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Department of Health and Human Services

Health Care Financing Administration

**42 CFR Parts 431, 433, 435, etc.
State Child Health; Implementing
Regulations for the State Children's
Health Insurance Program; Final Rule**

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).

FOR FURTHER INFORMATION CONTACT:

Regina Fletcher for general information, (410) 786-3293; Diona Kristian for subpart A, State plan, (410) 786-3283; Judy Rhoades for subpart C, Eligibility, (410) 786-4462; Regina Fletcher for subpart D, Benefits, (410) 786-5916; Nancy Fasciano for subpart E, Cost sharing, (410) 786-4578; Kathleen

Farrell for subpart G, Strategic planning, (410) 786-1236; Terese Klitenic for subpart H, Substitution of coverage, (410) 786-5942; Maurice Gagnon for subpart I, Program integrity (410) 786-60619; Cindy Shirk for subpart J, Allowable waivers, (410) 786-1304; Christina Moylan for subpart K, Applicant and enrollee protections (410) 786-6102; Judy Rhoades for Expanded coverage of children under Medicaid and Medicaid coordination, (410) 786-4462; Christine Hinds for Medicaid disproportionate share hospital expenditures, (410) 786-4578; and Joan Mahanes for the Vaccines for Children program, (410) 786-4583.

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I. Background

Section 4901 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 indicated 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

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- 457.520 Cost sharing for well-baby and well-child care.
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- 457.530 General cost-sharing protection for lower income children.
- 457.535 Cost-sharing protection to ensure enrollment of American Indians/Alaska Natives.
- 457.540 Cost-sharing charges for children in families with incomes at or below 150 percent of the FPL.
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- 457.560 Cumulative cost-sharing maximum.
- 457.570 Disenrollment protections.

Subpart F—[Reserved]

Subpart G—Strategic Planning, Reporting, and Evaluation

- 457.700 Basis, scope, and applicability.
- 457.710 State plan requirements: Strategic objectives and performance goals.
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Subpart H—Substitution of Coverage

- 457.800 Basis, scope, and applicability.
- 457.805 State plan requirements: Procedures to address substitution under group health plans.
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- 457.902 Definitions.
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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 (CHIP)* 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 (IHCA) 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 IHCA, 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 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 restricts 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 plan 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 nor 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 apprise 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 defined 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 delivery 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 it is 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