a new paragraph (c)(4) is added to read as follows:

§ 433.10 Rates of FFP for program services.

* * * * *

(c) *Special provisions.* * * *

(4) Under section 1905(b) of the Social Security Act, the Federal share of State expenditures described in § 433.11(a) for services provided to children, is the enhanced FMAP rate determined in accordance with § 457.622(b) of this chapter, subject to the conditions explained in § 433.11(b).

3. A new § 433.11 is added to read as follows:

§ 433.11 Enhanced FMAP rate for children.

(a) Subject to the conditions in paragraph (b) of this section, the enhanced FMAP determined in accordance with § 457.622 of this chapter will be used to determine the Federal share of State expenditures, except any expenditures pursuant to section 1923 of the Act for payments to disproportionate share hospitals for—

(1) Services provided to optional targeted low-income children described in § 435.4 or § 436.3 of this chapter; and

(2) Services provided to children born before October 1, 1983, with or without group health coverage or other health insurance coverage, who would be described in section 1902(l)(1)(D) of the Act (poverty-level-related children's groups) if—

(i) They had been born on or after that date; and

(ii) They would not qualify for medical assistance under the State plan in effect on March 31, 1997.

(b) Enhanced FMAP is not available if—

(1) A State adopts income and resource standards and methodologies for purposes of determining a child's eligibility under the Medicaid State plan that are more restrictive than those applied under policies of the State plan (as described in the definition of optional targeted low-income children at § 435.4 of this chapter) in effect on June 1, 1997; or

(2) No funds are available in the State's title XXI allotment, as determined under part 457, subpart F of this chapter for the quarter enhanced FMAP is claimed; or

(3) The State fails to maintain a valid method of identifying services provided on behalf of children listed in paragraph (a) of this section.

C. Part 435 is amended as set forth below:

PART 435—ELIGIBILITY IN THE STATES, DISTRICT OF COLUMBIA, THE NORTHERN MARIANA ISLANDS, AND AMERICAN SAMOA

1. The authority citation for part 435 continues to read as follows:

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

2. Section 435.4 is amended by adding a definition of ''optional targeted low-income child,'' in alphabetical order, to read as follows:

§ 435.4 Definitions and use of terms.

* * * * *

Optional targeted low-income child means a child under age 19 who meets the financial and categorical standards described below.

(1) *Financial need.* An optional targeted low-income child:

(i) Has a family income at or below 200 percent of the Federal poverty line for a family of the size involved; and

(ii) Resides in a State with no Medicaid applicable income level (as defined at § 457.10 of this chapter); or

(iii) Resides in a State that has a Medicaid applicable income level (as defined at § 457.10 of this chapter) and has family income that either:

(A) Exceeds the Medicaid applicable income level for the age of such child, but not by more than 50 percentage points; or

(B) Does not exceed the income level specified for such child to be eligible for medical assistance under the policies of the State plan under title XIX on June 1, 1997.

(2) *No other coverage and State maintenance of effort.* An optional targeted low-income child is not covered under a group health plan or health insurance coverage, or would not be eligible for Medicaid under the policies of the State plan in effect on March 31, 1997; except that, for purposes of this standard—

(i) A child shall not be considered to be covered by health insurance coverage based on coverage offered by the State under a program in operation prior to July 1, 1997 if that program received no Federal financial participation;

(ii) A child shall not be considered to be covered under a group health plan or health insurance coverage if the child did not have reasonable geographic access to care under that coverage.

(3) For purposes of this section, policies of the State plan a under title XIX plan include policies under a Statewide demonstration project under section 1115(a) of the Act other than a demonstration project that covered an expanded group of eligible children but that either—

(i) Did not provide inpatient hospital coverage; or

(ii) Limited eligibility to children previously enrolled in Medicaid, imposed premiums as a condition of initial or continued enrollment, and did not impose a general time limit on eligibility.

* * * * *

3. A new § 435.229 is added to read as follows:

§ 435.229 Optional targeted low-income children.

The agency may provide Medicaid to—

(a) All individuals under age 19 who are optional targeted low-income children as defined in § 435.4; or

(b) Reasonable categories of these individuals.

4. In § 435.910, paragraph (h) is added to read as follows:

§ 435.910 Use of social security number.

* * * * *

(h) *Exception.* (1) A State may give a Medicaid identification number to an applicant who, because of well established religious objections, refuses to obtain a Social Security Number (SSN). The identification number may be either an SSN obtained by the State on the applicant's behalf or another unique identifier.

(2) The term *well established religious objections* means that the applicant—

(i) Is a member of a recognized religious sect or division of the sect; and

(ii) Adheres to the tenets or teachings of the sect or division of the sect and for that reason is conscientiously opposed to applying for or using a national identification number.

(3) A State may use the Medicaid identification number established by the State to the same extent as an SSN is used for purposes described in paragraph (b)(3) of this section.

5. In § 435.1001, paragraph (a) is revised to read as follows:

§ 435.1001 FFP for administration.

(a) FFP is available in the necessary administrative costs the State incurs in—

(1) Determining and redetermining Medicaid eligibility and in providing Medicaid to eligible individuals; and

(2) Determining presumptive eligibility for children and providing services to presumptively eligible children.

* * * * *

6. Section 435.1002 is amended by adding a new paragraph (c) to read as follows:

§ 435.1002 FFP for services.

* * * * *

(c) FFP is available in expenditures for services covered under the plan that are furnished—

(1) To children who are determined by a qualified entity to be presumptively eligible;

(2) During a period of presumptive eligibility;

(3) By a provider that is eligible for payment under the plan; and

(4) Regardless of whether the children are determined eligible for Medicaid following the period of presumptive eligibility.

§ 435.1007 [Amended]

7. In § 435.1007, in paragraph (a), the second sentence is amended by adding ''and section 1905(u)'' between ''(X)'', and ''of the Act;''.

8. A new subpart L is added to part 435 to read as follows:

Subpart L—Option for Coverage of Special Groups

Sec.

Subpart L—Option for Coverage of Special Groups

§ 435.1100 Basis and scope.

(a) *Statutory basis.* Section 1920A of the Act allows States to provide Medicaid services to children under age 19 during a period of presumptive eligibility, prior to a formal determination of Medicaid eligibility.

(b) Scope. This subpart prescribes the requirements for providing medical assistance to special groups who are not eligible for Medicaid as categorically or medically needy.

Presumptive Eligibility for Children

§ 435.1101 Definitions related to presumptive eligibility for children.

Application form means at a minimum the form used to apply for Medicaid under the poverty-level-related eligibility groups described in section 1902(l) of the Act or a joint form for children to apply for the State Children's Health Insurance Program and Medicaid.

Period of presumptive eligibility means a period that begins on the date on which a qualified entity determines that a child is presumptively eligible and ends with the earlier of—

(1) In the case of a child on whose behalf a Medicaid application has been filed, the day on which a decision is made on that application; or

(2) In the case of a child on whose behalf a Medicaid application has not been filed, the last day of the month following the month in which the determination of presumptive eligibility was made.

Presumptive income standard means the highest income eligibility standard established under the plan that is most likely to be used to establish the regular Medicaid eligibility of a child of the age involved.

Qualified entity means an entity that is determined by the State to be capable of making determinations of presumptive eligibility for children, and that—

(1) Furnishes health care items and services covered under the approved plan and is eligible to receive payments under the approved plan;

(2) Is authorized to determine eligibility of a child to participate in a Head Start program under the Head Start Act;

(3) Is authorized to determine eligibility of a child to receive child care

services for which financial assistance is provided under the Child Care and Development Block Grant Act of 1990;

(4) Is authorized to determine eligibility of an infant or child to receive assistance under the special nutrition program for women, infants, and children (WIC) under section 17 of the Child Nutrition Act of 1966;

(5) Is an elementary or secondary school, as defined in section 14101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 8801);

(6) Is an elementary or secondary school operated or supported by the Bureau of Indian Affairs;

(7) Is a State or Tribal child support enforcement agency;

(8) Is an organization that is providing emergency food and shelter under a grant under the Stewart B. McKinney Homeless Assistance Act;

(9) Is a State or Tribal office or entity involved in enrollment in the program under Part A of title IV, title XIX, or title XXI; or

(10) Is an entity that determines eligibility for any assistance or benefits provided under any program of public or assisted housing that receives Federal funds, including the program under section 8 or any other section of the United States Housing Act of 1937 (42 U.S.C. 1437) or under the Native American Housing Assistance and Self Determination Act of 1996 (25 U.S.C. 4101 *et seq.*); or

(11) Any other entity the State so deems, as approved by the Secretary.

Services means all services covered under the plan including EPSDT (see part 440 of this chapter).

§ 435.1102 General rules.

(a) The agency may provide services to children under age 19 during one or more periods of presumptive eligibility following a determination by a qualified entity that the child's estimated gross family income or, at the State's option, the child's estimated family income after applying simple disregards, does not exceed the applicable income standard.

(b) If the agency elects to provide services to children during a period of presumptive eligibility, the agency must—

(1) Provide qualified entities with application forms for Medicaid and information on how to assist parents, caretakers and other persons in completing and filing such forms;

(2) Establish procedures to ensure that qualified entities—

(i) Notify the parent or caretaker of the child at the time a determination regarding presumptive eligibility is made, in writing and orally if appropriate, of such determination;

(ii) Provide the parent or caretaker of the child with a regular Medicaid application form;

(iii) Within five working days after the date that the determination is made, notify the agency that a child is presumptively eligible;

(iv) For children determined to be presumptively eligible, notify the child's parent or caretaker at the time the determination is made, in writing and orally if appropriate, that—

(A) If a Medicaid application on behalf of the child is not filed by the last day of the following month, the child's presumptive eligibility will end on that last day; and

(B) If a Medicaid application on behalf of the child is filed by the last day of the following month, the child's presumptive eligibility will end on the day that a decision is made on the Medicaid application; and

(v) For children determined not to be presumptively eligible, notify the child's parent or caretaker at the time the determination is made, in writing and orally if appropriate—

(A) Of the reason for the determination; and

(B) That he or she may file an application for Medicaid on the child's behalf with the Medicaid agency;

(3) Provide all services covered under the plan, including EPSDT; and

(4) Allow determinations of presumptive eligibility to be made by qualified entities on a Statewide basis.

(c) The agency must adopt reasonable standards regarding the number of periods of presumptive eligibility that will be authorized for a child in a given time frame.

D. Part 436 is amended as set forth below:

PART 436—ELIGIBILITY IN GUAM, PUERTO RICO, AND THE VIRGIN ISLANDS

1. The authority citation for part 436 continues to read as follows:

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

2. Section 436.3 is amended by adding a definition of ''optional targeted low-income child,'' in alphabetical order, to read as follows:

§ 436.3 Definitions and use of terms.

* * * * *

Optional targeted low-income child means a child under age 19 who meets the financial and categorical standards described below.

(1) *Financial need.* An optional targeted low-income child:

(i) Has a family income at or below 200 percent of the Federal poverty line for a family of the size involved;

(ii) Resides in a State with no Medicaid applicable income level (as defined in § 457.10 of this chapter); or,

(iii) Resides in a State that has a Medicaid applicable income level (as defined in § 457.10) and has family income that either:

(A) Exceeds the Medicaid applicable income level for the age of such child, but not by more than 50 percentage points (expressed as a percentage of the Federal poverty line); or

(B) Does not exceed the income level specified for such child to be eligible for medical assistance under the policies of the State plan under title XIX on June 1, 1997.

(2) *No other coverage and State maintenance of effort.* An optional targeted low-income child is not covered under a group health plan or health insurance coverage, or would not be eligible for Medicaid under the policies of the State plan in effect on March 31, 1997; except that, for purposes of this standard—

(i) A child shall not be considered to be covered by health insurance coverage based on coverage offered by the State under a program in operation prior to July 1, 1997 if that program received no Federal financial participation;

(ii) A child shall not be considered to be covered under a group health plan or health insurance coverage if the child did not have reasonable geographic access to care under that coverage.

(3) For purposes of this section, policies of the State plan under title XIX plan include policies under a Statewide demonstration project under section 1115(a) of the Act other than a demonstration project that covered an expanded group of eligible children but that either—

(i) Did not provide inpatient hospital coverage; or

(ii) Limited eligibility to children previously enrolled in Medicaid, imposed premiums as a condition of initial or continued enrollment, and did not impose a general time limit on eligibility.

3. A new § 436.229 is added to read as follows:

§ 436.229 Optional targeted low-income children.

The agency may provide Medicaid to—

(a) All individuals under age 19 who are optional targeted low-income children as defined in § 436.3; or

(b) Reasonable categories of these individuals.

4. In § 436.1001 paragraph (a) is revised to read as follows:

§ 436.1001 FFP for administration.

(a) FFP is available in the necessary administrative costs the State incurs in—

(1) Determining and redetermining Medicaid eligibility and in providing Medicaid to eligible individuals; and

(2) Determining presumptive eligibility for children and providing services to presumptively eligible children.

* * * * *

5. Section 436.1002 is amended by adding a new paragraph (c) to read as follows:

§ 436.1002 FFP for services.

* * * * *

(c) FFP is available in expenditures for services covered under the plan that are furnished—

(1) To children who are determined by a qualified entity to be presumptively eligible;

(2) During a period of presumptive eligibility;

(3) By a provider that is eligible for payment under the plan; and

(4) Regardless of whether the children are determined eligible for Medicaid following the period of presumptive eligibility.

6. A new subpart L is added to part 436 to read as follows:

Subpart L—Option for Coverage of Special Groups

Sec.

Subpart L—Option for Coverage of Special Groups

§ 436.1100 Basis and scope.

(a) *Statutory basis.* Section 1920A of the Act allows States to provide Medicaid services to children under age 19 during a period of presumptive eligibility, prior to a formal determination of Medicaid eligibility.

(b) *Scope.* This subpart prescribes the requirements for providing medical assistance to special groups who are not eligible for Medicaid as categorically or medically needy.

Presumptive Eligibility for Children

§ 436.1101 Definitions related to presumptive eligibility period for children.

Application form means at a minimum the form used to apply for Medicaid under the poverty-level-related eligibility groups described in section 1902(l) of the Act or a joint form for children to apply for the State Children's Health Insurance Program and Medicaid.

Period of presumptive eligibility means a period that begins on the date on which a qualified entity determines that a child is presumptively eligible and ends with the earlier of—

(1) In the case of a child on whose behalf a Medicaid application has been filed, the day on which a decision is made on that application; or

(2) In the case of a child on whose behalf a Medicaid application has not been filed, the last day of the month following the month in which the determination of presumptive eligibility was made.

Presumptive income standard means the highest income eligibility standard established under the plan that is most likely to be used to establish the regular Medicaid eligibility of a child of the age involved.

Qualified entity means an entity that is determined by the State to be capable of making determinations of presumptive eligibility for children, and that—

(1) Furnishes health care items and services covered under the approved plan and is eligible to receive payments under the approved plan;

(2) Is authorized to determine eligibility of a child to participate in a Head Start program under the Head Start Act;

(3) Is authorized to determine eligibility of a child to receive child care services for which financial assistance is provided under the Child Care and Development Block Grant Act of 1990;

(4) Is authorized to determine eligibility of an infant or child to receive assistance under the special nutrition program for women, infants, and children (WIC) under section 17 of the Child Nutrition Act of 1966;

(5) Is an elementary or secondary school, as defined in section 14101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 8801);

(6) Is an elementary or secondary school operated or supported by the Bureau of Indian Affairs;

(7) Is a State or Tribal child support enforcement agency;

(8) Is an organization that is providing emergency food and shelter under a grant under the Stewart B. McKinney Homeless Assistance Act;

(9) Is a State or Tribal office or entity involved in enrollment in the program under Part A of title IV, title XIX, or title XXI; or

(10) Is an entity that determines eligibility for any assistance or benefits provided under any program of public or assisted housing that receives Federal funds, including the program under section 8 or any other section of the United States Housing Act of 1937 (42 U.S.C. 1437) or under the Native American Housing Assistance and Self Determination Act of 1996 (25 U.S.C. 4101 *et seq.*); or

(11) Any other entity the State so deems, as approved by the Secretary.

Services means all services covered under the plan including EPSDT (see part 440 of this chapter.)

§ 436.1102 General rules.

(a) The agency may provide services to children under age 19 during one or more periods of presumptive eligibility following a determination made by a qualified entity that the child's estimated gross family income or, at the State's option, the child's estimated family income after applying simple disregards, does not exceed the applicable income standard.

(b) If the agency elects to provide services to children during a period of presumptive eligibility, the agency must—

(1) Provide qualified entities with application forms for Medicaid and information on how to assist parents, caretakers and other persons in completing and filing such forms;

(2) Establish procedures to ensure that qualified entities—

(i) Notify the parent or caretaker of the child at the time a determination regarding presumptive eligibility is made, in writing and orally if appropriate, of such determination;

(ii) Provide the parent or caretaker of the child with a Medicaid application form;

(iii) Within 5 working days after the date that the determination is made, notify the agency that a child is presumptively eligible;

(iv) For children determined to be presumptively eligible, notify the child's parent or caretaker at the time the determination is made, in writing and orally if appropriate, that—

(A) If a Medicaid application on behalf of the child is not filed by the last day of the following month, the child's presumptive eligibility will end on that last day; and

(B) If a Medicaid application on behalf of the child is filed by the last day of the following month, the child's presumptive eligibility will end on the day that a decision is made on the Medicaid application; and

(v) For children determined not to be presumptively eligible, notify the child's parent or caretaker at the time the determination is made, in writing and orally if appropriate—

(A) Of the reason for the determination; and

(B) That he or she may file an application for Medicaid on the child's behalf with the Medicaid agency; and

(3) Provide all services covered under the plan, including EPSDT.

(4) Allow determinations of presumptive eligibility to be made by qualified entities on a Statewide basis.

(c) The agency must adopt reasonable standards regarding the number of periods of presumptive eligibility that will be authorized for a child in a given time frame.

E. Part 457 is amended as follows:

PART 457—ALLOTMENTS AND GRANTS TO STATES

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

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

2. A new subpart A is added to read as follows:

Subpart A—Introduction; State Plans for Child Health Insurance Programs and Outreach Strategies

Sec.

Subpart A—Introduction; State Plans for Child Health Insurance Programs and Outreach Strategies

§ 457.1 Program description.

Title XXI of the Social Security Act, enacted in 1997 by the Balanced Budget Act, authorizes Federal grants to States for provision of child health assistance to uninsured, low-income children. The program is jointly financed by the Federal and State governments and administered by the States. Within broad Federal rules, each State decides eligible groups, types and ranges of services, payment levels for benefit coverage, and administrative and operating procedures.

§ 457.2 Basis and scope of subchapter D.

(a) *Basis.* This subchapter implements title XXI of the Act, which authorizes Federal grants to States for the provision of child health assistance to uninsured, low-income children.

(b) *Scope.* The regulations in subchapter D set forth State plan requirements, standards, procedures, and conditions for obtaining Federal financial participation (FFP) to enable States to provide health benefits coverage to targeted low-income children, as defined at § 457.310.

§ 457.10 Definitions and use of terms.

For purposes of this part the following definitions apply:

American Indian/Alaska Native (AI/AN) means—

(1) A member of a Federally recognized Indian tribe, band, or group;

(2) An Eskimo or Aleut or other Alaska Native enrolled by the Secretary of the Interior pursuant to the Alaska Native Claims Settlement Act, 43 U.S.C. 1601 et. seq.; or

(3) A person who is considered by the Secretary of the Interior to be an Indian for any purpose.

Applicant means a child who has filed an application (or who has an application filed on their behalf) for health benefits coverage through the State Children's Health Insurance Program. A child is an applicant until the child receives coverage through SCHIP.

Child means an individual under the age of 19.

Child health assistance means payment for part or all of the cost of health benefits coverage provided to targeted low-income children for the services listed at § 457.402.

Combination program means a program under which a State implements both a Medicaid expansion program and a separate child health program.

Cost sharing means premium charges, enrollment fees, deductibles, coinsurance, copayments, or other similar fees that the enrollee has responsibility for paying.

Creditable health coverage has the meaning given the term ''creditable coverage'' at 45 CFR 146.113 and includes coverage that meets the requirements of § 457.410 and is provided to a targeted low-income child.

Emergency medical condition means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in—

(1) Serious jeopardy to the health of the individual or, in the case of a pregnant woman, the health of a woman or her unborn child;

(2) Serious impairment of bodily function; or

(3) Serious dysfunction of any bodily organ or part.

Emergency services means health care services that are—

(1) Furnished by any provider qualified to furnish such services; and

(2) Needed to evaluate, treat, or stabilize an emergency medical condition.

Enrollee means a child who receives health benefits coverage through SCHIP.

Enrollment cap means a limit, established by the State in its State plan, on the total number of children permitted to enroll in a State's separate child health program.

Family income means income as determined by the State for a family as defined by the State.

Federal fiscal year starts on the first day of October each year and ends on the last day of the following September.

Fee-for-service entity has the meaning assigned in § 457.902.

Group health insurance coverage has the meaning assigned at 45 CFR 144.103.

Group health plan has the meaning assigned at 45 CFR 144.103.

Health benefits coverage means an arrangement under which enrolled individuals are protected from some or all liability for the cost of specified health care services.

Health care services means any of the services, devices, supplies, therapies, or other items listed in § 457.402.

Health insurance coverage has the meaning assigned at 45 CFR 144.103.

Health insurance issuer has the meaning assigned at 45 CFR 144.103.

Health maintenance organization (HMO) plan has the meaning assigned at § 457.420.

Health services initiatives means activities that protect the public health, protect the health of individuals, improve or promote a State's capacity to deliver public health services, or strengthen the human and material resources necessary to accomplish public health goals relating to improving the health of children (including targeted low-income children and other low-income children).

Joint application has the meaning assigned at § 457.301.

Low-income child means a child whose family income is at or below 200 percent of the poverty line for the size of the family involved.

Managed care entity (MCE) means an entity that enters into a contract to provide services in a managed care delivery system, including but not limited to managed care organizations, prepaid health plans, and primary care case managers.

Medicaid applicable income level means, with respect to a child, the effective income level (expressed as a percentage of the poverty line) specified under the policies of the State plan under title XIX of the Act (including for these purposes, a section 1115 waiver authorized by the Secretary or under the authority of section 1902(r)(2) of the Act) as of March 31, 1997 for the child to be eligible for medical assistance under either section 1902(l)(2) or 1905(n)(2) of the Act.

Medicaid expansion program means a program under which a State receives Federal funding to expand Medicaid eligibility to optional targeted low-income children.

Optional targeted low-income child has the meaning assigned at § 435.4 (for States) and § 436.3 (for Territories) of this chapter.

Period of presumptive eligibility has the meaning assigned at § 457.301.

Poverty line/Federal poverty level means the poverty guidelines updated annually in the **Federal Register** by the U.S. Department of Health and Human Services under authority of 42 U.S.C. 9902(2).

Preexisting condition exclusion has the meaning assigned at 45 CFR 144.103.

Premium assistance program means a component of a separate child health program, approved under the State plan, under which a State pays part or all of the premiums for a SCHIP enrollee or enrollees' group health insurance coverage or coverage under a group health plan.

Presumptive income standard has the meaning assigned at § 457.301.

Public agency has the meaning assigned in § 457.301.

Qualified entity has the meaning assigned at § 457.301.

Separate child health program means a program under which a State receives Federal funding from its title XXI allotment to provide child health assistance through obtaining coverage that meets the requirements of section 2103 of the Act and § 457.402.

State means all States, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa and the Northern Mariana Islands. The Territories are excluded from this definition for purposes of § 457.740.

State Children's Health Insurance Program (SCHIP) means a program established and administered by a State, jointly funded with the Federal government, to provide child health assistance to uninsured, low-income children through a separate child health program, a Medicaid expansion program, or a combination program.

State health benefits plan has the meaning assigned in § 457.301.

State plan means the title XXI State child health plan.

Targeted low-income child has the meaning assigned in § 457.310.

Uncovered or uninsured child means a child who does not have creditable health coverage.

Well-baby and well-child care services means regular or preventive diagnostic and treatment services necessary to ensure the health of babies, children and adolescents as defined by the State. For purposes of cost sharing, the term has the meaning assigned at § 457.520.

§ 457.30 Basis, scope, and applicability of subpart A.

(a) *Statutory basis.* This subpart implements the following sections of the Act:

(1) Section 2101(b), which requires that the State submit a State plan.

(2) Section 2102(a), which sets forth requirements regarding the contents of the State plan.

(3) Section 2102(b), which relates to eligibility standards and methodologies.

(4) Section 2102(c), which requires that the State plan include a description of the procedures to be used by the State to accomplish outreach and coordination with other health insurance programs.

(5) Section 2106, which specifies the process for submission, approval, and amendment of State plans.

(6) Section 2107(c), which requires that the State plan include a description of the process used to involve the public in the design and implementation of the plan.

(7) Section 2107(d), which requires that the State plan include a description of the budget for the plan.

(8) Section 2107(e), which provides that certain provisions of title XIX and title XI of the Act apply under title XXI in the same manner that they apply under title XIX.

(b) *Scope.* This subpart sets forth provisions governing the administration of SCHIP, the general requirements for a State plan, and a description of the process for review of a State plan or plan amendment.

(c) *Applicability.* This subpart applies to all States that request Federal financial participation to provide child health assistance under title XXI.

§ 457.40 State program administration.

(a) *Program operation.* The State must implement its program in accordance with the approved State plan, any approved State plan amendments, the requirements of title XXI and title XIX (as appropriate), and the requirements in this chapter. HCFA monitors the operation of the approved State plan and plan amendments to ensure compliance with the requirements of title XXI, title XIX (as appropriate) and this chapter.

(b) *State authority to submit State plan.* A State plan or plan amendment must be signed by the State Governor, or signed by an individual who has been delegated authority by the Governor to submit it.

(c) *State program officials.* The State must identify in the State plan or State plan amendment, by position or title, the State officials who are responsible for program administration and financial oversight.

(d) *State legislative authority.* The State plan must include an assurance that the State will not claim expenditures for child health assistance prior to the time that the State has legislative authority to operate the State plan or plan amendment as approved by HCFA.

§ 457.50 State plan.

The State plan is a comprehensive written statement, submitted by the State to HCFA for approval, that describes the purpose, nature, and scope of the State's SCHIP and gives an assurance that the program is administered in conformity with the specific requirements of title XXI, title XIX (as appropriate), and the regulations in this chapter. The State plan contains all information necessary for HCFA to determine whether the plan can be approved to serve as a basis for Federal financial participation (FFP) in the State program.

§ 457.60 Amendments.

A State may seek to amend its approved State plan in whole or in part at any time through the submission of an amendment to HCFA. When the State plan amendment has a significant impact on the approved budget, the amendment must include an amended budget that describes the State's planned expenditures for a 1-year period. A State must amend its State plan whenever necessary to reflect—

(a) Changes in Federal law, regulations, policy interpretations, or

court decisions that affect provisions in the approved State plan;

(b) Changes in State law, organization, policy, or operation of the program that affect the following program elements described in the State plan:

(1) Eligibility standards, enrollment caps, and disenrollment policies as described in § 457.305.

(2) Procedures to prevent substitution of private coverage, including exemptions or exceptions to required eligibility waiting periods without coverage under a group health plan as described in § 457.810.

(3) The type of health benefits coverage offered, consistent with the options described in § 457.410.

(4) Addition or deletion of specific categories of benefits covered under the State plan.

(5) Basic delivery system approach as described in § 457.490.

(6) Cost-sharing as described in § 457.505.

(7) Screen and enroll procedures, and other Medicaid coordination procedures as described in §§ 457.350 and 457.353.

(8) Review procedures as described in §§ 457.1130, 457.1160, 457.1170, 457.1180 and 457.1190.

(9) Other comparable required program elements.

(c) Changes in the source of the State share of funding, except for changes in the type of non-health care related revenues used to generate general revenue.

§ 457.65 Effective date and duration of State plans and plan amendments.

(a) *Effective date in general.* Except as otherwise limited by this section—

(1) A State plan or plan amendment takes effect on the day specified in the plan or plan amendment, but no earlier than October 1, 1997.

(2) The effective date may be no earlier than the date on which the State begins to incur costs to implement its State plan or plan amendment.

(3) A State plan amendment that takes effect prior to submission of the amendment to HCFA may remain in effect only until the end of the State fiscal year in which the State makes it effective, or, if later, the end of the 90-day period following the date on which the State makes it effective, unless the State submits the amendment to HCFA for approval before the end of that State fiscal year or that 90-day period.

(b) *Amendments relating to eligibility or benefits.* A State plan amendment that eliminates or restricts eligibility or benefits may not be in effect for longer than a 60-day period, unless the amendment is submitted to HCFA before the end of that 60-day period. The amendment may not take effect unless—

(1) The State certifies that it has provided prior public notice of the proposed change in a form and manner provided under applicable State law; and

(2) The public notice was published before the requested effective date of the change.

(c) *Amendments relating to cost sharing.* A State plan amendment that implements cost-sharing charges, increases existing cost-sharing charges, or increases the cumulative cost-sharing maximum as set forth at § 457.560 is considered an amendment that restricts benefits and must meet the requirements in paragraph (b) of this section.

(d) *Amendments relating to enrollment procedures.* A State plan amendment that implements a required period of uninsurance, increases the length of existing required periods of uninsurance, or institutes or extends the use of waiting lists, enrollments caps or closed enrollment periods is considered an amendment that restricts eligibility and must meet the requirements in paragraph (b) of this section.

(e) *Amendments relating to the source of State funding.* A State plan amendment that changes the source of the State share of funding can take effect no earlier than the date of submission of the amendment.

(f) *Continued approval.* An approved State plan continues in effect unless—

(1) The State adopts a new plan by obtaining approval under § 457.60 of an amendment to the State plan;

(2) Withdraws its plan in accordance with § 457.170(b); or

(3) The Secretary finds substantial noncompliance of the plan with the requirements of the statute or regulations.

§ 457.70 Program options.

(a) *Health benefits coverage options.* A State may elect to obtain health benefits coverage under its plan through—

(1) A separate child health program;

(2) A Medicaid expansion program; or

(3) A combination program.

(b) *State plan requirement.* A State must include in the State plan or plan amendment a description of the State's chosen program option.

(c) *Medicaid expansion program requirements.* A State plan under title XXI for a State that elects to obtain health benefits coverage through its Medicaid plan must—

(1) Meet the requirements of—

(i) Subpart A;

(ii) Subpart B (to the extent that the State claims administrative costs under title XXI);

(iii) Subpart F (with respect to determination of the allotment for purposes of the enhanced matching rate, determination of the enhanced matching rate, and payment of any claims for administrative costs under title XXI only);

(iv) Subpart G; and

(v) Subpart J (if the State claims administrative costs under title XXI and seeks a waiver of limitations on such claims based on a community based health delivery system).

(2) Be consistent with the State's Medicaid State plan, or an approvable amendment to that plan, as required under title XIX.

(d) *Separate child health program requirements.* A State that elects to obtain health benefits coverage under its plan through a separate child health program must meet all the requirements of part 457.

(e) *Combination program requirements.* A State that elects to obtain health benefits coverage through both a separate child health program and a Medicaid expansion program must meet the requirements of paragraphs (c) and (d) of this section.

§ 457.80 Current State child health insurance coverage and coordination.

A State plan must include a description of—

(a) The extent to which, and manner in which, children in the State, including targeted low-income children and other classes of children, by income level and other relevant factors, currently have creditable health coverage (as defined in § 457.10) and, if sufficient information is available, whether the creditable health coverage they have is under public health insurance programs or health insurance programs that involve public-private partnerships;

(b) Current State efforts to provide or obtain creditable health coverage for uncovered children, including the steps the State is taking to identify and enroll all uncovered children who are eligible to participate in public health insurance programs and health insurance programs that involve public-private partnerships; and

(c) Procedures the State uses to accomplish coordination of SCHIP with other public and private health insurance programs, sources of health benefits coverage for children, and relevant child health programs, such as title V, that provide health care services for low-income children. Such procedures include those designed to—

(1) Increase the number of children with creditable health coverage;

(2) Assist in the enrollment in SCHIP of children determined ineligible for Medicaid; and

(3) Ensure that only eligible targeted low-income children are covered under SCHIP, such as those procedures required under §§ 457.350 and 457.353, as applicable.

§ 457.90 Outreach.

(a) *Procedures required.* A State plan must include a description of procedures used to inform families of children likely to be eligible for child health assistance under the plan or under other public or private health coverage programs of the availability of the programs, and to assist them in enrolling their children in one of the programs.

(b) *Examples.* Outreach strategies may include but are not limited to the following:

(1) Education and awareness campaigns, including targeted mailings and information distribution through various organizations.

(2) Enrollment simplification, such as simplified or joint application forms.

(3) Application assistance, including opportunities to apply for child health assistance under the plan through community-based organizations and in combination with other benefits and services available to children.

§ 457.110 Enrollment assistance and information requirements.

(a) *Information disclosure.* The State must make accurate, easily understood, linguistically appropriate information available to families of potential applicants, applicants and enrollees, and provide assistance to these families in making informed decisions about their health plans, professionals, and facilities.

(b) *Required information.* The State must make available to potential applicants and provide applicants and enrollees the following information in a timely manner:

(1) Types of benefits, and amount, duration and scope of benefits available under the program.

(2) Cost-sharing requirements as described in § 457.525.

(3) Names and locations of current participating providers.

(4) If an enrollment cap is in effect or the State is using a waiting list, a description of the procedures relating to the cap or waiting list, including the process for deciding which children will be given priority for enrollment, how children will be informed of their status on a waiting list and the circumstances under which enrollment will reopen.

(5) Information on physician incentive plans as required by § 457.985.

(6) Review processes available to applicants and enrollees as described in the State plan pursuant to § 457.1120.

§ 457.120 Public involvement in program development.

A State plan must include a description of the method the State uses to—

(a) Involve the public in both the design and initial implementation of the program;

(b) Ensure ongoing public involvement once the State plan has been implemented; and

(c) Ensure interaction with Indian Tribes and organizations in the State on the development and implementation of the procedures required at § 457.125.

§ 457.125 Provision of child health assistance to American Indian and Alaska Native children.

(a) *Enrollment.* A State must include in its State plan a description of procedures used to ensure the provision of child health assistance to American Indian and Alaska Native children.

(b) *Exemption from cost sharing.* The procedures required by paragraph (a) of this section must include an exemption from cost sharing for American Indian and Alaska Native children in accordance with § 457.535.

§ 457.130 Civil rights assurance.

The State plan must include an assurance that the State will comply with all applicable civil rights requirements, including title VI of the Civil Rights Act of 1964, title II of the Americans with Disabilities Act of 1990, section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, 45 CFR part 80, part 84, and part 91, and 28 CFR part 35.

§ 457.135 Assurance of compliance with other provisions.

The State plan must include an assurance that the State will comply, under title XXI, with the following provisions of titles XIX and XI of the Social Security Act:

(a) Section 1902(a)(4)(C) (relating to conflict of interest standards).

(b) Paragraphs (2), (16) and (17) of section 1903(i) (relating to limitations on payment).

(c) Section 1903(w) (relating to limitations on provider donations and taxes).

(d) Section 1132 (relating to periods within which claims must be filed).

§ 457.140 Budget.

The State plan, or plan amendment that has a significant impact on the approved budget, must include a budget that describes the State's planned expenditures for a 1-year period. The budget must describe—

(a) Planned use of funds, including—

(1) Projected amount to be spent on health services;

(2) Projected amount to be spent on administrative costs, such as outreach, child health initiatives, and evaluation; and

(3) Assumptions on which the budget is based, including cost per child and expected enrollment; and

(b) Projected sources of non-Federal plan expenditures, including any requirements for cost sharing by enrollees.

§ 457.150 HCFA review of State plan material.

(a) *Basis for action.* HCFA reviews each State plan and plan amendment to determine whether it meets or continues to meet the requirements for approval under relevant Federal statutes, regulations, and guidelines furnished by HCFA to assist in the interpretation of these regulations.

(b) *Action on complete plan.* HCFA approves or disapproves the State plan or plan amendment only in its entirety.

(c) *Authority.* The HCFA Administrator exercises delegated authority to review and then to approve or disapprove the State plan or plan amendment, or to determine that previously approved material no longer meets the requirements for approval. The Administrator does not make a final determination of disapproval without first consulting the Secretary.

(d) *Initial submission.* The Administrator designates an official to receive the initial submission of State plans.

(e) *Review process.* (1) The Administrator designates an individual to coordinate HCFA's review for each State that submits a State plan.

(2) HCFA notifies the State of the identity of the designated individual in the first correspondence relating to that plan, and at any time there is a change in the designated individual.

(3) In the temporary absence of the designated individual during regular business hours, an alternate individual will act in place of the designated individual.

§ 457.160 Notice and timing of HCFA action on State plan material.

(a) *Notice of final determination.* The Administrator provides written notification to the State of the approval

or disapproval of a State plan or plan amendment.

(b) *Timing.* (1) A State plan or plan amendment will be considered approved unless HCFA, within 90 calendar days after receipt of the State plan or plan amendment in the HCFA central office, sends the State—

(i) Written notice of disapproval; or

(ii) Written notice of additional information it needs in order to make a final determination.

(2) A State plan or plan amendment is considered received when the designated official or individual, as determined in § 457.150(d) and (e), receives an electronic, fax or paper copy of the complete material.

(3) If HCFA requests additional information, the 90-day review period for HCFA action on the State plan or plan amendment—

(i) Stops on the day HCFA sends a written request for additional information or the next business day if the request is sent on a Federal holiday or weekend; and

(ii) Resumes on the next calendar day after the HCFA designated individual receives an electronic, fax, or hard copy from the State of all the requested additional information, unless the information is received after 5 p.m. eastern standard time on a day prior to a non-business day or any time on a non-business day, in which case the review period resumes on the following business day.

(4) The 90-day review period cannot stop or end on a non-business day. If the 90th calendar day falls on a non-business day, HCFA will consider the 90th day to be the next business day.

(5) HCFA may send written notice of its need for additional information as many times as necessary to obtain the complete information necessary to review the State plan or plan amendment.

§ 457.170 Withdrawal process.

(a) *Withdrawal of proposed State plans or plan amendments.* A State may withdraw a proposed State plan or plan amendment, or any portion of a proposed State plan or plan amendment, at any time during the review process by providing written notice to HCFA of the withdrawal.

(b) *Withdrawal of approved State plans.* A State may request withdrawal of an approved State plan by submitting a State plan amendment to HCFA in accordance with § 457.60.

Subpart B—General Administration—Reviews and Audits; Withholding for Failure to Comply; Deferral and Disallowance of Claims; Reduction of Federal Medical Payments

3. A new § 457.203 is added to read as follows:

§ 457.203 Administrative and judicial review of action on State plan material.

(a) *Request for reconsideration.* Any State dissatisfied with the Administrator's action on State plan material under § 457.150 may, within 60 days after receipt of the notice of final determination provided under § 457.160(a), request that the Administrator reconsider whether the State plan or plan amendment conforms with the requirements for approval.

(b) *Notice of hearing.* Within 30 days after receipt of the request, the Administrator notifies the State of the time and place of a hearing to be held for the purpose of reconsideration.

(c) *Hearing procedures.* The hearing procedures set forth in part 430, subpart D of this chapter govern a hearing requested under this section.

(d) *Effect of hearing decision.* HCFA does not delay the denial of Federal funds, if required by the Administrator's original determination, pending a hearing decision. If the Administrator determines that his or her original decision was incorrect, HCFA will pay the State a lump sum equal to any funds incorrectly denied.

4. Paragraph (d)(2) of § 457.204 is revised to read as follows:

§ 457.204 Withholding of payment for failure to comply with Federal requirements.

* * * * *

(d) * * *

(2) *Opportunity for corrective action.* If enforcement actions are proposed, the State must submit evidence of corrective action related to the findings of noncompliance to the Administrator within 30 days from the date of the preliminary notification. Corrective action is action to ensure that the plan is, and will be, administered consistent with applicable law and regulations, to ameliorate past deficiencies in plan administration, or to ensure that enrollees will be treated equitably.

* * * * *

5. Paragraph (a) of § 457.208 is revised to read as follows:

§ 457.208 Judicial review.

(a) *Right to judicial review.* Any State dissatisfied with the Administrator's final determination on approvability of plan material (§ 457.203) or compliance with Federal requirements (§ 457.204) has a right to judicial review.

* * * * *

§ 457.234 [Removed]

6. Section 457.234 is removed.

7. New subparts C, D, and E are added to read as follows:

Subpart C—State Plan Requirements: Eligibility, Screening, Applications, and Enrollment

Sec.

Subpart D—State Plan Requirements: Coverage and Benefits

Subpart E—State Plan Requirements: Enrollee Financial Responsibilities

Subpart C—State Plan Requirements: Eligibility, Screening, Applications, and Enrollment

§ 457.300 Basis, scope, and applicability.

(a) *Statutory basis.* This subpart interprets and implements —

(1) Section 2102 of the Act, which relates to eligibility standards and methodologies, coordination with other health insurance programs, and outreach and enrollment efforts to identify and enroll children who are eligible to participate in other public health insurance programs;

(2) Section 2105(c)(6)(B) of the Act, which relates to the prohibition against expenditures for child health assistance provided to children eligible for coverage under other Federal health care programs other than programs operated or financed by the Indian Health Service; and

(3) Section 2110(b) of the Act, which provides a definition of targeted low-income child.

(b) *Scope.* This subpart sets forth the requirements relating to eligibility standards and to screening, application and enrollment procedures.

(c) *Applicability.* The requirements of this subpart apply to child health assistance provided under a separate child health program. Regulations relating to eligibility, screening, applications and enrollment that are applicable to a Medicaid expansion program are found at § 431.636, § 435.4, § 435.229, § 435.1102, § 436.3, § 436.229, and § 436.1102 of this chapter.

§ 457.301 Definitions and use of terms.

As used in this subpart—

Joint application means a form used to apply for the separate child health program that, when transmitted to the Medicaid agency following a screening that shows the child is potentially eligible for Medicaid, may also be used to apply for Medicaid.

Qualified entity means an entity that is determined by the State to be capable of making determinations of presumptive eligibility for children, and that—

(1) Furnishes health care items and services covered under the approved plan and is eligible to receive payments under the approved plan;

(2) Is authorized to determine eligibility of a child to participate in a Head Start program under the Head Start Act;

(3) Is authorized to determine eligibility of a child to receive child care services for which financial assistance is provided under the Child Care and Development Block Grant Act of 1990;

(4) Is authorized to determine eligibility of an infant or child to receive assistance under the special nutrition program for women, infants, and children (WIC) under section 17 of the Child Nutrition Act of 1966;

(5) Is an elementary or secondary school, as defined in section 14101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 8801);

(6) Is an elementary or secondary school operated or supported by the Bureau of Indian Affairs;

(7) Is a State or Tribal child support enforcement agency;

(8) Is an organization that is providing emergency food and shelter under a grant under the Stewart B. McKinney Homeless Assistance Act;

(9) Is a State or Tribal office or entity involved in enrollment in the program under Part A of title IV, title XIX, or title XXI; or

(10) Is an entity that determines eligibility for any assistance or benefits provided under any program of public or assisted housing that receives Federal funds, including the program under section 8 or any other section of the United States Housing Act of 1937 (42 U.S.C. 1437) or under the Native American Housing Assistance and Self Determination Act of 1996 (25 U.S.C. 4101 *et seq.*); or

(11) Any other entity the State so deems, as approved by the Secretary.

Period of presumptive eligibility means a period that begins on the date on which a qualified entity determines that a child is presumptively eligible and ends with the earlier of—

(1) In the case of a child on whose behalf a separate child health program application has been filed, the day on which a decision is made on that application; or

(2) In the case of a child on whose behalf an application for the separate child health program has not been filed, the last day of the month following the month in which the determination of presumptive eligibility was made.

Public agency means a State, county, city or other type of municipal agency, including a public school district, transportation district, irrigation district, or any other type of public entity.

Presumptive income standard means the highest income eligibility standard established under the plan that is most likely to be used to establish eligibility of a child of the age involved.

§ 457.305 State plan provisions.

The State plan must include a description of—

(a) The standards, consistent with §§ 457.310 and 457.320, used to determine the eligibility of children for coverage under the State plan.

(b) The State's policies governing enrollment and disenrollment; processes for screening applicant children for and, if eligible, facilitating their enrollment in Medicaid; and processes for implementing waiting lists and enrollment caps (if any).

§ 457.310 Targeted low-income child.

(a) *Definition.* A targeted low-income child is a child who meets the standards set forth below and the eligibility standards established by the State under § 457.320.

(b) *Standards.* A targeted low-income child must meet the following standards:

(1) *Financial need standard.* A targeted low-income child:

(i) Has a family income at or below 200 percent of the Federal poverty line for a family of the size involved;

(ii) Resides in a State with no Medicaid applicable income level or;

(iii) Resides in a State that has a Medicaid applicable income level and has family income that either—

(A) Exceeds the Medicaid applicable income level for the age of such child, but not by more than 50 percentage points; or

(B) Does not exceed the income level specified for such child to be eligible for medical assistance under policies of the State plan under title XIX on June 1, 1997.

(2) *No other coverage standard.* A targeted low-income child must not be—

(i) Found eligible or potentially eligible for Medicaid under policies of the State plan (determined through either the Medicaid application process or the screening process described at § 457.350); or

(ii) Covered under a group health plan or under health insurance coverage, as defined in section 2791 of the Public Health Service Act, unless the plan or health insurance coverage program has been in operation since before July 1, 1997 and is administered by a State that receives no Federal funds for the program's operation. A child is not considered covered under a group health plan or health insurance coverage if the child does not have reasonable geographic access to care under that plan.

(3) For purposes of this section, policies of the State plan under title XIX plan include policies under a Statewide demonstration project under section 1115(a) of the Act other than a demonstration project that covered an

expanded group of eligible children but that either—

(i) Did not provide inpatient hospital coverage; or

(ii) Limited eligibility to children previously enrolled in Medicaid, imposed premiums as a condition of initial or continued enrollment, and did not impose a general time limit on eligibility.

(c) *Exclusions.* Notwithstanding paragraph (a) of this section, the following groups are excluded from the definition of targeted low-income children:

(1) *Children eligible for certain State health benefits coverage.* (i) A targeted low-income child may not be eligible for health benefits coverage under a State health benefits plan in the State on the basis of a family member's employment with a public agency, even if the family declines to accept the coverage.

(ii) A child is considered eligible for health benefits coverage under a State health benefits plan if a more than nominal contribution to the cost of health benefits coverage under a State health benefits plan is available from the State or public agency with respect to the child or would have been available from those sources on November 8, 1999. A contribution is considered more than nominal if the State or public agency makes a contribution toward the cost of an employee's dependent(s) that is $10 per family, per month, more than the State or public agency's contribution toward the cost of covering the employee only.

(2) *Residents of an institution.* A child must not be—

(i) An inmate of a public institution as defined at § 435.1009 of this chapter; or

(ii) A patient in an institution for mental diseases, as defined at § 435.1009 of this chapter, at the time of initial application or any redetermination of eligibility.

§ 457.320 Other eligibility standards.

(a) *Eligibility standards.* To the extent consistent with title XXI of the Act and except as provided in paragraph (b) of this section, the State plan may adopt eligibility standards for one or more groups of children related to—

(1) Geographic area(s) served by the plan;

(2) Age (up to, but not including, age 19);

(3) Income;

(4) Resources;

(5) Spenddowns;

(6) Disposition of resources;

(7) Residency, in accordance with paragraph (d) of this section;

(8) Disability status, provided that such standards do not restrict eligibility;

(9) Access to, or coverage under, other health coverage; and

(10) Duration of eligibility, in accordance with paragraph (e) of this section.

(b) *Prohibited eligibility standards.* In establishing eligibility standards and methodologies, a State may *not*—

(1) Cover children with a higher family income without covering children with a lower family income within any defined group of covered targeted low-income children;

(2) Deny eligibility based on a preexisting medical condition;

(3) Discriminate on the basis of diagnosis;

(4) Require that any individual provide a social security number (SSN), including the SSN of the applicant child or that of a family member whose income or resources might be used in making the child's eligibility determination;

(5) Exclude American Indian or Alaska Native children based on eligibility for, or access to, medical care funded by the Indian Health Service;

(6) Exclude individuals based on citizenship or nationality, to the extent that the children are U.S. citizens, U.S. nationals or qualified aliens, (as defined at section 431 of the Personal Responsibility and Work Opportunity Reconciliation Act (PRWORA) of 1996, as amended by the BBA of 1997, except to the extent that section 403 of PRWORA precludes them from receiving Federal means-tested public benefits); or

(7) Violate any other Federal laws or regulations pertaining to eligibility for a separate child health program under title XXI.

(c) *Self-declaration of citizenship.* In establishing eligibility for coverage under a separate child health plan, a State may accept self-declaration of citizenship (including nationals of the U.S.), provided that the State has implemented effective, fair, and nondiscriminatory procedures for ensuring the integrity of its application process.

(d) *Residency.* The State may establish residency requirements, except that a State may not—

(1) Impose a durational residency requirement;

(2) Preclude the following individuals from declaring residence in a State—

(i) A non-institutionalized child who is not a ward of the State, if the child is physically located in that State, including as a result of the parent's or caretaker's employment in that State;

(ii) An institutionalized child who is not a ward of a State, if the State is the State of residence of the child's custodial parent's or caretaker at the time of placement;

(iii) A child who is a ward of a State, regardless of the child's physical location; or

(iv) A child whose custodial parent or caretaker is involved in work of a transient nature, if the State is the parent's or caretaker's home State.

(e) *Duration of eligibility.* (1) The State may not impose a lifetime cap or other time limit on the eligibility of an individual applicant or enrollee, based on the length of time such applicant or enrollee has received benefits under the State's separate child health program.

(2) Eligibility must be redetermined at least every 12 months.

§ 457.340 Application for and enrollment in a separate child health program.

(a) *Application assistance.* A State must afford families an opportunity to apply for child health assistance without delay, provided that the State has not reached an approved enrollment cap, and offer assistance to families in understanding and completing applications and in obtaining any required documentation.

(b) *Notice of rights and responsibilities.* A State must inform applicants at the time of application, in writing and orally if appropriate, about the application and eligibility requirements, the time frame for determining eligibility, and the right to review of eligibility determinations as described in § 457.1130.

(c) *Timely determinations of eligibility.* (1) The agency must promptly determine eligibility and issue a notice of decision within the time standards established, except in circumstances that are beyond the agency's control.

(2) A State must establish time standards for determining eligibility. These standards may not exceed forty-five calendar days (excluding days during which the application has been suspended, pursuant to § 457.350(f)(1)).

(3) In applying the time standards, the State must define ''date of application'' and must count each calendar day from the date of application to the day the agency mails or otherwise provides notice of its eligibility decision.

(d) *Notice of decision concerning eligibility.* A State must provide each applicant or enrollee a written notice of any decision on the application or other determination concerning eligibility.

(1) If eligibility is approved, the notice must include information on the enrollee's rights and responsibilities under the program, including the opportunity for review of matters described in § 457.1130.

(2) If eligibility is denied, suspended or terminated, the State must provide

notice in accordance with § 457.1180. In the case of a suspension or termination of eligibility, the State must provide sufficient notice to enable the child's parent or caretaker to take any appropriate actions that may be required to allow coverage to continue without interruption.

(e) *Effective date of eligibility.* A State must specify a method for determining the effective date of eligibility for its separate child health program, which can be determined based on the date of application or through any other reasonable method.

§ 457.350 Eligibility screening and facilitation of Medicaid enrollment.

(a) *State plan requirement.* The State plan must include a description of—

(1) The screening procedures that the State will use, at intake and any follow-up eligibility determination, including any periodic redetermination, to ensure that only targeted low-income children are furnished child health assistance under the plan; and

(2) The procedures that the State will use to ensure that the Medicaid application and enrollment process is initiated and that Medicaid enrollment is facilitated for children found, through the screening process, to be potentially eligible for Medicaid.

(b) *Screening objectives.* A State must use screening procedures to identify, at a minimum, any applicant or enrollee who is potentially eligible for Medicaid under one of the poverty-level-related groups described in section 1902(l) of the Act, section 1931 of the Act, or a Medicaid demonstration project approved under section 1115 of the Act, applying whichever standard and corresponding methodology generally results in a higher income eligibility level for the age group of the child being screened.

(c) *Income eligibility test.* To identify the children described in paragraph (b) of this section, a State must either initially apply the gross income test described in paragraph (c)(1) of this section and then use an adjusted income test described in paragraph (c)(2) of this section for applicants whose gross income is above the appropriate Medicaid income standard, or use only the adjusted income test.

(1) *Initial gross income test.* Under this test, a State initially screens for Medicaid eligibility by comparing gross family income to the appropriate Medicaid income standard.

(2) *Adjusted income test.* Under this test, a State screens for Medicaid eligibility by comparing adjusted family income to the appropriate Medicaid income standard. The State must apply Medicaid standards and methodologies relating to income for the particular Medicaid eligibility group, including all income exclusions and disregards, except those that apply only in very limited circumstances.

(d) *Resource eligibility test.* (1) If a State applies a resource test for children under the Medicaid eligibility group used for screening purposes as described in paragraph (b) of this section and a child has been determined potentially income eligible for Medicaid, the State must also screen for Medicaid eligibility by comparing family resources to the appropriate Medicaid resource standard.

(2) In conducting the screening, the State must apply Medicaid standards and methodologies related to resources for the particular Medicaid eligibility group, including all resource exclusions and disregards, except those that apply only in very limited circumstances.

(e) *Children found potentially ineligible for Medicaid.* If a State uses a screening procedure other than a full determination of Medicaid eligibility under all possible eligibility groups, and the screening process reveals that the child does not appear to be eligible for Medicaid, the State must provide the child's family with the following in writing:

(1) A statement that based on a limited review, the child does not appear eligible for Medicaid, but Medicaid eligibility can only be determined based on a full review of a Medicaid application under all Medicaid eligibility groups;

(2) Information about Medicaid eligibility and benefits; and

(3) Information about how and where to apply for Medicaid under all eligibility groups.

(f) *Children found potentially eligible for Medicaid.* If the screening process reveals that the child is potentially eligible for Medicaid, the State must establish procedures in coordination with the Medicaid agency that facilitate enrollment in Medicaid and avoid duplicative requests for information and documentation and must—

(1) Except as provided in § 457.355, find the child ineligible, provisionally ineligible, or suspend the child's application for the separate child health program unless and until a completed Medicaid application for that child is denied, or the child's circumstances change, and promptly transmit the separate child health application to the Medicaid agency as provided in paragraph (f)(3)(ii) of this section; and

(2) If a State uses a joint application for its Medicaid and separate child health programs, promptly transmit the application, or the information obtained through the application, and all relevant documentation to the Medicaid agency; or

(3) If a State does not use a joint application for its Medicaid and separate child health programs:

(i) Promptly inform the child's parent or caretaker in writing and, if appropriate, orally that the child has been found likely to be eligible for Medicaid; provide the family with a Medicaid application and offer information about what, if any, further information, documentation, or other steps are needed to complete the Medicaid application process; and offer assistance in completing the application process;

(ii) Promptly transmit the separate child health program application; or the information obtained through the application, and all other relevant information and documentation, including the results of the screening process, to the Medicaid agency for a final determination of Medicaid eligibility in accordance with the requirements of §§ 431.636 and 457.1110 of this chapter; or

(4) Establish other effective and efficient procedures, in coordination with the Medicaid agency, as described and approved in the State plan that ensure that children who are screened as potentially eligible for Medicaid are able to apply for Medicaid without delay and, if eligible, are enrolled in Medicaid in a timely manner; and

(5) Determine or redetermine eligibility for the separate child health program, if—

(i) The State is notified pursuant to § 431.636 of this chapter that the child has been found ineligible for Medicaid, consistent with the time standards established pursuant to § 457.340(c); or

(ii) The State is notified prior to the final Medicaid eligibility determination that the child's circumstances have changed and another screening shows that the child is not likely to be eligible for Medicaid.

(iii) For purposes of such determination or redetermination, the State must not require the child to complete a new application for the separate child health program, but may require supplemental information to account for any changes in the child's circumstances that may affect eligibility.

(g) *Informed application decisions.* To enable a family to make an informed decision about applying for Medicaid or completing the Medicaid application process, a State must provide the child's family with information, in writing, about—

(1) The State's Medicaid program, including the benefits covered, and restrictions on cost sharing; and

(2) Eligibility rules that prohibit children who have been screened eligible for Medicaid from being enrolled in a separate child health program, other than provisional temporary enrollment while a final Medicaid eligibility determination is being made.

(h) *Waiting lists, enrollment caps and closed enrollment.* The State must establish procedures to ensure that—

(1) The procedures developed in accordance with this section have been followed for each child applying for a separate child health program before placing the child on a waiting list or otherwise deferring action on the child's application for the separate child health program; and

(2) Families are informed that a child may be eligible for Medicaid if circumstances change while the child is on a waiting list for separate child health program.

§ 457.353 Monitoring and evaluation of screening process.

States must monitor and establish a mechanism to evaluate the screen and enroll process described at § 457.350 to ensure that children who are screened potentially eligible for Medicaid are enrolled in Medicaid, if eligible, and that children who are found ineligible for Medicaid are enrolled in the separate child health program, if eligible.

§ 457.355 Presumptive eligibility.

Consistent with subpart D of this part, the State may pay costs of coverage under a separate child health program, during a period of presumptive eligibility for children applying for coverage under the separate child health program, pending the screening process and a final determination of eligibility (including applicants found through screening to be potentially eligible for Medicaid)

(a) *Expenditures for coverage during a period of presumptive eligibility.* (1) Expenditures for coverage during a period of presumptive eligibility for a child ultimately determined eligible for the separate child health program, will be considered, for that period, as expenditures for child health assistance for targeted low-income children under the plan.

(2) Expenditures for coverage during a period of presumptive eligibility implemented in accordance with § 435.1101 of this part for a child ultimately determined ineligible for both the separate child health program and Medicaid for that period, and for a child whose family does not complete the Medicaid application process, will be considered as expenditures for targeted low-income children under the plan.

(3) Expenditures for coverage during a period of presumptive eligibility for a child ultimately determined to be eligible for Medicaid may not be considered expenditures under the separate child health program.

§ 457.380 Eligibility verification.

(a) The State must establish procedures to ensure the integrity of the eligibility determination process.

(b) A State may establish reasonable eligibility verification mechanisms to promote enrollment of eligible children and may permit applicants and enrollees to demonstrate that they meet eligibility requirements through self-declaration or affirmation except that a State may permit self-declaration of citizenship only if the State has effective, fair and non-discriminatory procedures to ensure the integrity of the application process in accordance with § 457.320(c).

Subpart D—State Plan Requirements: Coverage and Benefits

§ 457.401 Basis, scope, and applicability.

(a) *Statutory basis.* This subpart interprets and implements—

(1) Section 2102(a)(7) of the Act, which requires that States make assurances relating to, the quality and appropriateness of care, and access to covered services;

(2) Section 2103 of the Act, which outlines coverage requirements for children's health insurance;

(3) Section 2109 of the Act, which describes the relation of the SCHIP program to other laws;

(4) Section 2110(a) of the Act, which describes child health assistance; and

(5) Section 2110(c) of the Act, which contains definitions applicable to this subpart.

(b) *Scope.* This subpart sets forth requirements for health benefits coverage and child health assistance under a separate child health plan.

(c) *Applicability.* The requirements of this subpart apply to child health assistance provided under a separate child health program and do not apply to a Medicaid expansion program.

§ 457.402 Definition of child health assistance.

For the purpose of this subpart, the term ''child health assistance'' means payment for part or all of the cost of health benefits coverage provided to targeted low-income children for the following services:

(a) Inpatient hospital services.

(b) Outpatient hospital services.

(c) Physician services.

(d) Surgical services.

(e) Clinic services (including health center services) and other ambulatory health care services.

(f) Prescription drugs and biologicals and the administration of these drugs and biologicals, only if these drugs and biologicals are not furnished for the purpose of causing, or assisting in causing, the death, suicide, euthanasia, or mercy killing of a person.

(g) Over-the-counter medications.

(h) Laboratory and radiological services.

(i) Prenatal care and pre-pregnancy family planning services and supplies.

(j) Inpatient mental health services, other than services described in paragraph (r) of this section but including services furnished in a State-operated mental hospital and including residential or other 24-hour therapeutically planned structured services.

(k) Outpatient mental health services, other than services described in paragraph (s) of this section but including services furnished in a State-operated mental hospital and including community-based services.

(l) Durable medical equipment and other medically-related or remedial devices (such as prosthetic devices, implants, eyeglasses, hearing aids, dental devices and adaptive devices).

(m) Disposable medical supplies.

(n) Home and community-based health care services and related supportive services (such as home health nursing services, personal care, assistance with activities of daily living, chore services, day care services, respite care services, training for family members and minor modification to the home.)

(o) Nursing care services (such as nurse practitioner services, nurse midwife services, advanced practice nurse services, private duty nursing, pediatric nurse services and respiratory care services) in a home, school, or other setting.

(p) Abortion only if necessary to save the life of the mother or if the pregnancy is the result of rape or incest.

(q) Dental services.

(r) Inpatient substance abuse treatment services and residential substance abuse treatment services.

(s) Outpatient substance abuse treatment services.

(t) Case management services.

(u) Care coordination services.

(v) Physical therapy, occupational therapy, and services for individuals with speech, hearing and language disorders.

(w) Hospice care.

(x) Any other medical, diagnostic, screening, preventive, restorative, remedial, therapeutic, or rehabilitative services (whether in a facility, home, school, or other setting) if recognized by State law and only if the service is—

(1) Prescribed by or furnished by a physician or other licensed or registered practitioner within the scope of practice as defined by State law;

(2) Performed under the general supervision or at the direction of a physician; or

(3) Furnished by a health care facility that is operated by a State or local government or is licensed under State law and operating within the scope of the license.

(y) Premiums for private health care insurance coverage.

(z) Medical transportation.

(aa) Enabling services (such as transportation, translation, and outreach services) only if designed to increase the accessibility of primary and preventive health care services for eligible low-income individuals.

(bb) Any other health care services or items specified by the Secretary and not excluded under this subchapter.

§ 457.410 Health benefits coverage options.

(a) *Types of health benefits coverage.* States may choose to obtain any of the following four types of health benefits coverage:

(1) Benchmark coverage in accordance with § 457.420.

(2) Benchmark-equivalent coverage in accordance with § 457.430.

(3) Existing comprehensive State-based coverage in accordance with § 457.440.

(4) Secretary-approved coverage in accordance with § 457.450.

(b) *Required coverage.* Regardless of the type of health benefits coverage, described at paragraph (a) of this section, that the State chooses to obtain, the State must obtain coverage for—

(1) Well-baby and well-child care services as defined by the State;

(2) Age-appropriate immunizations in accordance with the recommendations of the Advisory Committee on Immunization Practices (ACIP); and

(3) Emergency services as defined in § 457.10.

§ 457.420 Benchmark health benefits coverage.

Benchmark coverage is health benefits coverage that is substantially equal to the health benefits coverage in one of the following benefit plans:

(a) *Federal Employees Health Benefit Plan (FEHBP).* The standard Blue Cross/Blue Shield preferred provider option service benefit plan that is described in, and offered to Federal employees under, 5 U.S.C. 8903(1).

(b) *State employee plan.* A health benefits plan that is offered and generally available to State employees in the State.

(c) *Health maintenance organization (HMO) plan.* A health insurance coverage plan that is offered through an HMO (as defined in section 2791(b)(3) of the Public Health Service Act) and has the largest insured commercial, non-Medicaid enrollment in the State.

§ 457.430 Benchmark-equivalent health benefits coverage.

(a) *Aggregate actuarial value.* Benchmark-equivalent coverage is health benefits coverage that has an aggregate actuarial value determined in accordance with § 457.431 that is at least actuarially equivalent to the coverage under one of the benchmark packages specified in § 457.420.

(b) *Required coverage.* In addition to the coverage required under § 457.410(b), benchmark-equivalent health benefits coverage must include coverage for the following categories of services:

(1) Inpatient and outpatient hospital services.

(2) Physicians' surgical and medical services.

(3) Laboratory and x-ray services.

(c) *Additional coverage.* (1) In addition to the categories of services in paragraph (b) of this section, benchmark-equivalent coverage may include coverage for any additional services specified in § 457.402.

(2) If the benchmark coverage package used by the State for purposes of comparison in establishing the aggregate actuarial value of the benchmark-equivalent coverage package includes coverage for prescription drugs, mental health services, vision services or hearing services, then the actuarial value of the coverage for each of these categories of service in the benchmark-equivalent coverage package must be at least 75 percent of the value of the coverage for such a category or service in the benchmark plan used for comparison by the State.

(3) If the benchmark coverage package does not cover one of the categories of services in paragraph (c)(2) of this section, then the benchmark-equivalent coverage package may, but is not required to, include coverage for that category of service.

§ 457.431 Actuarial report for benchmark-equivalent coverage.

(a) To obtain approval for benchmark-equivalent health benefits coverage described under § 457.430, the State must submit to HCFA an actuarial report that contains an actuarial opinion that the health benefits coverage meets the actuarial requirements under § 457.430. The report must also specify the benchmark coverage used for comparison.

(b) The actuarial report must state that it was prepared—

(1) By an individual who is a member of the American Academy of Actuaries;

(2) Using generally accepted actuarial principles and methodologies of the American Academy of Actuaries;

(3) Using a standardized set of utilization and price factors;

(4) Using a standardized population that is representative of privately insured children of the age of those expected to be covered under the State plan;

(5) Applying the same principles and factors in comparing the value of different coverage (or categories of services);

(6) Without taking into account any differences in coverage based on the method of delivery or means of cost control or utilization used; and

(7) Taking into account the ability of a State to reduce benefits by considering the increase in actuarial value of health benefits coverage offered under the State plan that results from the limitations on cost sharing (with the exception of premiums) under that coverage.

(c) The actuary who prepares the opinion must select and specify the standardized set and population to be used under paragraphs (b)(3) and (b)(4) of this section.

(d) The State must provide sufficient detail to explain the basis of the methodologies used to estimate the actuarial value or, if requested by HCFA, to replicate the State's result.

§ 457.440 Existing comprehensive State-based coverage.

(a) *General requirements.* Existing comprehensive State-based health benefits is coverage that—

(1) Includes coverage of a range of benefits;

(2) Is administered or overseen by the State and receives funds from the State;

(3) Is offered in the State of New York, Florida or Pennsylvania; and

(4) Was offered as of August 5, 1997.

(b) *Modifications.* A State may modify an existing comprehensive State-based coverage program described in paragraph (a) of this section if—

(1) The program continues to include a range of benefits;

(2) The State submits an actuarial report demonstrating that the modification does not reduce the

actuarial value of the coverage under the program below the lower of either—

(i) The actuarial value of the coverage under the program as of August 5, 1997; or

(ii) The actuarial value of a benchmark benefit package as described in § 457.430 evaluated at the time the modification is requested.

§ 457.450 Secretary-approved coverage.

Secretary-approved coverage is health benefits coverage that, in the determination of the Secretary, provides appropriate coverage for the population of targeted low-income children covered under the program. Secretary-approved coverage, for which no actuarial analysis is required, may include—

(a) Coverage that is the same as the coverage provided to children under the Medicaid State plan;

(b) Comprehensive coverage offered by the State under a Medicaid demonstration project approved by the Secretary under section 1115 of the Act that either includes coverage for the full Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit or that the State has extended to the entire Medicaid population in the State;

(c) Coverage that includes benchmark health benefits coverage, as specified in § 457.420, plus any additional coverage; or

(d) Coverage, including coverage under a group health plan purchased by the State, that the State demonstrates to be substantially equivalent to or greater than coverage under a benchmark health benefits plan, as specified in § 457.420, through use of a benefit-by-benefit comparison of the coverage demonstrating that coverage for each benefit meets or exceeds the corresponding coverage under the benchmark health benefits plan.

§ 457.470 Prohibited coverage.

A State is not required to provide health benefits coverage under the plan for an item or service for which payment is prohibited under title XXI even if any benchmark health benefits plan includes coverage for that item or service.

§ 457.475 Limitations on coverage: Abortions.

(a) *General rule.* FFP under title XXI is not available in expenditures for an abortion, or in expenditures for the purchase of health benefits coverage that includes coverage of abortion services unless the abortion services meet the conditions specified in paragraph (b) of this section.

(b) *Exceptions.* (1) *Life of mother.* FFP is available in expenditures for abortion services when a physician has found that the abortion is necessary to save the life of the mother.

(2) *Rape or incest.* FFP is available in expenditures for abortion services performed to terminate a pregnancy resulting from an act of rape or incest.

(c) *Partial Federal funding prohibited.* (1) FFP is not available to a State for any amount expended under the title XXI plan to assist in the purchase, in whole or in part, of health benefits coverage that includes coverage of abortions other than those specified in paragraph (b) of this section.

(2) If a State wishes to have managed care entities provide abortions in addition to those specified in paragraph (b) of this section, those abortions must be provided under a separate contract using non-Federal funds. A State may not set aside a portion of the capitated rate paid to a managed care entity to be paid with State-only funds, or append riders, attachments or addenda to existing contracts with managed care entities to separate the additional abortion services from the other services covered by the contract.

(3) Nothing in this section affects the expenditure by a State, locality, or private person or entity of State, local, or private funds (other than those expended under the State plan) for any abortion services or for health benefits coverage that includes coverage of abortion services.

§ 457.480 Preexisting condition exclusions and relation to other laws.

(a) *Preexisting condition exclusions.* (1) Except as permitted under paragraph (a)(2) of this section, the State may not permit the imposition of any pre-existing condition exclusion for covered services under the State plan.

(2) If the State obtains health benefits coverage through payment or a contract for health benefits coverage under a group health plan or group health insurance coverage, the State may permit the imposition of a pre-existing condition exclusion but only to the extent that the exclusion is permitted under the applicable provisions of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (ERISA) and title XXVII of the Public Health Service Act.

(b) *Relation of title XXI to other laws.* (1) ERISA. Nothing in this title affects or modifies section 514 of ERISA with respect to a group health plan as defined by section 2791(a)(1) of the Public Health Service Act.

(2) *Health Insurance Portability and Accountability Act (HIPAA).* Health benefits coverage provided under a State plan and coverage provided as a cost-effective alternative, as described in subpart J of this part, is creditable coverage for purposes of part 7 of subtitle B of title II of ERISA, title XXVII of the Public Health Service Act, and subtitle K of the Internal Revenue Code of 1986.

(3) *Mental Health Parity Act (MHPA).* Health benefits coverage under a group health plan provided under a State plan must comply with the requirements of the MHPA of 1996 regarding parity in the application of annual and lifetime dollar limits to mental health benefits in accordance with 45 CFR 146.136.

(4) *Newborns and Mothers Health Protection Act (NMHPA).* Health benefits coverage under a group health plan provided under a State plan must comply with the requirements of the NMHPA of 1996 regarding requirements for minimum hospital stays for mothers and newborns in accordance with 45 CFR 146.130 and 148.170.

§ 457.490 Delivery and utilization control systems.

A State that elects to obtain health benefits coverage through a separate child health program must include in its State plan a description of the child health assistance provided under the plan for targeted low-income children, including a description of the proposed methods of delivery and utilization control systems. A State must—

(a) Describe the methods of delivery of child health assistance including the choice of financing and the methods for assuring delivery of the insurance products and delivery of health care services covered by such products to the enrollees, including any variations; and

(b) Describe utilization control systems designed to ensure that enrollees receiving health care services under the State plan receive only appropriate and medically necessary health care consistent with the benefit package described in the approved State plan.

§ 457.495 State assurance of access to care and procedures to assure quality and appropriateness of care.

A State plan must include a description of the methods that a State uses for assuring the quality and appropriateness of care provided under the plan, including how the State will assure:

(a) Access to well-baby care, well-child care, well-adolescent care and childhood and adolescent immunizations.

(b) Access to covered services, including emergency services as defined at § 457.10.

(c) Appropriate and timely procedures to monitor and treat enrollees with

chronic, complex, or serious medical conditions, including access to an adequate number of visits to specialists experienced in treating the specific medical condition and access to out-of-network providers when the network is not adequate for the enrollee's medical condition.

(d) That decisions related to the prior authorization of health services are completed in accordance with the medical needs of the patient, within 14 days after receipt of a request for services. A possible extension of up to 14 days may be permitted if the enrollee requests the extension or if the physician or health plan determines that additional information is needed.

Subpart E—State Plan Requirements: Enrollee Financial Responsibilities

§ 457.500 Basis, scope, and applicability.

(a) *Statutory basis.* This subpart implements—

(1) Section 2101(a) of the Act, which provides that the purpose of title XXI is to provide funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner; and

(2) Section 2103(e) of the Act, which sets forth provisions regarding State plan requirements and options for cost sharing.

(b) *Scope.* This subpart consists of provisions relating to the imposition under a separate child health program of cost-sharing charges including enrollment fees, premiums, deductibles, coinsurance, copayments, and similar cost-sharing charges.

(c) *Applicability.* The requirements of this subpart apply to separate child health programs.

§ 457.505 General State plan requirements.

The State plan must include a description of—

(a) The amount of premiums, deductibles, coinsurance, copayments, and other cost sharing imposed;

(b) The methods, including the public schedule, the State uses to inform enrollees, applicants, providers and the general public of the cost-sharing charges, the cumulative cost-sharing maximum, and any changes to these amounts;

(c) The disenrollment protections as required under § 457.570;

(d) In the case of coverage obtained through premium assistance for group health plans—

(1) The procedures the State uses to ensure that enrollees are not charged copayments, coinsurance, deductibles or similar fees on well-baby and well-child care services described at § 457.520, and that any cost sharing complies with the requirements of this subpart;

(2) The procedures to ensure that American Indian and Alaska Native children are not charged premiums, copayments, coinsurance, deductibles, or similar fees in accordance with § 457.535;

(3) The procedures to ensure that enrollees are not charged cost sharing in excess of the cumulative cost-sharing maximum specified in § 457.560.

(e) Procedures that do not primarily rely on a refund given by the State for overpayment by an enrollee to ensure compliance with this subpart.

§ 457.510 Premiums, enrollment fees, or similar fees: State plan requirements.

When a State imposes premiums, enrollment fees, or similar fees on enrollees, the State plan must describe—

(a) The amount of the premium, enrollment fee or similar fee imposed on enrollees;

(b) The time period for which the charge is imposed;

(c) The group or groups that are subject to the premiums, enrollment fees, or similar charges;

(d) The consequences for an enrollee or applicant who does not pay a charge, and the disenrollment protections adopted by the State in accordance with § 457.570; and

(e) The methodology used to ensure that total cost-sharing liability for a family does not exceed the cumulative cost-sharing maximum specified in § 457.560.

§ 457.515 Co-payments, coinsurance, deductibles, or similar cost-sharing charges: State plan requirements.

To impose copayments, coinsurance, deductibles or similar charges on enrollees, the State plan must describe—

(a) The service for which the charge is imposed;

(b) The amount of the charge;

(c) The group or groups of enrollees that may be subject to the cost-sharing charge;

(d) The consequences for an enrollee who does not pay a charge, and the disenrollment protections adopted by the State in accordance with § 457.570;

(e) The methodology used to ensure that total cost-sharing liability for a family does not exceed the cumulative cost-sharing maximum specified in § 457.560; and

(f) An assurance that enrollees will not be held liable for cost-sharing amounts for emergency services that are provided at a facility that does not participate in the enrollee's managed care network beyond the copayment amounts specified in the State plan for emergency services as defined in § 457.10.

§ 457.520 Cost sharing for well-baby and well-child care services.

(a) A State may not impose copayments, deductibles, coinsurance or other cost sharing with respect to the well-baby and well-child care services covered under the State plan in either the managed care delivery setting or the fee-for-service delivery setting.

(b) For the purposes of this subpart, at a minimum, any of the following services covered under the State plan will be considered well-baby and well-child care services:

(1) All healthy newborn physician visits, including routine screening, whether provided on an inpatient or outpatient basis.

(2) Routine physical examinations as recommended and updated by the American Academy of Pediatrics (AAP) ''Guidelines for Health Supervision III'' and described in ''Bright Futures: Guidelines for Health Supervision of Infants, Children and Adolescents.''

(3) Laboratory tests associated with the well-baby and well-child routine physical examinations as described in paragraph (b)(2) of this section.

(4) Immunizations and related office visits as recommended and updated by the Advisory Committee on Immunization Practices (ACIP).

(5) Routine preventive and diagnostic dental services (such as oral examinations, prophylaxis and topical fluoride applications, sealants, and x-rays) as described in the most recent guidelines issued by the American Academy of Pediatric Dentistry (AAPD).

§ 457.525 Public schedule.

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

(1) Current cost-sharing charges.

(2) Enrollee groups subject to the charges.

(3) Cumulative cost-sharing maximums.

(4) Mechanisms for making payments for required charges.

(5) The consequences for an applicant or an enrollee who does not pay a charge, including the disenrollment protections required by § 457.570.

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

(1) Enrollees, at the time of enrollment and reenrollment after a

redetermination of eligibility, and when cost-sharing charges and cumulative cost-sharing maximums are revised.

(2) Applicants, at the time of application.

(3) All participating providers.

(4) The general public.

§ 457.530 General cost-sharing protection for lower income children.

The State may vary premiums, deductibles, coinsurance, copayments or any other cost sharing based on family income only in a manner that does not favor children from families with higher income over children from families with lower income.

§ 457.535 Cost-sharing protection to ensure enrollment of American Indians and Alaska Natives.

States may not impose premiums, deductibles, coinsurance, copayments or any other cost-sharing charges on children who are American Indians or Alaska Natives, as defined in § 457.10.

§ 457.540 Cost-sharing charges for children in families with incomes at or below 150 percent of the FPL.

The State may impose premiums, enrollment fees, deductibles, copayments, coinsurance, cost sharing and other similar charges for children whose family income is at or below 150 percent of the FPL as long as—

(a) Aggregate monthly enrollment fees, premiums, or similar charges imposed on a family are less than or equal to the maximum amounts permitted under § 447.52 of this chapter for a Medicaid eligible family of the same size and income;

(b) Any copayments, coinsurance, deductibles or similar charges for children whose family income is at or below 100 percent of the FPL are equal to or less than the amounts permitted under § 447.54 of this chapter;

(c) For children whose family income is from 101 percent to 150 percent of the FPL, any copayments, coinsurance, deductibles or similar charges are equal to or less than the maximum amounts permitted under § 457.555;

(d) The State does not impose more than one type of cost-sharing charge (deductible, copayment, or coinsurance) on a service;

(e) The State only imposes one copayment based on the total cost of services furnished during one office visit; and

(f) Aggregate annual cost sharing of all types, with respect to all targeted low-income children in a family, does not exceed the maximum permitted under § 457.560(b).

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

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

(1) Any copayment or similar charge the State imposes under a fee-for-service delivery system does not exceed the following amounts:

Total cost of services provided during a visit	Maximum amount chargeable to enrollee
$15.00 or less	$1.00
$15.01 to $40	2.00
$40.01 to $80	3.00
$80.01 or more	5.00

(2) Any copayment that the State imposes for services provided by a managed care organization may not exceed $5.00 per visit;

(3) Any coinsurance rate the State imposes may not exceed 5 percent of the payment the State directly or through contract makes for the service; and

(4) Any deductible the State imposes may not exceed $3.00 per month, per family for each period of eligibility.

(b) *Institutional services.* For targeted low-income children whose family income is from 101 to 150 percent of the FPL, the maximum deductible, coinsurance or copayment charge for each institutional admission may not exceed 50 percent of the payment the State would make under the Medicaid fee-for-service system for the first day of care in the institution.

(c) *Institutional emergency services.* Any copayment that the State imposes on emergency services provided by an institution may not exceed $5.00.

(d) *Nonemergency use of the emergency room.* For targeted low-income children whose family income is from 101 to 150 percent of the FPL, the State may charge up to twice the charge for non-institutional services, up to a maximum amount of $10.00, for services furnished in a hospital emergency room if those services are not emergency services as defined in § 457.10.

(e) *Standard copayment amount.* For targeted low-income children whose family income is from 101 to 150 percent of the FPL, a standard copayment amount for any service may be determined by applying the maximum copayment amounts specified in paragraphs (a), (b), and (c) of this section to the State's average or typical payment for that service.

§ 457.560 Cumulative cost-sharing maximum.

(a) *Computation.* A State must count cost-sharing amounts that the family has a legal obligation to pay in computing whether a family has met the cumulative cost-sharing maximum. A family will be considered to have a legal obligation to pay amounts a provider actually charges the family for covered services furnished to enrollees, and any other amounts for which payment is required under applicable State law for covered services furnished to eligible children, even if the family never pays those amounts.

(b) *Children with family incomes at or below 150 percent of the FPL.* For targeted low-income children with family income at or below 150 percent of the FPL, the State may not impose premiums, deductibles, copayments, coinsurance, enrollment fees, or similar cost-sharing charges that, in the aggregate, exceed 2.5 percent of total family income for the length of the child's eligibility period in the State.

(c) *Children with family incomes above 150 percent of the FPL.* For targeted low-income children with family income above 150 percent of the FPL, the State may not impose premiums, enrollment fees, copayments, coinsurance, deductibles, or similar cost-sharing charges that, in the aggregate, exceed 5 percent of total family income for the length of the child's eligibility period in the State.

(d) The State must inform the enrollee's family in writing and orally if appropriate of their individual cumulative cost-sharing maximum amount at the time of enrollment and reenrollment.

§ 457.570 Disenrollment protections.

(a) The State must give enrollees reasonable notice of and an opportunity to pay past due premiums, copayments, coinsurance, deductibles or similar fees prior to disenrollment.

(b) The disenrollment process must afford the enrollee an opportunity to show that the enrollee's family income has declined prior to disenrollment for non payment of cost-sharing charges, and in the event that such a showing indicates that the enrollee may have become eligible for Medicaid or for a lower level of cost sharing, the State must facilitate enrolling the child in Medicaid or adjust the child's cost-sharing category as appropriate.

(c) The State must provide the enrollee with an opportunity for an impartial review to address

disenrollment from the program in accordance with § 457.1130(a)(3).

Subpart F—Payments to States

§ 457.624 [Removed]

8. Section 457.624 is removed.

9. New subparts G, H, I, J, and K are added to read as follows:

Subpart G—Strategic Planning, Reporting, and Evaluation

Subpart H—Substitution of Coverage

Subpart I—Program Integrity

Subpart J—Allowable Waivers: General Provisions

Subpart K—State Plan Requirements: Applicant and Enrollee Protections

Subpart G—Strategic Planning, Reporting, and Evaluation

§ 457.700 Basis, scope, and applicability.

(a) *Statutory basis.* This subpart implements—

(1) Sections 2107(a), (b) and (d) of the Act, which set forth requirements for strategic planning, reports, and program budgets; and

(2) Section 2108 of the Act, which sets forth provisions regarding annual reports and evaluation.

(b) *Scope.* This subpart sets forth requirements for strategic planning, monitoring, reporting and evaluation under title XXI.

(c) *Applicability.* The requirements of this subpart apply to separate child health programs and Medicaid expansion programs.

§ 457.710 State plan requirements: Strategic objectives and performance goals.

(a) *Plan description.* A State plan must include a description of—

(1) The strategic objectives as described in paragraph (b) of this section;

(2) The performance goals as described in paragraph (c) of this section; and

(3) The performance measurements, as described in paragraph (d) of this section, that the State has established for providing child health assistance to targeted low-income children under the plan and otherwise for maximizing health benefits coverage for other low-income children and children generally in the State.

(b) *Strategic objectives.* The State plan must identify specific strategic objectives relating to increasing the extent of creditable health coverage among targeted low-income children and other low-income children.

(c) *Performance goals.* The State plan must specify one or more performance goals for each strategic objective identified.

(d) *Performance measurements.* The State plan must describe how performance under the plan is—

(1) Measured through objective, independently verifiable means; and

(2) Compared against performance goals.

(e) *Core elements.* The State's strategic objectives, performance goals and performance measures must include a common core of national performance goals and measures consistent with the data collection, standard methodology, and verification requirements, as developed by the Secretary.

§ 457.720 State plan requirement: State assurance regarding data collection, records, and reports.

A State plan must include an assurance that the State collects data, maintains records, and furnishes reports to the Secretary, at the times and in the standardized format the Secretary may require to enable the Secretary to monitor State program administration and compliance and to evaluate and compare the effectiveness of State plans under title XXI.

§ 457.740 State expenditures and statistical reports.

(a) *Required quarterly reports.* A State must submit reports to HCFA that contain quarterly program expenditures and statistical data no later than 30 days after the end of each quarter of the Federal fiscal year. A State must collect required data beginning on the date of implementation of the approved State plan. Territories are exempt from the definition of ''State'' for purposes of the required quarterly reporting under this section. The quarterly reports must include data on—

(1) Program expenditures;

(2) The number of children enrolled in the title XIX Medicaid program, the separate child health program, and the Medicaid expansion program, as applicable, as of the last day of each quarter of the Federal fiscal year; and

(3) The number of children under 19 years of age who are enrolled in the title XIX Medicaid program, the separate child health program, and in the Medicaid expansion program, as appropriate, by the following categories:

(i) Age (under 1 year of age, 1 through 5 years of age, 6 through 12 years of age, and 13 through 18 years of age).

(ii) Gender, race, and ethnicity.

(iii) Service delivery system (managed care, fee-for-service, and primary care case management).

(iv) Family income as a percentage of the Federal poverty level as described in paragraph (b) of this section.

(b) *Reportable family income categories.* (1) A State that does not impose cost sharing or a State that imposes cost sharing based on a fixed percentage of income must report by two family income categories:

(i) At or below 150 percent of FPL.

(ii) Over 150 percent of FPL.

(2) A State that imposes a different level or percentage of cost sharing at different poverty levels must report by poverty level categories that match the

poverty level categories used for purposes of cost sharing.

(c) *Required unduplicated counts.* Thirty days after the end of the Federal fiscal year, the State must submit an unduplicated count for the Federal fiscal year of children who were enrolled in the Medicaid program, the separate child health program, and the Medicaid expansion program, as appropriate, by age, gender, race, ethnicity, service delivery system, and poverty level categories described in paragraphs (a) and (b) of this section.

§ 457.750 Annual report.

(a) *Report required for each Federal fiscal year.* A State must report to HCFA by January 1 following the end of each Federal fiscal year, on the results of the State's assessment of the operation of the State plan.

(b) *Contents of annual report.* In the annual report required under paragraph (a) of this section, a State must—

(1) Describe the State's progress in reducing the number of uncovered, low-income children and; in meeting other strategic objectives and performance goals identified in the State plan; and provide information related to a core set of national performance goals and measures as developed by the Secretary;

(2) Report on the effectiveness of the State's policies for discouraging the substitution of public coverage for private coverage;

(3) Identify successes and barriers in State plan design and implementation, and the approaches the State is considering to overcome these barriers;

(4) Describe the State's progress in addressing any specific issues (such as outreach) that the State plan proposed to periodically monitor and assess;

(5) Provide an updated budget for a 3-year period that describes those elements required in § 457.140, including any changes in the sources of the non-Federal share of State plan expenditures;

(6) Identify the total State expenditures for family coverage and total number of children and adults, respectively, covered by family coverage during the preceding Federal fiscal year;

(7) Collect and provide data regarding the primary language of SCHIP enrollees; and

(8) Describe the State's current income standards and methodologies for its Medicaid expansion program, separate child health program, and title XIX Medicaid program, as appropriate.

(c) *Methodology for estimate of number of uninsured, low-income children.* (1) To report on the progress made in reducing the number of uninsured, low-income children as required in paragraph (b) of this section, a State must choose a methodology to establish an initial baseline estimate of the number of low-income children who are uninsured in the State.

(i) A State may base the estimate on data from—

(A) The March supplement to the Current Population Survey (CPS);

(B) A State-specific survey;

(C) A statistically adjusted CPS; or

(D) Another appropriate source.

(ii) If the State does not base the estimate on data from the March supplement to the CPS, the State must submit a description of the methodology used to develop the initial baseline estimate and the rationale for its use.

(2) The State must provide an annual estimate of changes in the number of uninsured in the State using—

(i) The same methodology used in establishing the initial baseline; or

(ii) Another methodology based on new information that enables the State to establish a new baseline.

(3) If a new methodology is used, the State must also provide annual estimates based on either the March supplement to the CPS or the methodology used to develop the initial baseline.

Subpart H—Substitution of Coverage

§ 457.800 Basis, scope, and applicability.

(a) *Statutory basis.* This subpart interprets and implements section 2102(b)(3)(C) of the Act, which provides that the State plan must include a description of procedures the State uses to ensure that health benefits coverage provided under the State plan does not substitute for coverage under group health plans.

(b) *Scope.* This subpart sets forth State plan requirements relating to substitution of coverage in general and specific requirements relating to substitution of coverage under premium assistance programs.

(c) *Applicability.* The requirements of this subpart apply to separate child health programs.

§ 457.805 State plan requirement: Procedures to address substitution under group health plans.

The State plan must include a description of reasonable procedures to ensure that health benefits coverage provided under the State plan does not substitute for coverage provided under group health plans as defined at § 457.10.

§ 457.810 Premium assistance programs: Required protections against substitution.

A State that operates a premium assistance program, as defined at § 457.10, must provide the protections against substitution of SCHIP coverage for coverage under group health plans specified in this section. The State must describe these protections in the State plan; and report on results of monitoring of substitution in its annual reports.

(a) *Minimum period without coverage under a group health plan.* For health benefits coverage provided through premium assistance for group health plans, the following rules apply:

(1) An enrollee must not have had coverage under a group health plan for a period of at least 6 months prior to enrollment in a premium assistance program. A State may not require a minimum period without coverage under a group health plan that exceeds 12 months.

(2) States may permit reasonable exceptions to the requirement for a minimum period without coverage under a group health plan for—

(i) Involuntary loss of coverage under a group health plan, due to employer termination of coverage for all employees and dependents;

(ii) Economic hardship;

(iii) Change to employment that does not offer dependent coverage; or

(iv) Other reasons proposed by the State and approved as part of the State plan.

(3) The requirement for a minimum period without coverage under a group health plan does not apply to a child who, within the previous 6 months, has received coverage under a group health plan through Medicaid under section 1906 of the Act.

(4) The Secretary may waive the 6-month waiting period requirement described in this section at her discretion.

(b) *Employer contribution.* For health benefits coverage obtained through premium assistance for group health plans, the employee who is eligible for the coverage must apply for the full premium contribution available from the employer.

(c) *Cost effectiveness.* In establishing cost effectiveness—

(1) The State's cost for coverage for children under premium assistance programs must not be greater than the cost of other SCHIP coverage for these children; and

(2) The State may base its demonstration of cost effectiveness on an assessment of the cost of coverage for children under premium assistance programs to the cost of other SCHIP coverage for these children, done on a case-by-case basis, or on the cost of premium assisted coverage in the aggregate.

(d) *State evaluation.* The State must evaluate and report in the annual report (in accordance with § 457.750(b)(2)) the amount of substitution that occurs as a result of premium assistance programs and the effect of those programs on access to coverage.

Subpart I—Program Integrity

§ 457.900 Basis, scope and applicability.

(a) *Statutory basis.* This subpart implements—

(1) Section 2101(a) of the Act, which provides that the purpose of title XXI is to provide funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner; and

(2) Section 2107(e) of the Act, which provides that certain title XIX and title XI provisions, including the following, apply to States under title XXI in the same manner as they apply to a State under title XIX:

(i) Section 1902(a)(4)(C) of the Act, relating to conflict of interest standards.

(ii) Paragraphs (2), (16), and (17), of section 1903(i) of the Act, relating to limitations on payment.

(iii) Section 1903(w) of the Act, relating to limitations on provider taxes and donations.

(iv) Section 1124 of the Act, relating to disclosure of ownership and related information.

(v) Section 1126 of the Act, relating to disclosure of information about certain convicted individuals.

(vi) Section 1128 of the Act, relating to exclusions.

(vii) Section 1128A of the Act, relating to civil monetary penalties.

(viii) Section 1128B(d) of the Act, relating to criminal penalties for certain additional charges.

(ix) Section 1132 of the Act, relating to periods within which claims must be filed.

(b) *Scope.* This subpart sets forth requirements, options, and standards for program integrity assurances that must be included in the approved State plan.

(c) *Applicability.* This subpart applies to separate child health programs. Medicaid expansion programs are subject to the program integrity rules and requirements specified under title XIX.

§ 457.902 Definitions

As used in this subpart—

Actuarially sound principles means generally accepted actuarial principles and practices that are applied to determine aggregate utilization patterns, are appropriate for the population and services to be covered, and have been certified by actuaries who meet the qualification standards established by the Actuarial Standards Board.

Fee-for-service entity means any individual or entity that furnishes services under the program on a fee-for-service basis, including health insurance services.

§ 457.910 State program administration.

The State's child health program must include—

(a) Methods of administration that the Secretary finds necessary for the proper and efficient operation of the separate child health program; and

(b) Safeguards necessary to ensure that—

(1) Eligibility will be determined appropriately in accordance with subpart C of this part; and

(2) Services will be provided in a manner consistent with administrative simplification and with the provisions of subpart D of this part.

§ 457.915 Fraud detection and investigation.

(a) *State program requirements.* The State must establish procedures for ensuring program integrity and detecting fraudulent or abusive activity. These procedures must include the following:

(1) Methods and criteria for identifying suspected fraud and abuse cases.

(2) Methods for investigating fraud and abuse cases that—

(i) Do not infringe on legal rights of persons involved; and

(ii) Afford due process of law.

(b) *State program integrity unit.* The State may establish an administrative agency responsible for monitoring and maintaining the integrity of the separate child health program.

(c) *Program coordination.* The State must develop and implement procedures for referring suspected fraud and abuse cases to the State program integrity unit (if such a unit is established) and to appropriate law enforcement officials. Law enforcement officials include the—

(1) U.S. Department of Health and Human Services Office of Inspector General (OIG);

(2) U.S. Attorney's Office, Department of Justice (DOJ);

(3) Federal Bureau of Investigation (FBI); and

(4) State Attorney General's office.

§ 457.925 Preliminary investigation.

If the State agency receives a complaint of fraud or abuse from any source or identifies questionable practices, the State agency must conduct a preliminary investigation or take otherwise appropriate action within a reasonable period of time to determine whether there is sufficient basis to warrant a full investigation.

§ 457.930 Full investigation, resolution, and reporting requirements.

The State must establish and implement effective procedures for investigating and resolving suspected and apparent instances of fraud and abuse. Once the State determines that a full investigation is warranted, the State must implement procedures including, but not limited to the following:

(a) Cooperate with and refer potential fraud and abuse cases to the State program integrity unit, if such a unit exists.

(b) Conduct a full investigation.

(c) Refer the fraud and abuse case to appropriate law enforcement officials.

§ 457.935 Sanctions and related penalties.

(a) A State may not make payments for any item or service furnished, ordered, or prescribed under a separate child health program to any provider who has been excluded from participating in the Medicare and Medicaid programs.

(b) The following provisions and their corresponding regulations apply to a State under title XXI, in the same manner as these provisions and regulations apply to a State under title XIX:

(1) Part 455, subpart B of this chapter.

(2) Section 1124 of the Act pertaining to disclosure of ownership and related information.

(3) Section 1126 of the Act pertaining to disclosure by institutions, organizations, and agencies of owners and certain other individuals who have been convicted of certain offenses.

(4) Section 1128 of the Act pertaining to exclusions.

(5) Section 1128A of the Act pertaining to civil monetary penalties.

(6) Section 1128B of the Act pertaining to criminal penalties for acts involving Federal health care programs.

(7) Section 1128E of the Act pertaining to the reporting of final adverse actions on liability findings made against health care providers, suppliers, and practitioners under the health care fraud and abuse data collection program.

§ 457.940 Procurement standards.

(a) A State must submit to HCFA a written assurance that title XXI services will be provided in an effective and efficient manner. The State must submit the assurance—

(1) With the initial State plan; or

(2) For States with approved plans, with the first request to amend the approved plan.

(b) A State must—

(1) Provide for free and open competition, to the maximum extent practical, in the bidding of all procurement contracts for coverage or other services in accordance with the procurement requirements of 45 CFR 74.43; or

(2) Use payment rates based on public or private payment rates for comparable services for comparable populations, consistent with principles of actuarial soundness as defined at § 457.902.

(c) A State may establish higher rates than permitted under paragraph (b) of this section if such rates are necessary to ensure sufficient provider participation, provider access, or to enroll providers who demonstrate exceptional efficiency or quality in the provision of services.

(d) All contracts under this part must include provisions that define a sound and complete procurement contract, as required by 45 CFR part 74.

(e) The State must provide to HCFA, if requested, a description of the manner in which rates were developed in accordance with the requirements of paragraphs (b) or (c) of this section.

§ 457.945 Certification for contracts and proposals.

Entities that contract with the State under a separate child health program must certify the accuracy, completeness, and truthfulness of information in contracts and proposals, including information on subcontractors, and other related documents, as specified by the State.

§ 457.950 Contract and payment requirements including certification of payment-related information.

(a) *Managed care entity (MCE).* A State that makes payments to an MCE under a separate child health program, based on data submitted by the MCE, must ensure that its contract requires the MCE to provide—

(1) Enrollment information and other information required by the State;

(2) An attestation to the accuracy, completeness, and truthfulness of claims and payment data, under penalty of perjury;

(3) Access for the State, HCFA, and the HHS Office of the Inspector General to enrollee health claims data and payment data, in conformance with the appropriate privacy protections in the State; and

(4) A guarantee that the MCE will not avoid costs for services covered in its contract by referring enrollees to publicly supported health care resources.

(b) *Fee-for-service entities.* A State that makes payments to fee-for-service entities under a separate child health program must—

(1) Establish procedures to ensure that the entity certifies and attests that information on claim forms is truthful, accurate, and complete;

(2) Ensure that fee-for-service entities understand that payment and satisfaction of the claims will be from Federal and State funds, and that any false claims may be prosecuted under applicable Federal or State laws; and

(3) Require, as a condition of participation, that fee-for-service entities provide the State, HCFA and/or the HHS Office of the Inspector General with access to enrollee health claims data, claims payment data and related records.

§ 457.955 Conditions necessary to contract as a managed care entity (MCE).

(a) The State must assure that any entity seeking to contract as an MCE under a separate child health program has administrative and management arrangements or procedures designed to safeguard against fraud and abuse.

(b) The State must ensure that the arrangements or procedures required in paragraph (a) of this section—

(1) Enforce MCE compliance with all applicable Federal and State standards;

(2) Prohibit MCEs from conducting any unsolicited personal contact with a potential enrollee by an employee or agent of a managed care entity for the purpose of influencing the individual to enroll with the entity; and

(3) Include a mechanism for the MCE to report to the State, to HCFA, or to the Office of Inspector General (OIG) as appropriate, information on violations of law by subcontractors or enrollees of an MCE and other individuals.

(c) With respect to enrollees, the reporting requirement in paragraph (b)(3) of this section applies only to information on violations of law that pertain to enrollment in the plan, or the provision of, or payment for, health services.

(d) The State may inspect, evaluate, and audit MCEs at any time, as necessary, in instances where the State determines that there is a reasonable possibility of fraudulent and abusive activity.

§ 457.960 Reporting changes in eligibility and redetermining eligibility.

If the State requires reporting of changes in circumstances that may affect the enrollee's eligibility for child health assistance, the State must:

(a) Establish procedures to ensure that enrollees make timely and accurate reports of any such change; and

(b) Promptly redetermine eligibility when the State has information about these changes.

§ 457.965 Documentation.

The State must include in each applicant's record facts to support the State's determination of the applicant's eligibility for SCHIP.

§ 457.980 Verification of enrollment and provider services received.

(a) The State must establish methodologies to verify whether beneficiaries have received services for which providers have billed.

(b) The State must establish and maintain systems to identify, report, and verify the accuracy of claims for those enrolled children who meet requirements of section 2105(a) of the Act, where enhanced Federal medical assistance percentage computations apply.

§ 457.985 Integrity of professional advice to enrollees.

The State must ensure through its contracts for coverage and services that its contractors comply with—

(a) Section 422.206(a) of this chapter, which prohibits interference with health care professionals' advice to enrollees and requires that professionals provide information about treatment in an appropriate manner; and

(b) Sections 422.208 and 422.210 of this chapter, which place limitations on physician incentive plans, and information disclosure requirements related to those physician incentive plans, respectively.

Subpart J—Allowable Waivers: General Provisions

§ 457.1000 Basis, scope, and applicability.

(a) *Statutory basis.* This subpart interprets and implements—

(1) Section 2105(c)(2)(B) of the Act, which sets forth the requirements for a waiver to permit a State to exceed the 10 percent cost limit on expenditures other than benefit expenditures; and

(2) Section 2105(c)(3) of the Act, which permits a waiver for the purchase of family coverage.

(b) *Scope.* This subpart sets forth requirements for obtaining a waiver under title XXI.

(c) *Applicability.* This subpart applies to separate child health programs; and applies to Medicaid expansion programs when the State claims administrative costs under title XXI and seeks a waiver of limitations on such claims for use of a community-based health delivery

system. This subpart does not apply to demonstrations requested under section 1115 of the Act.

§ 457.1003 HCFA review of waiver requests.

HCFA will review the waiver requests under this subpart using the same time frames used for State plan amendments, as specified in § 457.160.

§ 457.1005 Waiver for cost-effective coverage through a community-based health delivery system.

(a) *Availability of waiver.* The Secretary may waive the requirements of § 457.618 (the 10 percent limit on expenditures not used for health benefits coverage for targeted low-income children, that meets the requirements of § 457.410) in order to provide child health assistance to targeted low-income children under the State plan through a cost-effective, community-based health care delivery system, such as through contracts with health centers receiving funds under section 330 of the Public Health Service Act or with hospitals such as those that receive disproportionate share payment adjustments under section 1886(c)(5)(F) or section 1923 of the Act.

(b) *Requirements for obtaining a waiver.* To obtain a waiver for cost-effective coverage through a community-based health delivery system, a State must demonstrate that—

(1) The coverage meets all of the requirements of this part, including subpart D and subpart E.

(2) The cost of such coverage, on an average per child basis, does not exceed the cost of coverage under the State plan.

(c) *Three-year approval period.* An approved waiver remains in effect for no more than 3 years.

(d) *Application of cost savings.* If the cost of coverage of a child under a community-based health delivery system is equal to or less than the cost of coverage of a child under the State plan, the State may use the difference in the cost of coverage for each child enrolled in a community-based health delivery system for—

(1) Other child health assistance, health services initiatives, or outreach; or

(2) Any reasonable costs necessary to administer the State's program.

§ 457.1010 Waiver for purchase of family coverage.

A State may purchase family coverage that includes coverage for targeted low-income children if the State establishes that—

(a) Purchase of family coverage is cost-effective under the standards described in § 457.1015;

(b) The State does not purchase the coverage if it would otherwise substitute for health insurance coverage that would be provided to targeted, low-income children but for the purchase of family coverage; and

(c) The coverage for the family otherwise meets the requirements of this part.

§ 457.1015 Cost-effectiveness.

(a) *Definition.* For purposes of this subpart, ''cost-effective'' means that the State's cost of purchasing family coverage that includes coverage for targeted low-income children is equal to or less than the State's cost of obtaining coverage under the State plan only for the eligible targeted low-income children involved.

(b) *Cost comparisons.* A State may demonstrate cost-effectiveness by comparing the cost of coverage for the family to the cost of coverage only for the targeted low-income children under the health benefits package offered by the State under the State plan for which the child is eligible.

(c) *Individual or aggregate basis.* (1) The State may base its demonstration of the cost-effectiveness of family coverage on an assessment of the cost of family coverage for individual families, done on a case-by-case basis, or on the cost of family coverage in the aggregate.

(2) The State must assess cost-effectiveness in its initial request for a waiver and then annually.

(3) For any State that chooses the aggregate cost method, if an annual assessment of the cost-effectiveness of family coverage in the aggregate reveals that it is not cost-effective, the State must assess cost-effectiveness on a case-by-case basis.

(d) *Reports on family coverage.* A State with a waiver under this section must include in its annual report pursuant to § 457.750, the cost of family coverage purchased under the waiver, and the number of children and adults, respectively, covered under family coverage pursuant to the waiver.

Subpart K—State Plan Requirements: Applicant and Enrollee Protections

§ 457.1100 Basis, scope and applicability.

(a) *Statutory basis.* This subpart interprets and implements—

(1) Section 2101(a) of the Act, which states that the purpose of title XXI of the Act is to provide funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner;

(2) Section 2102(a)(7)(B) of the Act, which requires that the State plan include a description of the methods used to assure access to covered services, including emergency services;

(3) Section 2102(b)(2) of the Act, which requires that the State plan include a description of methods of establishing and continuing eligibility and enrollment; and

(4) Section 2103 of the Act, which outlines coverage requirements for a State that provides child health assistance through a separate child health program.

(b) *Scope.* This subpart sets forth minimum standards for privacy protection and for procedures for review of matters relating to eligibility, enrollment, and health services.

(c) *Applicability.* This subpart only applies to a separate child health program.

§ 457.1110 Privacy protections.

The State must ensure that, for individual medical records and any other health and enrollment information maintained with respect to enrollees, that identifies particular enrollees (in any form), the State establishes and implements procedures to—

(a) Abide by all applicable Federal and State laws regarding confidentiality and disclosure, including those laws addressing the confidentiality of information about minors and the privacy of minors, and privacy of individually identifiable health information;

(b) Comply with subpart F of part 431 of this chapter;

(c) Maintain the records and information in a timely and accurate manner;

(d) Specify and make available to any enrollee requesting it—

(1) The purposes for which information is maintained or used; and

(2) To whom and for what purposes the information will be disclosed outside the State;

(e) Except as provided by Federal and State law, ensure that each enrollee may request and receive a copy of records and information pertaining to the enrollee in a timely manner and that an enrollee may request that such records or information be supplemented or corrected.

§ 457.1120 State plan requirement: Description of review process.

A State plan must include a description of the State's review process that meets the requirements of §§ 457.1130, 457.1140, 457.1150, 457.1160, 457.1170, 457.1180, and 457.1190.

§ 457.1130 Matters subject to review.

(a) *Eligibility or enrollment matter.* A State must ensure that an applicant or enrollee has an opportunity for review, consistent with §§ 457.1140 and 457.1150, of a—

(1) Denial of eligibility;

(2) Failure to make a timely determination of eligibility; and

(3) Suspension or termination of enrollment, including disenrollment for failure to pay cost sharing.

(b) *Health services matter.* A State must ensure that an enrollee has an opportunity for external review of a—

(1) Delay, denial, reduction, suspension, or termination of health services, in whole or in part, including a determination about the type or level of services; and

(2) Failure to approve, furnish, or provide payment for health services in a timely manner.

(c) *Exception.* A State is not required to provide an opportunity for review of a matter described in paragraph (a) or (b) of this section if the sole basis for the decision is a provision in the State plan or in Federal or State law requiring an automatic change in eligibility, enrollment, or a change in coverage under the health benefits package that affects all applicants or enrollees or a group of applicants or enrollees without regard to their individual circumstances.

§ 457.1140 Core elements of review.

In adopting the procedures for review of matters described in § 457.1130, a State must ensure that—

(a) Reviews are conducted by an impartial person or entity in accordance with § 457.1150;

(b) Review decisions are timely in accordance with § 457.1160;

(c) Review decisions are written; and

(d) Applicants and enrollees have an opportunity to—

(1) Represent themselves or have representatives of their choosing in the review process;

(2) Timely review their files and other applicable information relevant to the review of the decision;

(3) Fully participate in the review process, whether the review is conducted in person or in writing, including by presenting supplemental information during the review process; and

(4) Receive continued enrollment in accordance with § 457.1170.

§ 457.1150 Impartial review.

(a) *Eligibility or enrollment matter.* The review of a matter described in § 457.1130(a) must be conducted by a person or entity who has not been directly involved in the matter under review.

(b) *Health services matter.* The State must ensure that an enrollee has an opportunity for an independent external review of a matter described in § 457.1130(b). External review must be conducted by the State or a contractor other than the contractor responsible for the matter subject to external review.

§ 457.1160 Time frames.

(a) *Eligibility or enrollment matter.* A State must complete the review of a matter described in § 457.1130(a) within a reasonable amount of time. In setting time frames, the State must consider the need for expedited review when there is an immediate need for health services.

(b) *Health services matter.* The State must ensure that reviews are completed in accordance with the medical needs of the patient. If the medical needs of the patient do not dictate a shorter time frame, the review must be completed within the following time frames:

(1) *Standard timeframe.* A State must ensure that external review, as described in § 457.1150(b), is completed within 90 calendar days of the date an enrollee requests internal (if available) or external review. If both internal and external review are available to the enrollee, both types of review must be completed within the 90 calendar day period.

(2) *Expedited timeframe.* A State must ensure that external review, as described in § 457.1150(b), is completed within 72 hours of the time an enrollee requests external review, if the enrollee's physician or health plan determines that operating under the standard time frame could seriously jeopardize the enrollee's life or health or ability to attain, maintain or regain maximum function. If the enrollee has access to internal and external review, then each level of review may take no more than 72 hours. The State may extend the 72-hour time frame by up to 14 calendar days, if the enrollee requests an extension.

§ 457.1170 Continuation of enrollment.

A State must ensure the opportunity for continuation of enrollment pending the completion of review of a suspension or termination of enrollment, including a decision to disenroll for failure to pay cost sharing.

§ 457.1180 Notice.

A State must provide enrollees and applicants timely written notice of any determinations required to be subject to review under § 457.1130 that includes the reasons for the determination, an explanation of applicable rights to review of that determination, the standard and expedited time frames for review, the manner in which a review can be requested, and the circumstances under which enrollment may continue pending review.

§ 457.1190 Application of review procedures when States offer premium assistance for group health plans.

A State that has a premium assistance program through which it provides coverage under a group health plan that does not meet the requirements of §§ 457.1130(b), 457.1140, 457.1150(b), 457.1160(b), and 457.1180 must give applicants and enrollees the option to obtain health benefits coverage other than through that group health plan. The State must provide this option at initial enrollment and at each redetermination of eligibility.

(Catalog of Federal Domestic Assistance Program No. 00.000, State Children's Health Insurance Program)

Dated: January 4, 2001.

Robert A. Berenson,

Acting Deputy Administrator, Health Care Financing Administration.

Dated: January 4, 2001.

Donna E. Shalala,

Secretary.

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