

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

42 CFR Part 457

[CMS-2127-F]

RIN 0938-AL37

State Children's Health Insurance Program; Eligibility for Prenatal Care and Other Health Services for Unborn Children

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

ACTION: Final rule.

SUMMARY: In order to provide prenatal care and other health services, this final rule revises the definition of "child" under the State Children's Health Insurance Program (SCHIP) to clarify that an unborn child may be considered a "targeted low-income child" by the State and therefore eligible for SCHIP if other applicable State eligibility requirements are met. Under this definition, the State may elect to extend eligibility to unborn children for health benefits coverage, including prenatal care and delivery, consistent with SCHIP requirements.

EFFECTIVE DATE: These regulations are effective on November 1, 2002.

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I. Background

Section 4901 of the Balanced Budget Act, (Pub. L. 105-33), as amended by Public Law 105-100, added title XXI to the Act. Title XXI authorizes the State Children's Health Insurance Program (SCHIP) 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), that meets the applicable requirements of title XXI and is approved by the Secretary.

Benefits under SCHIP are jointly financed by the Federal and State governments and are 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. Under section 2102(b) of the Act, States have discretion to adopt eligibility standards that are related to age, and thus may extend SCHIP eligibility only to certain age groups of targeted low-income children (who must be under age 19). SCHIP provides a capped amount of funds to States on a matching basis for Federal fiscal years (FY) 1998 through 2007. Regulations implementing SCHIP are set forth at 42 CFR 457.

II. Provisions of the Proposed Regulations

On March 5, 2002, we published a proposed rule in the **Federal Register** that proposed to revise the definition of "child" under the SCHIP program (67 FR 9936). In the interest of providing necessary prenatal care and other health services to children, we proposed to clarify and expand the definition of the term "child" so that a State may elect to make individuals in the period between conception and birth eligible for coverage under the State plan. Specifically, we proposed to revise the definition at § 457.10 to clarify that "child" means an individual under the age of 19 and may include any period of time from conception to birth up to age 19. In this rule, we explained that while a pregnant woman under age 19 could be eligible as a targeted low-

income child, and her child would benefit from needed prenatal care and delivery services by virtue of the mother's eligibility status, a pregnant woman over age 19 could not be eligible as a targeted low-income child.

We stated that the proposed definition would provide States with the option to consider an unborn child to be a targeted low-income child and therefore eligible for SCHIP if other applicable State eligibility requirements are met. This would permit States to ensure that needed services are available to benefit unborn children independent of the mother's eligibility status. We also discussed in detail the Department's 1999 report, *Trends in the Well-Being of America's Children and Youth*, which describes the benefits of prenatal care for the mother and the child. We stated that our proposed revisions were intended to benefit both the unborn children and their mothers by promoting continuity of important medical care.

In order to protect against the substitution of title XXI enhanced payments for Medicaid payments, we proposed to add a new paragraph (a)(3) to § 457.626(a), Prevention of duplicate payments, to clarify that payment is not available under title XXI when payment may be reasonably expected to be made under Medicaid on the basis of the Medicaid eligibility or enrollment of the pregnant woman.

With regard to maintenance of effort requirements, we proposed that if a State elects to include unborn children in the SCHIP definition of children, the State must also apply that same interpretation in assessing compliance with the Medicaid maintenance of effort provision of section 2105(d)(1) of the Act. Specifically, we proposed to revise § 457.622, Rate of Federal Financial Participation (FFP) for State expenditures, to provide that the State does not adopt eligibility standards and methodologies for purposes of determining a child's eligibility under the Medicaid State plan that were more restrictive than those applied under policies of the State plan in effect on June 1, 1997. This limitation applies also to more restrictive standards and methodologies for determining eligibility for services for a child based on the eligibility of a pregnant woman.

We also stated that, a State that defines children under SCHIP to include unborn children would need to apply the same definition in the screen-and-enroll process described in SCHIP regulations at § 457.350, Eligibility screening and facilitation of Medicaid enrollment. We proposed to add a new § 457.350(b)(2) to clarify that screening

procedures must identify any applicant or enrollee who would be potentially eligible for Medicaid services based on the eligibility of his or her mother under one of the poverty level groups described in section 1902(l) of the Act, section 1931 of the Act, or a Medicaid demonstration project approved under section 1115 of the Act.

We noted that under our proposed regulation, States would continue to have the authority to set eligibility requirements under their State plans, including age limits so long as the age limit is under 19 years of age. Hence, States would not be required to extend coverage to this population. States that opt to extend eligibility to unborn children must submit a State plan amendment in accordance with § 457.60. States can use the preprinted application template for the State Children's Health Insurance Program, sections 4.1.2 and 4.4, and the preprinted budget template in submitting this State plan amendment.

III. Analysis of and Responses to Public Comments

We received and accepted 7,783 comments. The majority of these were form letters that were part of write-in campaigns. Because of possible residual delays in the Washington, DC mail, resulting from new security procedures, we accepted comments that were postmarked up to and including May 13, 2002. All public comments have been summarized and are discussed in detail in the following discussion.

1. General Comments

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

Comment: We received a great number of comments from people who viewed the proposed rule as having a hidden agenda of providing unborn children with formal legal rights as the first step in abolishing abortion.

Commenters stated that since the child in the womb would be recognized as a patient, there would never be a case where abortion is justified. Another commenter stated that the unborn child's status as a patient in need of health care has long enjoyed international recognition and cited the United Nations Declaration on the Rights of the Child and the 1990 Convention implementing its principles, which declared that the child needs special safeguards and care, including

appropriate legal protection, before as well as after birth. Other commenters viewed the proposed rule as empowering lower-income women to choose life for their children and enhance their ability to raise their families with dignity.

Many commenters expressed opposing views on this issue, saying that this is an anti-choice proposal disguised as a health care proposal. Commenters considered the proposal as the Administration's attempt to create legal precedent for viewing unborn children as separate physical and legal entities, which they believe devalues women as persons and is counterproductive to the health and well being of both women and children. Commenters stated that the underlying purpose of the proposed rule is to advance fetal personhood and deny the right of every woman to determine the direction of her own life. They believe the proposed rule would undermine the foundation of the right to choose abortion and threatens a woman's reproductive freedom. They said the proposed rule would lay the legal groundwork for an adversarial relationship between a woman and her unborn child.

Commenters expressed the opinion that the proposed rule is a tactic for extending the rights of a person under the constitution to an unborn child through the regulatory process as a means of circumventing the legislative process where it can be debated and voted on openly by elected representatives. Many commenters considered the proposed rule an attempt to provoke controversy over *Roe v. Wade* and provide the groundwork for having it overturned with the long-term goal of having abortion declared illegal.

Response: CMS does not believe that this revised definition of "child" is inconsistent with the United Nations Declaration on the Rights of the Child or with *Roe v. Wade*.

At the core of a number of commenters' arguments against the rule is a fundamental misconception that this rule would set up an adversarial relationship between the mother and her unborn child that might threaten the mother's autonomy.

Such reasoning overlooks the reality that the SCHIP program is a voluntary assistance program that begins when an individual applies for the benefit. If the woman did not want the health insurance coverage offered by the State's SCHIP program, she simply would not apply for it or would discontinue her participation in the program.

This rule, rather than limiting an uninsured woman's choices in fact

expands them by offering important health care that may not otherwise be available to her.

In general, patient education literature affirms that prenatal care benefits both the mother and the unborn child. For example, the Web site of the American College of Obstetricians and Gynecologists (ACOG) provides excerpts from its patient education material. ACOG Education Pamphlet AP098—Special Tests for Monitoring Fetal Health explains that, "[e]arly prenatal care gives your doctor a chance to check on your health and the progress of your pregnancy. Based on the results of routine prenatal care, your doctor may suggest tests to check the health of the baby. Most of the time, these tests help assure you and your doctor that all is going well. Monitoring helps you and your doctor during your pregnancy by telling more about the well being of the baby. Monitoring may be done during pregnancy to help assess the health, activity level, and growth of the unborn child. Some of the tests used for monitoring check the movement, heartbeat, blood flow, and rate of growth of the unborn child. If so, the baby may need special care or may need to be delivered right away."

In another article, "Nutrition During Pregnancy," available through the *Medem.com* Web site, ACOG explains that, "[a] balanced diet is a basic part of good health at all times in your life. During pregnancy, diet is even more important. The foods you eat are the main source of the nutrients for your baby. As your baby grows, you will need more of most nutrients."

This rule reflects the common understanding that prenatal care benefits both mother and child and therefore does not create tension between them.

It is also useful to bear in mind that these generally are children who will otherwise be eligible for their respective SCHIP program in a State at birth. It only makes sense, and indeed is medically obvious that establishing eligibility during the prenatal stage advances the likelihood of a healthy pregnancy, healthy birth, and healthy life.

Comment: Many of the commenters asserted that if the intent of the proposed regulation is to provide additional health care to pregnant women, it could be done through existing regulations. Commenters were concerned that the designation of the unborn child as a child would raise legal and operational issues that would take years to resolve, resulting in litigation that would prevent many pregnant women from receiving needed

health care. For this reason, numerous commenters recommended the withdrawal of this rule. One commenter mentioned that for States to adopt this rule, they would be required to act through their State legislatures to redefine a "child" as being from conception through age 19, which would cause enormous tension in State capitals across the country and unproductive bipartisan politics, which would not further the health care needs of pregnant women or children.

Since States already have the means to cover pregnant women, the commenter urged HHS to facilitate the process and not complicate it and many commenters stated that they believe the regulation is unnecessary. As examples, commenters cited the States of New Jersey and Rhode Island that have applied for and received section 1115 waivers to expand coverage to low-income women. They noted that SCHIP waivers are relatively easy for States to secure since under the existing SCHIP waiver program, the Federal government does not require "budget neutrality", States can spend additional funds up to the State's unspent SCHIP allotment and there is already a template in place to streamline the waiver application process.

Commenters suggested alternative options to HHS rather than implementing the rule that included: use options under Medicaid to provide comprehensive prenatal and pregnancy-related care to women; use the existing authority of approving waivers and implement a process for expediting the approval of waiver applications; amend the SCHIP statute to provide prenatal care for pregnant women by expanding eligibility to the woman rather than to the unborn child; and support and work with the Congress to approve pending legislation that would provide access to prenatal care for uninsured women as well as additional funding for States.

Response: This regulation bridges a gap in eligibility between the Medicaid and the SCHIP programs that has now existed for five years. Members of the Congress have also recognized this gap and have introduced various pieces of legislation over the years to address this gap. The opportunity to expand vital health insurance coverage during a critical time is at hand.

We welcome all of these suggestions for expanding health insurance coverage and indeed States and the Secretary have already used the flexibility in current regulations. However, there are still gaps. We also welcome support for the actions of the Secretary in granting waivers to States that expand eligibility for individuals who would not

otherwise be eligible for Medicaid or SCHIP. But the Secretary's ability to intervene through one mechanism (a waiver) should not be the sole option for States and may in fact be an inferior option. Waivers are discretionary on the part of the Secretary and time limited while State plan amendments are permanent, and are subject to allotment neutrality.

Commenters recognize that certain low-income pregnant women are not currently eligible for coverage under either Medicaid or SCHIP. We recognize that States already have the ability to provide prenatal care to pregnant women through expanding their title XIX coverage of pregnant women either through an amendment to their approved State Plan or through a demonstration project under section 1115 of the Act. However, States have been reluctant to do so under the regular Medicaid match rate. It is the enhanced match under title XXI that has proven to be the incentive for States to increase eligibility.

The approval process for a SCHIP demonstration project to extend coverage to pregnant women under section 1115 is a relatively streamlined process. However, as the commenters also acknowledge, only five States have applied to cover pregnant women (Colorado, Maryland, Michigan, New Jersey and Rhode Island) of which two have been approved as of July 2002 (New Jersey and Rhode Island).

States may decide not to pursue this option because of the local political climate, the need for State legislative modifications or a variety of other reasons. Our regulation is simply an option to make it faster and easier for States that want to use SCHIP funds to expand prenatal services for low-income women and to do so without having to go through the 1115 process or wait for the passage of legislation.

With respect to comments relating to potential legislative changes to the Medicaid and SCHIP statute, discussion of such changes are beyond the scope of this regulation.

Comment: One commenter said that another way the Administration could help ensure prenatal care was to change the Medicaid system to make it less confusing and more accessible, by reducing the complexity of the eligibility process, the burdensome application forms and by addressing the lack of knowledge surrounding access and other regulatory barriers that prevent women from accessing this health care insurance.

Response: Many States in fact have taken action to lower barriers to enrollment, renewal, and access.

Barriers to enrollment have been one of the major areas CMS has worked on with States in recent years. States were given significant flexibility to simplify the eligibility process in the SCHIP statute and regulations, and CMS has encouraged States to take similar steps within the framework of Medicaid requirements. States have the option to provide presumptive eligibility for pregnant women and the Medicaid regulations have mandated simplification and streamlining of the enrollment process. It is the State's option how they choose to accomplish this. However, administrative simplification has its limits and cannot bridge the eligibility gap as the proposed regulation would.

Comment: A commenter noted that the unborn child was a feature of the Medicaid program until 1986 when it was replaced with a coverage category tied directly to the woman's pregnancy status (Pub. L. 99-509, the Budget Reconciliation Act of 1986). The commenter considered that option to be an invaluable means of permitting coverage of certain children whose mothers could not for a variety of reasons qualify for Medicaid coverage. The commenter believes that the recognition of this option in SCHIP at least partially restores this State flexibility, which was lost 16 years ago, and positions State programs to extend public health insurance to pregnant women who are currently unqualified in their own right.

Response: We appreciate the commenter's support and agree that the intent of this regulation is to provide States with flexibility in selecting the options that are available to them in providing this vital care.

The proposed regulation in fact would restore flexibility that the previous Federal policy provided that allowed welfare and Medicaid coverage for not-yet-born children.

As early as 1941, the Bureau of Public Assistance, a predecessor agency within the Department of Health, Education and Welfare (HEW), determined that unborn children could be covered under the Social Security Act of 1935. It was determined that under the Act, Federal funds could be provided to the States for the aid of unborn children. The Agency's 1946 Handbook of Public Assistance Administration permitted the inclusion of unborn children among those eligible for State-plan aid "on the basis of the same eligibility conditions as apply to other children." The operating policy remained unchanged through 1971. The option remained with State welfare plans to determine whether to include unborn children as

dependents. At the time of the institution of the Medicaid program, many State social service agencies adopted similar eligibility definitions for the purposes of qualifying for Medicaid under a State plan. The approaches were later changed through a decision by the HEW Secretary. While this change was in part a reaction to the determination with respect to the historic Aid to Families with Dependent Children program in *Burns v. Alcala*, 420 U.S. 575 (1975) that States were not required to extend eligibility based on unborn children, this decision is not applicable to the SCHIP statute and does not reflect the congressional intent to provide broad State flexibility under SCHIP to expand the provision of child health assistance. These precedents are important as we look for ways for all women to receive prenatal care.

Comment: A commenter noted that several States have sought and obtained waivers allowing them to provide SCHIP coverage to unborn children as beneficiaries of SCHIP and felt that this offers in itself a strong argument for making that inclusion uniform among the States and independent of the waiver process.

Response: We agree with the commenter, but note that States still retain the option to apply for section 1115 waivers to provide prenatal coverage to low-income pregnant women.

Comment: A commenter noted that the U.S. House of Representatives also recognizes the value of Secretary Thompson's decision and has, therefore, drafted a Congressional Resolution (H.R. Res. 346) commending the decision to recognize that pregnant mothers and unborn children are deserving of concern about their health and well being. Another commenter mentioned the bills currently being considered by the Congress that would allow States to provide low-income women with prenatal coverage under SCHIP, specifically the "Start Healthy, Stay Healthy Act of 2001 (S. 1016/H.R. 3729), the "Mothers and Newborns Health Insurance Act of 2001 (S. 724/H.R. 2610), and the "Legal Immigrant Children's Health Improvement Act of 2001 (S. 582/H.R. 1143) on which the Congress has yet to schedule action. The commenters said that absent the change in statute, they are pleased that, once finalized, the proposed CMS regulation will allow States to extend coverage to pregnant women without delay. Commenters concluded that extending eligibility for SCHIP coverage to unborn children, including prenatal care and delivery, as consistent with SCHIP requirements, is the best way to provide

needed medical care to those low-income children and pregnant women that would otherwise be without health insurance.

Response: We agree and appreciate the commenters' support.

2. Definition of Targeted Low-Income Child

Comment: The commenters expressed their belief that life begins at conception and unborn children are human beings who should be eligible for health care. The commenters asserted that any threshold for eligibility other than conception is inevitably arbitrary, because conception is the point when an individual human life comes into existence. Commenters stated that the proposed rule reflects the medical reality that the life of a child begins before birth at conception, and is thoroughly consistent with precedent, according legal significance to, and protecting the life of the unborn child. The commenters stated that the proposed rule's definition of "child" is consistent with a vast body of scientific literature, and with modern medical practice, which recognizes that the life of a child begins at conception and continues until adulthood.

The commenters mentioned that the statute defines the maximum age of eligibility for services as 19, but specifies no minimum age. Thus, without this regulatory clarification, it is possible that many otherwise eligible children would not receive prenatal care under this program, and might suffer severe health consequences as a result. Another commenter noted that *Pediatrics*, Vol 81, #5, May 1988, p. 736, defines commitment to the health of the individual as beginning at conception. The commenter supported the proposed rule based on the importance of ensuring adequate health care for children, both before and after birth, and the health of their mothers.

Response: We appreciate all of the comments as important contributions to the public record, which helps shape the Secretary's decision-making. We recognize that while the intent of this rule is to extend health insurance coverage, policy determinations are often carried into other important public discussions. We agree with these commenters that conception can be a logical point to recognize a targeted low income child, and thus, we are retaining our revised definition to permit States the option in administering the SCHIP program.

Comment: Commenters stated that the proposed rule has ample legal precedent. Outside the abortion context, they stated that unborn children are often recognized as persons who

warrant the law's protection. As examples, the commenters said that most States allow recovery in one form or another for prenatal injuries. Thus, several commenters cited *Roe v. Wade*, 410 U.S. 113, 161–2 (1973) and an article by Paul Benjamin Linton, *Planned Parenthood v. Casey*, 13 St. Louis U. Public Law Rev. 15, 46–64 (1993). Another commenter noted that roughly half the States criminalize fetal homicide. Commenters said that unborn children have long been recognized as persons for purposes of inheritance, *Roe*, 410 U.S., at 162, and a child unborn at the time of his or her father's wrongful death has been held to be among the children for whose benefit a wrongful death action may be brought, 22A Am.Jur.2d death § 99 (1988). A commenter cited a Kansas bill (HB2797) that would treat a fetus as "an unborn child" and declare the "unborn child" to be a "person or human being" so as to allow, under State criminal law, prosecution following the "death or injury of a fetus." (See Hanna, AP/Topeka Capital-Journal, April 2, 2002.)

One commenter said that Federal statute similarly recognizes the unborn child as a human subject deserving protection from harmful research as soon as pregnancy is confirmed, 42 U.S.C. 289g(b); 45 CFR part 46 §§ 46.203 *et seq.* Therefore, the commenters did not consider it to be an innovation to treat an unborn child as a human individual for the purpose of providing quality prenatal care to the child and his or her mother.

Response: We appreciate all of the comments as important contributions to the public record, which helps shape the Secretary's decision-making. We recognize that while the intent of this rule is to extend health insurance coverage, policy determinations are often carried into other important public discussions. We agree with these commenters that unborn children are often recognized for other purposes under State law, and thus are retaining our revised definition to permit States such an option in administering the SCHIP program.

Comment: Commenters said that defining unborn children as children is not an appropriate administrative decision. Commenters considered defining a child in this way to be arbitrary and they asserted that most of this country's population does not agree with this position. The commenters go on to say that this approach will enforce a minority point of view, is highly political, and is not in the best interests of women and their children. One commenter noted that the government should not be in the business of

deciding when life begins. Another commenter noted that to define childhood as beginning at conception is an idea not universally held by religious or medical experts and imposes a particular theological view on the American public. Another commenter noted that the proposed rule is both cynical and futile given the widespread disagreement and confusion about what constitutes life and when an unborn child becomes a person. They went on to say that there is no ethical or medical justification for expanding the definition of "child" to include the unborn under the SCHIP provisions, when all medical services offered to an unborn child must be performed on a pregnant woman. Another commenter noted that it is inconceivable that a child be defined as "from conception to 19 years of age." If all of the world's greatest theologians, sociologists and scientists and other great minds cannot determine when life begins, the commenter asserted, then DHHS certainly cannot. Another commenter expressed concern that these rules have the hidden agenda of attempting to define "when life begins"—a deeply divisive issue around which the American public has not achieved consensus. The commenter stated that the fact of existence outside the body of its mother has consistently been the point at which legal personhood (including the ability to receive benefits) has been distinguished from the unborn child, which is not yet a legal person. The commenter believes that changing this understanding by an executive department must inevitably lead to Constitutional challenges.

Response: We appreciate all of the comments as important contributions to the public record, which helps shape the Secretary's decision-making. We recognize that while the intent of this rule is to extend health insurance coverage, policy determinations are often carried into other important public discussions. We disagree with these commenters' contention that there is only one appropriate interpretation of the statutory term at issue, and we believe the range of comments supports our view that States should have the option to include unborn children as eligible targeted low income children. We are therefore retaining a revised definition that does not attempt to define when life begins but permits States maximum flexibility in extending SCHIP eligibility.

Comment: The commenters said that in their view, unborn children are not children who should be deemed eligible for health care. The commenters stated that until birth occurs, mother and the

unborn child are one and not two different people. Another commenter said that the proposed change would make an arbitrary separation between a woman and her developing unborn child and goes on to say that such a separation can only be a concept, for the unborn child is a functioning part of the mother, sharing physical systems. Other commenters noted that the unborn child is a part of the mother's body that cannot survive without the use of the mother's heart, the mother's lungs and so forth. The commenters asserted that as a society we must allow women to control their own bodies and not turn them into mere holding vessels for an unborn child. The commenters believe that the emphasis should be placed upon the pregnant woman on whom the unborn child's health care is completely dependent. They believe that life begins at birth, not at conception and noted that defining childhood as beginning at conception is not an idea universally held by religious or medical experts.

Response: We appreciate all of the comments as important contributions to the public record, which helps shape the Secretary's decision-making. We recognize that while the intent of this rule is to extend health insurance coverage, policy determinations are often carried into other important public discussions. We disagree with these commenters that extending SCHIP eligibility to unborn children would work to the disadvantage of, or devalue the role of, the mother. Indeed, we believe the extension of SCHIP eligibility will be in the best interest of both mother and child, and thus are retaining our revised definition to permit States such an option in administering the SCHIP program.

Comment: Two commenters asked what the status of zygotes held in infertility clinics would be. They asked if such clinics would be faced with criminal suits for the practice of destroying embryos? Another commenter asked why sperm are not classified as children so sexually active men could receive funding to maintain the health of their sperm. The commenters asked who will arbitrate when a third party decides the interests of the woman conflict with those of the unborn child she is carrying? And, will the State decide whether to save the life of the mother or her unborn child? Commenters also asked if another person could be appointed the guardian of an unborn child?

Response: While the questions raised by the commenters are interesting, they are well beyond the issue of providing eligibility under a publicly funded health insurance program. The

important medical and ethical issues raised in the comments existed prior to the promulgation of the proposed regulation and are resolved separately from the specific issue of eligibility for a publicly funded health insurance program. Guardianship is established through legal proceedings and is unlikely to be an issue in the routine application, enrollment, and participation process.

Comment: Commenters discussed the language of the majority in *Roe v. Wade* that they believe clearly States "the word 'person' as used in the 14th Amendment does not include the unborn." The commenters asserted that the Administration does not have the right to reverse this clear and unambiguous statement unilaterally in a regulation. The commenters stated that the unborn child is not recognized as a person in our legal system, where mothers and fathers are responsible for decision making when it comes to health care for their offspring.

Response: While we understand the views of the commenters, we do not believe that limiting the definition of child is consistent with the flexibility that Congress accorded to States under the SCHIP statute. We believe that the range of comments supports our view that States should have the option to include unborn children as eligible targeted low income children. We are therefore retaining a revised definition that permits States maximum flexibility in extending SCHIP eligibility.

We appreciate all of the comments as important contributions to the public record, which helps shape the Secretary's decision-making. We recognize that while the intent of this rule is to extend health insurance coverage, policy determinations are often carried into other important public discussions.

Comment: Commenters asked if defining the unborn child as a person means that we will restructure the National Census and tax forms to include this new population of citizens? They asked if we will rethink our welfare policies to consider unborn children in deciding an individual's or family's benefits? Commenters expressed concern that the proposed rule will lay the legal groundwork for an adversarial relationship between a woman and her unborn child by defining the unborn child as a person, who would then have full legal status, equal to that of the woman. A commenter noted that an unborn child is not given a social security number; it is not a Medicaid beneficiary; pregnant women do not receive an exemption on their income taxes for the unborn child;

and census-takers count only born individuals.

Response: These comments extend beyond the scope of this regulation, which concerns only the ability of States to extend SCHIP eligibility to unborn children, and would not change any other Federal programs. The only government forms affected are those directly connected to the SCHIP program.

Comment: Commenters expressed concern that for women of color, distinguishing the needs of the unborn child from those of the mother has more than once resulted in adverse consequences for the mother. The commenters referred to *Ferguson v. City of Charleston*, 532 U.S. 67 (2001), where the Supreme Court considered issues related to a South Carolina hospital that, pursuant to State law, reported women, all of color, to the police because her unborn child in the third trimester or her newborn tested positive for drugs. Consequently, the commenters asked us to reconsider the definition in this rule.

Response: We appreciate all of the comments as important contributions to the public record, which helps shape the Secretary's decision-making. We recognize that while the intent of this rule is to extend health insurance coverage, policy determinations are often carried into other important public discussions.

While we understand the commenters' concern, we do not agree that extending SCHIP eligibility to unborn children would work to the disadvantage of, or devalue the role of, the mother. Indeed, we believe the extension of SCHIP eligibility will be in the best interest of both mother and child. Furthermore, we believe that it is consistent with congressional intent to provide broad State flexibility under SCHIP to expand the provision of child health assistance.

Comment: Commenters stated that language in SCHIP suggests that the term "child" does not include an unborn child because the statute makes reference to the State in which the child "resides," 42 U.S.C. section. 1397jj(b)(1)(ii)(III). Commenters asserted that in ordinary usage, an unborn child is not considered to have a "reside[nce]." And, the commenters continued that Federal courts have ruled that in other Federal benefits programs, including AFDC and Medicaid, that the term "child" does not include a fetus. Therefore, the commenters asserted, the same reasoning applies here, and it is clear that the Congress did not intend the phrase "individual under 19 years of age" to include the "unborn."

Response: As previously mentioned, recognition of the unborn child in Federal assistance programs can be traced back more than half a century. Currently some Federally funded programs such as Medicaid include, (or as in SCHIP, provide States with the option to include), the unborn child in the size of a family for purposes of determining eligibility for members of that family. Eligibility for some families may indeed rest on counting the unborn child.

Comment: The commenter stated that in numerous cases related to child abuse statutes, courts have ruled that the term "child" does not include "unborn children" and as such, this rule's "clarification" is without merit. In support of this argument, the commenter cited *U.S. v. Spencer*, 839 F.2d 1341 (9th Cir. 1988) in which the defendant's infliction of injuries on an unborn child, who was born alive, but died as a result of such injuries, was within the Federal statutory definition of murder. The commenter mentioned that the key to the holding in that case was that the unborn child was born alive. Under the Uniform Code of Military Justice, the term "human being" was defined as a child that was "born alive." *U.S. v. Nelson*, 53 M.J. 319 (U.S. Armed Forces, 2000). Moreover, in numerous other cases, courts have held that the term "child" contained in a State's child abuse statute does not include "unborn children." As an example, commenters cited *In re Unborn Child*, 18 P.3d342 (Okla.2001) (holding fetus is not a "child" for purposes of State children's code); *State v. Dunn*, 916 P.2d 952 (Wash. Ct. App.1996) (dismissing child mistreatment charges, finding that the legislature did not intend to include unborn children within the scope of the term "child," which was defined as a "person under eighteen years of age"); *Reinesto v. Superior Court*, 894 P.2d 733, 735 (Ariz. Ct. App. 1995) (ordinary meaning of "child" does not include "activity that affects fetuses"); *State v. Gray*, 584 N.E. 2d 710, 711-713 (Ohio 1992) (same).

Response: We recognize there is not a single, uniform standard for treating an unborn child under all State and Federal statutes. We do not agree with the commenter's basic premise that the interpretation of the term "child" under SCHIP must be controlled by the interpretation of that term under other, unrelated statutes that deal with criminal issues or other purposes. Thus we are retaining our revised definition in this final rule.

Comment: Commenters stated their belief that the statutory language is clear

regarding the age determination as post-birth. Commenters asserted that the Congress does not mention care for unborn children in SCHIP and that, by omission, Congress has spoken on this issue. Commenters cited *Chevron v. Natural Resources Defense Council, Inc. et al.*, for the proposition that, in constructing a statute, primary weight must go to whether Congress has spoken on the issue and only when Congress has not spoken is weight given to a permissible agency construction of the statute." Commenters cited *State of Wyoming v. United States of America et al.*, 279 F. 3d 1214, 1230 (10th Cir. 2002) and said the "question of whether Federal law authorized certain Federal agency action is one of congressional intent." The commenters asserted that it cannot be assumed that the Congress would have intended "child" to mean a fertilized egg, embryo or fetus unless it had been explicitly discussed. As an example, commenters cited *State v. Ashley*, 701 So.2d 338, 342-43 (Fla. 1997) (rejecting homicide prosecution of a woman who shot herself in the abdomen while pregnant, causing premature birth and the subsequent death of her unborn child).

The commenters stated that in the months leading up to the creation of the SCHIP program there was extensive discussion in the Congress about the need for a comprehensive children's health insurance program. And, the commenters said that when describing the problem of uninsured children, the very first statistic Senator Daschle used was that "[e]very 48 seconds a child is born without insurance" [emphasis added]. Commenters mentioned that in the House, Congresswoman Furse promoted as a model an Oregon policy that "cover[ed] a child from birth to 18 years." The commenters asserted that not once in the legislative history does the Congress mention including fetuses or embryos as beneficiaries of a children's health insurance program, and the problems it identified were problems afflicting children, not embryos and fetuses. Commenters continued, that when the Congress spoke of the need for health insurance for prenatal care, "uninsured pregnant women were specifically mentioned."

The commenters continued by stating that an examination of the Congress' intent in passing the SCHIP statute demonstrates that the Secretary's action in promulgating this rule is ultra vires. They asserted that although the Secretary's interpretation of the term "child" is consistent with a possible legal meaning of the word, it is entirely inconsistent with the legislative history and the structure of the legislation.

First, they asserted, there is no evidence from any of the Congressional debates on the SCHIP statute that the Congress intended to extend SCHIP benefits to include "unborn children." And, they stated, it seems unlikely that the Congress would have intended the statute to cover this group unless it had been explicitly discussed.

The commenters argued that this is further supported by the fact that the Congress deliberately chose to include "well-baby and well-child care" in the list of benefits that must be included in a basic benefit package to determine actuarial equivalence under SCHIP. If the Congress had intended that the children covered by this statute would include "unborn children" then including these specific benefits would have been unnecessary. The commenters said that it seems unlikely that coverage for unborn children was intended because it was not included on the list.

Furthermore, the commenters noted that the Balanced Budget Act of 1997 (BBA), contains other sections that explicitly use the term "unborn child." Title IV of that Act amended sections of the Medicare and Medicaid statutes to define the term "emergency medical condition" as a medical condition which "place[s] the health of the individual) or, with respect to a pregnant woman, the health of the woman or her *unborn child*) in serious jeopardy. BBA of 1997, Pub. L. No. 105-33, §§ 4001, 4704, 111 Stat. 251, 290, 496 (1997) (codified as amended at 42 U.S.C. § 1395w-22(d)(3)(B)(i) and 42 U.S.C. 1396u-2(b)(2)(C)(i)) [emphasis added].

The commenters asserted that if the Congress intended to include a fetus as a "child" eligible for SCHIP, it would have explicitly used the term "unborn child" in this section of the Act as it did in the Medicare and Medicaid sections of the same statute. The proposed amendment to the SCHIP regulations is therefore unauthorized. The commenters concluded by stating that the proposed change appears to use a rule change to advance an ideological position on the "personhood" of an unborn "a position never contemplated by the Congress during debate on this program.

Response: We do not believe that Congress directly spoke to the issue of whether the term "child" could include unborn children, because the statute contains no limitation on such an interpretation. We believe the commenters effectively conceded that point by focusing on congressional silence and raising peripheral issues and statements by individual legislators

taken out of context. The argument that Congress explicitly used the term "unborn child" in a number of legislative enactments and did not do so in SCHIP goes both ways, because while Congress did not expressly include unborn children, Congress did not exclude them either. Instead, Congress clearly sought to provide a maximum level of State flexibility under SCHIP. Thus we do not see a compelling reason to change our proposed interpretation in this final rule.

The reference to "well child" benefits in the statute simply means that the Congress chose to specify some benefits rather than others as it gave States wide latitude and broad authority to establish what benefits would be offered to those enrolled in the program. The suggestion that the Congress limited benefits to those expressly defined is wrong as indicated by the language of section 2103 (c)(3), "Nothing in this subsection shall be construed as preventing a State child health plan from providing coverage of benefits that are not within a category of services described in paragraph (1) or (2)." Furthermore, the definition of "child health assistance" at section 2110(a)(9) expressly includes prenatal care.

The construction of title XXI is a broad delegation of authority to the Secretary and the States. The Congress considered various forms of expanding health insurance including one limited solely to the expansion of Medicaid. The Congress chose not to duplicate the Medicaid program, but rather constructed a program that left a great deal of authority up to the Secretary and the States to design eligibility and benefits.

Comment: Commenters stated that no regulation or Federal statute currently on the books treats the unborn child as the equivalent of a person and no Federal regulation should do so. The commenters asserted that the SCHIP statute nowhere states or suggests that "child" as used in the statute includes a fetus and they asserted that defining a "child" to include a fetus is inconsistent with the plain and ordinary meaning of the term.

Commenters mentioned that Federal courts have been asked to rule on whether AFDC and Medicaid apply to fetuses and in both contexts, Federal courts have concluded that the term "child" does not include a fetus. In *Burns v. Alcala*, 420 U.S. 575 (1975), the Supreme Court held that the term "dependent child," as used in the AFDC statute, does not include "unborn children." 420 U.S. at 580-81. Likewise, the commenters asserted, in *Lewis v. Grinker*, 794 F. Supp. 1193

(E.D.N.Y.1991), *aff'd on other grounds*, 965 F.2d 1206 (2d Cir. 1992), the Federal district concluded that fetuses are not eligible for Medicaid. 794 F. Supp.at 1198. Commenters stated that it held that in all events, the phrase "individuals under the age of 21" does not easily apply to unborn children under ordinary usage. The unborn are not "persons" under the Constitution. *Roe v. Wade*, 410 U.S. 113, 93 S. Ct. 705, 35 L. Ed.2d 147 (1973).

In addition, one commenter noted that the "age" of any individual is normally computed from birth. The commenter asserted that while the statute does not require calculation of the precise age "under 21," it is apparent that any construction of the phrase "individuals under the age of 21," which will accommodate the unborn is not ordinary usage. Accordingly, this commenter concluded that the Congress did not intend the phrase "individuals under the age of 21" to include the unborn.

Other commenters asserted that the same reasoning applies here: under ordinary rules of statutory construction, it is clear that the Congress did not intend the phrase "individual under 19 years of age," within the meaning of the SCHIP statute, to include the "unborn."

For this reason, commenters asserted that the Secretary lacks the authority to promulgate the proposed regulation. The commenters contended that the definition can only be changed by amending the current statute and that is far beyond the reach of the Department. The commenters went on to say that what the Department calls a "clarification" of the definition is an attempt to change what the Congress intended to include in the definition of child for the purposes of SCHIP eligibility.

Response: As noted above, the SCHIP statute is silent on the issue of eligibility for unborn children, and we do not believe that the interpretation of the term "child," is appropriately controlled by the cases cited, which involved other programs and situations. We believe instead that Congress had a broader purpose under title XXI, which included maximizing State flexibility in offering access to child health assistance under SCHIP.

There is little doubt that the purpose of title XXI is to provide access to health insurance. This regulation would provide eligibility at an earlier point in time that is also one of the most critical times in the lifecycle.

The statute clearly established an age ceiling of 19 that could not be circumvented absent a waiver. However, other broad eligibility standards were

left to the States. A State has the authority to target to different ages below age 19. For example, Federal statute requires Medicaid eligibility at 133 percent of the Federal poverty level up to age 6. After age 6, the Federal minimum is 100 percent of poverty. To fill the gap in Medicaid eligibility, a State could have used the enhanced funding provided by title XXI and designed their SCHIP program to simply cover children at 133 percent of poverty between the ages of 6 and 19.

A State could target resources to younger children as an early childhood development program and thus create an eligibility category at higher income levels specifically for infants and children up to age 4 for example.

Many commenters who oppose this rule have indicated their belief that the Secretary does have authority to extend eligibility to a pregnant woman who is over the age limit set by statute and indeed have indicated support for such a waiver. We believe the Secretary's authority extends to the adoption of definitions through the rulemaking process.

Comment: One commenter suggested that the Secretary might be exceeding his authority by applying the revised SCHIP definition of child in assessing compliance with the Medicaid maintenance of effort provision of section 2105(d)(1), as stated in the preamble to the proposed rule at 67 FR 9938.

Response: We disagree with the commenter because we believe the Secretary's authority clearly extends to the interpretation of statutory terms such as the SCHIP term "child." Furthermore, in this instance, we have used rulemaking procedures to ensure that we have fully considered the issues. We clarify that we interpret the maintenance of effort provision at 2105(d)(1) for purposes of the SCHIP statute, consistent with our overall definition of the term "child." Thus, because a State may extend SCHIP eligibility to unborn children, we will review compliance with SCHIP maintenance of effort provisions by including unborn children in our review. The provision at issue is a SCHIP provision, and it ensures that SCHIP funds will not be used to replace Medicaid coverage.

Comment: Commenters stated that by defining an egg as a child and consequently, when life begins, DHHS is imposing a religious belief on all women. The commenters stated that for each group of people whose religion teaches them that an unborn child is a child at any stage of development, there is another whose religion teaches them

precisely the contrary. One commenter mentioned that forcing people to proceed against their religious beliefs in order to access a public benefit is almost certainly illegal and to dangle prenatal care in front of needy women who do not happen to share a particular religious viewpoint would not only be illegal, it would be morally reprehensible.

In support of this position, one of the commenters stated that the Supreme Court found as much in the seminal case of *Sherbert v. Verner*, 374 U.S. 398 (1963), while more recently holding that a State may deny unemployment benefits for illegal conduct, even if that conduct is religiously motivated.

The commenter continued by saying, that the free exercise of religion means, first and foremost, the right to believe and profess whatever religious doctrine one desires. Thus, the commenter asserted that the *First Amendment* obviously excludes all "governmental regulation of religious beliefs as such" and cited *Sherbert v. Verner*, supra, at 402. The commenter asserted that the government may not compel affirmation of religious belief, and cited several cases in support of this argument, including *Torcaso v. Watkins*, 367 U.S. 488 (1961), *United States v. Ballard*, 322 U.S. 78, 86–88 (1944), *McDaniel v. Paty*, 435 U.S. 618 (1978); *Fowler v. Rhode Island*, 345 U.S. 67, 69 (1953); cf. *Larson v. Valente*, 456 U.S. 228, 245 (1982), *Presbyterian Church in U.S. v. Mary Elizabeth Blue Hull Memorial Presbyterian Church*, 393 U.S. 440, 445–452 (1969); *Kedroff v. St. Nicholas Cathedral*, 344 U.S. 94, 95–119 (1952); *Serbian Eastern Orthodox Diocese v. Milivojevic*, 426 U.S. 696, 708–725 (1976), *Employment Div. of Oregon v. Smith*, 494 U.S. 872, 877 (1990).

The commenter stated that in the *Sherbert* case, a person was denied unemployment benefits on the basis of work related misconduct because she refused to work on her Sabbath. The Court ruled that forcing a person to choose between following her religious beliefs and receiving a public benefit violates the First Amendment, and in the absence of criminal behavior, that remains the statute today.

The commenter contended that the regime proposed by CMS will confront many pregnant women with just such a choice in that they must either be willing to publicly declare the unborn child they are carrying to be a human being, even if their religion teaches them otherwise, or they must forego perhaps prenatal care and delivery services. The commenter asserted that CMS would be attempting to "lend its power to one or the other side in

controversies over religious authority or dogma." *Smith*, supra at 877.

Response: Application for SCHIP benefits is voluntary, and there is nothing in the SCHIP statute that forces a mother to accept SCHIP benefits. While it is certainly possible that acceptance of SCHIP benefits for an unborn child may be contrary to some women's religious beliefs, we do not believe this should preclude States from offering such benefits. If a woman has a religious objection, she simply would not accept SCHIP benefits.

Comment: Commenters stated that by establishing eligibility benefits from the point of conception, a woman's right to make decisions about her health care is undermined. The commenters pointed out that the U.S. Supreme Court has consistently ruled that women's health interests may not be supplanted by State or fetal health interests and cited the following cases: in *Stenberg v. Carhart*, the Court struck down a State law imposing government restrictions on abortion that failed to provide an adequate exception for preservation of the woman's health; and in *Colautti v. Franklin*, the Court invalidated a statute that failed to guarantee that a woman's health would always prevail over the life and health of her unborn child.

The commenters believe that this rule opens up the possibility for the government or others to claim the right to represent such fetal interests, and thus the right to make decisions about a woman's pregnancy over her objections. The commenters asserted that amending the definition of a covered "child" to include "the period from conception to birth," thereby allowing health insurance coverage for a zygote, embryo and fetus *in utero* has legal and practical problems and could actually undermine the health of the pregnant woman. The commenters stated that current constitutional statute allows States to place limited restrictions on a woman's access to abortion, but a pregnant woman holds an absolute right to make decisions about her pregnancy during the first trimester, including decisions about her health care.

The commenters believe the proposed regulation is inconsistent with the constitutionally protected right of a woman to determine the course of her pregnancy.

Response: As stated previously, enrollment and participation in the SCHIP program is voluntary. There is no conflict as the services to be provided benefit both mother and child.

Comment: One commenter stated that the term "conception" should be understood to mean at the time of

fertilization when the new genetically complete and unique individual begins his or her existence. The commenter said it would be good to define clearly what is meant by "conception" since there are other potentially confusing definitions being used.

Response: We do not generally believe there is any confusion about the term "conception." To the extent that there is, however, we believe States should have flexibility to adopt any reasonable definition of that term.

3. Program Eligibility

Comment: Several commenters asked about when coverage of the unborn child would begin, given the logistical difficulties in establishing the exact date of conception. These commenters also asked whether or not the pregnancy would need to be medically verified, and whether coverage could be retroactive to the date of conception.

Response: Under title XXI, States have discretion in adopting administrative procedures regarding eligibility for coverage. States, at their option, may elect to offer retroactive coverage or may require medical confirmation of the pregnancy before any prenatal care would be provided. If the application had been filed prior to such confirmation and it turned out that the woman was not pregnant, the costs of the pregnancy test could be paid as an administrative cost, at the State's option. If the pregnancy were confirmed, the cost of the pregnancy test and any prenatal care subsequently provided could be treated as child health assistance.

Comment: One commenter asked whether Medicaid rules should be applied to SCHIP. A few commenters asked about whose income would be used to determine the unborn child's eligibility. One specifically asked whether States would need the mother's income and resource information. Another asked whether income from the parents of an unwed pregnant teen living at home should be counted, as would be the case if the teenager were applying for coverage as a pregnant woman under Medicaid. This commenter also asked whether child support enforcement requirements apply to the unborn child or to the mother.

Response: Medicaid eligibility rules only apply when a State has implemented its SCHIP through a Medicaid expansion program. Medicaid eligibility rules do not apply to separate child health programs. States have broad discretion in defining "family income" for purposes of determining eligibility under a separate child health

program. States have discretion to determine whose income shall be considered in determining a child's eligibility. Similarly, States have broad discretion on whether to have a resource test for their separate child health program and, if so, whose resources to count. Thus, in the example cited by one commenter, a State could opt to count the income and/or resources of a pregnant teen's parents in determining eligibility. However, it is not required to do so.

There are no Federal child support enforcement requirements for separate child health programs. Thus, while States can impose such requirements, they are not required to do so.

Comment: One commenter asked whether the baby would be eligible for a year of presumptive eligibility.

Response: In general, infants born to mothers who were eligible for and receiving Medicaid at the time of the infant's birth automatically are eligible for Medicaid for one year. It is unclear whether this commenter is asking if babies, who were covered by SCHIP while in utero, would be covered by this rule, or whether the commenter is asking if such babies would be eligible for one year of presumptive eligibility under SCHIP. We will respond to both questions.

Under 42 CFR 457.350(b) regarding the SCHIP regulation's screen and enroll requirements, if a mother is Medicaid eligible, the unborn child cannot be eligible for SCHIP. Conversely, if the unborn child is covered under SCHIP, that means that the State determined, in the screening and eligibility process, that the mother was not eligible for, or receiving, Medicaid. Accordingly, the automatic one-year eligibility enjoyed by infants born to mothers on Medicaid would not apply to infants covered by SCHIP while in utero.

If a State has adopted presumptive eligibility for its separate child health program, an unborn child could be determined to be presumptively eligible, to the same extent as any other child, consistent with the regulations at 42 CFR 457.355. However, presumptive eligibility cannot be applied to a child once the child has been determined to be eligible for coverage under SCHIP. This basic principle is true for a child determined eligible for coverage while in utero, as well as one who is first determined eligible after birth.

This does not mean, however, that an infant eligible in utero loses coverage at birth. Under current regulations at 42 CFR 457.320(e)(2), States have the flexibility to establish an eligibility period of up to 12 months. A child's eligibility for a separate child health

program must be redetermined at the end of the eligibility period adopted by the State. Between regularly scheduled redeterminations, States are not required to reevaluate a child's continued eligibility, regardless of changes in circumstances (other than the child turning 19).

Under this regulation, the term "targeted low-income child" is defined to include an unborn child, who otherwise meets the State's income eligibility criteria. Thus, whatever period of eligibility the State has adopted for children covered under its separate child health program also would apply to an unborn child. Birth in and of itself does not alter the baby's status as a "targeted low-income child." Thus, once born, the infant would remain eligible for coverage under the separate child health program until the next regularly scheduled redetermination.

For example, suppose that a State has adopted a 12-month eligibility period and that an unborn child was determined eligible for SCHIP three months prior to birth. At birth, the infant would remain eligible for coverage under the State's separate child health program for 1 year from the date of initial eligibility, or, in this case, nine months from the date of birth.

Note that, at any point a parent or other caretaker has the right to file a Medicaid application on behalf of the infant. If such an application were filed, the State then would be required to determine the infant's eligibility for Medicaid.

Comment: One commenter asked if the continuous eligibility afforded to pregnant women by Medicaid "under which pregnant women retain eligibility for the duration of their pregnancy and postpartum period regardless of changes in income—would be available to unborn children eligible for SCHIP under this regulation.

Response: No. As explained above, Medicaid rules do not apply to separate child health programs. However, as also explained above, under current regulations at 42 CFR 457.320(e)(2), States can adopt continuous eligibility for children eligible for their separate child health program, with an eligibility period of up to 12 months. A child's eligibility must be redetermined at the end of the eligibility period adopted by the State. Between regularly scheduled redeterminations, States are not required to reevaluate a child's continued eligibility, regardless of changes in income or other circumstances (other than the child turning 19).

Comment: One commenter asked whether an unborn child could be eligible for SCHIP if the mother is not eligible for Medicaid because she does not satisfy the State's residency requirement.

Response: Subject to the provisions of 42 CFR 457.320(d), States may establish residency requirements for their separate child health programs. An application for an unborn child for this program would be treated the same as any other application for coverage. Thus, it also would be subject to the residency requirements established by the State.

Comment: One commenter asked whether States would need the mother's social security number (SSN).

Response: States are not permitted to require the SSN of anyone, other than the child applying for coverage, as a condition of eligibility. This rule does not change that situation. Thus, States may not require that the unborn child's mother provide her SSN. However, States would likely assign a unique identifier to every unborn child that is found eligible for coverage and enrolled in a separate child health program in order to perform normal administrative functions. The mechanism used to assign such an identifier is left to the discretion of each State.

As in current practice, a State may request the pregnant woman's SSN as long as the State makes it clear for what purpose her SSN would be used; and that she is not required to provide her SSN and that eligibility will not be affected if she does not do so.

Comment: One commenter asked whether either parent would be able to submit an application on behalf of the unborn child.

Response: Under title XXI of the Social Security Act, States have broad discretion to adopt administrative procedures governing the filing and processing of applications. Thus, States can, but are not required, to place restrictions on who can file an application on behalf of a child. There is nothing in this regulation, however, that would permit any individual to compel another to seek or use health care services.

Comment: A few commenters asked whether an unborn child would have to be issued a SSN or other unique identifier. These commenters also asked what method the State would use to track services provided to the unborn child.

Response: We are not aware of any circumstances in which the Social Security Administration assigns a SSN to an individual prior to birth. This rule

does not request, let alone require, that it do so.

Therefore, we do not anticipate that an unborn child that is determined to be eligible for coverage under a separate child health program would be given a SSN. Consequently, it will be necessary for States to assign a unique identifier to appropriately process claims. The mechanism used to assign the identifier is left to the discretion of each State.

The data collection and reporting requirements for separate child health programs are set forth at 42 CFR subpart G. Regulations governing payment for and verification of services provided are found at 42 CFR 457.950 and 42 CFR 457.980. States are required to comply with these requirements with respect to coverage of all enrolled individuals. This rule does not impose any additional requirements on States with respect to services provided to an unborn child.

Comment: In the March 5, 2002 proposed rule, we explained that this regulation will give States the option to consider an unborn child to be a targeted low-income child and therefore eligible for SCHIP "if other applicable eligibility criteria are met." One commenter asked whether the "other eligibility criteria" applies to the unborn child or the pregnant woman.

Response: The "other eligibility criteria" pertain to the unborn child.

Comment: One commenter emphasized the importance of the screen and enroll requirements.

Response: We agree with the commenter that the screen and enroll requirements are very important. As we explained in the March 5, 2002 proposed rule, the purpose of the rule is to encourage States to increase the availability of prenatal care. In order to ensure that funding for prenatal care under SCHIP does not replace funding for prenatal care under Medicaid, we explained that States must apply the screen and enroll process described in the SCHIP regulations at 42 CFR 457.350. Consistent with the terms of that regulation, States must screen the unborn child's mother for Medicaid eligibility. If the State determines that the mother is potentially eligible for Medicaid, then the State must assist her in completing the Medicaid application process, again, consistent with the requirements set forth in 42 CFR 457.350.

Comment: One commenter asked whether a State could include this group in an existing Medicaid waiver, such as the family planning and Healthy Start waivers.

Response: Section 1115 waivers are demonstration projects awarded to

States at the Secretary's discretion on a case by case basis. As such, consideration of this eligibility group could be considered for inclusion in an existing waiver but a sufficient rationale would need to be provided by the State. Also, it may not make sense to include this group, as in the case of family planning waivers, for example.

Comment: Two commenters said that all States should be required to cover the unborn child.

Response: We cannot require States to cover unborn children. The statute does not require that States cover all children who meet the definition of a targeted low-income child. Section 2102(b)(1) of the Act and implementing regulations at 42 CFR 457.320(a)(2) specifically permit States to adopt eligibility standards based on age. Thus, we are precluded from mandating that all States cover unborn children.

4. Immigration Status

Comment: Commenters stated that the proposed regulations do not address how the unborn child will be classified in determining its citizenship or immigration status. Many commenters urged the Department to make clear in the final rule that unborn children will be eligible for SCHIP benefits under the rule, regardless of the immigration status of their mothers. The commenters asserted that since no unborn child is a citizen or a qualified immigrant, there is no basis for making distinctions among unborn children on nationality and immigration status grounds.

Commenters stated that low-income pregnant women who are either recent legal immigrants (subject to the 5 year bar on receipt of Federal public benefits) or are undocumented immigrants are often unable to secure prenatal care, and such an exclusion is likely to result in serious harm to the unborn child.

Yet, commenters noted, the babies born to these women in the United States will become citizens immediately upon their birth. Commenters asserted that effective health care for these children, no less than others, must begin with access to prenatal care. In addition, this would provide effective coverage for the maximum number of unborn children. One commenter noted that the proposed regulation would permit States to ensure that essential prenatal services are available "to benefit unborn children regardless of the mother's eligibility status." (67 FR 9937) The commenter noted that this position is consistent with existing statute and practice since many children whose parents would not be eligible for SCHIP are currently enrolled in the SCHIP program. These include children whose

parents are subject to the 5-year bar. The commenter states that with the exception of income available to the child, parents' eligibility for SCHIP is irrelevant. They noted that SCHIP eligibility is based upon the age, immigration status, insurance coverage and other factors specific to the child. 42 U.S.C. 1397bb(b)(1)(A); 42 CFR 457.320, as amended by interim final rule published at 66 FR 33810 (June 25, 2001).

The commenters stated that HHS should amend the proposed regulation to clarify that all unborn children will be treated equally for SCHIP eligibility purposes. One commenter specifically requested that we amend § 457.320(b)(6) to state that "In establishing eligibility standards and methodologies a State may not exclude individuals based on citizenship or nationality to the extent that the children are U.S. citizens, which includes unborn children from conception to birth who upon birth will be U.S. citizens, U.S. nationals or qualified aliens." Commenters contended that if the regulation were adopted, treating all unborn children as constructively born in the U.S. would be the most straightforward way to accomplish this end and cited *Lewis v. Thompson*, 252 F.3d 567, 581 (2d Cir. 2001), (discussing the "constructive birth" provisions of 42 U.S.C. 1396d(n)(1)(A), which treats a childless pregnant woman as a parent with one child for TANF eligibility purposes.)

Response: We agree with the commenters that requiring exclusion of unborn children on the basis of immigration status is neither legally mandated nor desirable. Unborn children do not have immigration status as "aliens" and thus are not precluded from receiving Federal means-tested benefits under the provisions of Title IV of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA), Public Law No. 104-193. Under PRWORA, these restrictions apply only to "aliens" who are not "qualified aliens"; since unborn children are not "aliens," they are not within the scope of this preclusion nor are unborn children subject to the 5-year bar. Furthermore, as we stated in the preamble to the proposed rule, the goal is to permit States to ensure that needed services are "available to benefit unborn children independent of the mother's eligibility status" (67 FR 9937). Because prenatal care is a key element to ensuring healthy infants and children, this goal would maximize the availability of prenatal care and, consequently, promote the overall health of infants and children. It would be inconsistent with this goal to tie

services for prenatal care to the immigration status of the mother.

We do not, however, believe that it is necessary to explicitly amend the proposed rule to express this interpretation of applicable law. Since unborn children would not be precluded from receiving benefits under applicable law, there is no reason to further address the issue in the regulation text.

Comment: One commenter noted that the unborn child of an ineligible immigrant woman is indistinguishable from that of any other woman present in that State. In the real world, upon birth, that unborn child becomes a child and a U.S. citizen. This commenter asked, "But if CMS adopts a position that deems that fetus a 'child' in utero, then what possible justification could there be for denying SCHIP benefits to such a 'child'?" Another commenter recommended that the proposed regulation should not be clarified to deny coverage to the unborn children of immigrant women merely because the women would themselves be ineligible to receive benefits under Federal statute. This commenter stated that any clarification of the regulation should make explicit that the woman's immigration status is irrelevant to the provision of SCHIP benefits. If the proposed regulation is adopted, there is no principal basis on which to distinguish the unborn children of immigrant women from the unborn children of citizen women. The commenter said that although Federal statute provides that "an alien who is not a qualified alien is not eligible for any Federal public benefit * * *" 8 U.S.C. 1611(a), an unborn child has no citizenship or immigration status whatsoever, and is therefore not made ineligible for coverage by reason of 8 U.S.C. 1611(a) or any other immigration-related eligibility restriction. The commenter stated that any exclusion of the unborn children of ineligible immigrant women would thus have to be accomplished by altering the proposed regulation to exclude such unborn children explicitly. The commenter contended that such a change would be contrary to the avowed purpose of the proposed regulation and would have no basis in logic, given that the regulation is premised entirely on the unborn child's status and not the woman's and in support of this position cited *Plyler v. Doe*, 457 U.S. 202, 220 (1982) (invalidating State law denying public schooling to the children of undocumented immigrants because the denial "directed the onus of a parent's misconduct against his children").

Response: We agree that it does not make sense to try to impute an immigration status to an unborn child based on the status of the mother. As discussed above, an unborn child is not an alien, and the status of the child is not necessarily tied to the status of the mother. Moreover, to do so would not be consistent with the purpose of providing States with the flexibility to maximize the availability of prenatal care to ensure healthy infants and children.

Comment: Commenters stated that the rule should be clarified to make clear that undocumented immigrants may not be reported to immigration authorities for seeking medical care for their unborn children. Commenters were concerned that in the absence of such a protection, undocumented immigrant mothers may not seek medical care, and their unborn children will not receive care they need to help ensure a healthy birth and are entitled to as a U.S. citizen. Commenters stated that since the pregnant woman will never be the recipient, it would seem that a State, pursuant to the "Tri-Agency Guidance" issued by the Departments of Health and Human Services and Agriculture (on 9/21/00), would be prohibited from inquiring about her immigration status.

Response: Nothing in this regulation alters section 434 of the 1996 welfare reform statute, which prohibits the Federal government from restricting State or local government entities from sending to or receiving from the Immigration and Naturalization Service information regarding the immigration status of an alien in the U.S. Further, nothing in this regulation alters the Tri-Agency Guidance with respect to inquiries about immigration status of nonapplicants.

Comment: The commenter was concerned about the additional cost of covering all unborn children conceived in the United States by illegal immigrant women. The commenter believes that under this rule, the unborn child should be eligible for benefits if (she is conceived in the United States. The commenter was concerned that if women are permitted to self-declare whether conception occurred in United States that the Administration's cost estimate is too low because of the large numbers of undocumented immigrants who would be receiving coverage.

Response: The question of where conception occurred is irrelevant to the question of the unborn child's immigration status or this final rule. This regulation provides states with the flexibility to assure essential prenatal care to the maximum number of unborn children, regardless of the immigration

status of their mothers. States, in deciding whether or not to adopt this option under their title XXI state plan, will certainly weigh, along with numerous other factors, the potential costs associated with providing coverage to unborn children since States cannot receive Federal funding that exceeds title XXI allotment.

Comment: One commenter stated that prenatal care is even more important among Latinas, who suffer from higher rates of pregnancy-induced hypertension and maternal mortality. The commenter noted that 12 States offer prenatal care to immigrant women who are ineligible for Federally funded medical assistance, which has lessened the effects of PRWORA. The commenter stated that if the new regulation explicitly covers children of undocumented immigrants, it would increase the number of States that provide prenatal care services to pregnant immigrant women and provide an incentive for those States that have seen a large influx of Latina immigrants in recent years.

Response: This rule ensures that States have maximum flexibility to extend SCHIP eligibility to unborn children, independent of the immigration status of the mother. We believe that this rule addresses the concerns of the commenter since the intent of this rule is to benefit both the unborn child and their mothers by promoting continuity of important medical care.

5. Benefits

Comment: Commenters, whether in favor of this rule or not, expressed their belief that all women should receive regular and adequate prenatal care because there is overwhelming data that shows that there are still too many women who receive no or less than adequate care during pregnancy. Commenters agreed that health care should be provided from the prenatal stage.

Many commenters, in support of this rule, expressed their belief that all women should be able to receive prenatal services that increase the chances of every child being born healthy. This regulation would allow pregnant women and unborn children to receive the medical treatment they need. Commenters noted that the lack of prenatal care results in increased health costs for taxpayers in caring for problems and complications after birth, and some noted that coverage of the unborn child may result in the incidental improvement in the health of the mother. But, all too often proper prenatal care has been cost prohibitive

to low-income women, and the commenters view this proposal as assisting the millions of women of childbearing age who lose or lack health insurance. Proper prenatal care can prevent avoidable birth defects. Fetal surgery is able to correct many life-threatening congenital disorders. There is no reason the unborn child should be denied the lifesaving procedures that will permit him or her to live a full, normal life after birth, particularly with the recent medical advances that will continue to develop and evolve. Providing this care is a benefit, not only for the unborn child, but for women and families as well. Commenters stated that this policy provides a way for the mother to make positive choices with regard to caring for her unborn child and herself.

Some commenters noted that coverage would decrease infant mortality rates. Two commenters cited a DHHS report, "Trends in the Well-Being of America's Children & Youth 2000," that indicated prenatal care can improve birth outcomes and decrease health costs. Two commenters also cited an American Academy of Pediatrics (AAP) policy that indicates " * * * physical and psychosocial growth, development, and health of the individual begins prior to birth when conception is apparent * * * the responsibility of pediatrics may therefore begin with the fetus * * * ."

Commenters expressed a concern that it is in the public's interest to assure that expectant mothers have access to quality prenatal health care coverage as highlighted in Healthy People 2010. Additionally, commenters noted that it is less expensive to care for healthy babies than unhealthy babies and that access to prenatal care means long-term reduction in the cost of health care for these children. Expanding Federal health programs to give more low-income pregnant women access to prenatal care is an important step in making sure children get a healthy start in life.

Response: We appreciate the commenters' support of our goal in developing this rule. By providing States with the option of ensuring that needed prenatal care is available under SCHIP to benefit unborn children, uninsured low-income women, who are less likely to receive prenatal care, would be able to access crucial services that they may not otherwise be able to receive. This regulatory clarification is intended to benefit both the unborn child and the mother by promoting continuity of important medical care. We agree that healthy pregnancies should also result in significant savings

in public expenditures over a child's lifetime.

Comment: While commenters agreed with the importance of prenatal care as essential for the mother and child, many disagreed with the mechanism this Administration has taken for accessing that care. They feel very strongly that eligibility should be extended to the pregnant woman and not to the unborn child. Several commenters opposed this approach as a false separation of the woman and child. Commenters were concerned that the medical needs of the embryo would take precedence over the needs of the mother and stressed their belief that the benefit should be conferred to the woman and not to the unborn child. They expressed concern that this regulation may create a conflict of interest between the woman and the unborn child.

They believe that a crucial question is whose needs take priority? Many felt that treating the unborn child as if it exists separately and should be considered before and above the health of the woman carrying the unborn child is a false separation that would ultimately prove detrimental to the health of many women as well as to their unborn children or newborns. They believe that this proposal interferes with women's autonomy to make medical care decisions and represents an arbitrary separation of the woman and child (since one cannot be cared for without the other also receiving care). One commenter indicated that conflicts of interest between the mother and child would not arise if the woman was determined the patient, as under the Medicaid program (42 U.S.C. 1396a(a)(10)(A)(i)(III), (IV), (VI), (VII), (A)(ii) and (1).)

Response: We understand the commenters' concerns. The intent of this rule is to maximize the availability of SCHIP benefits in the interest of both pregnant women and unborn children. The statutory provisions of title XXI are very clear that only targeted low-income children can be eligible for the program. Although, under § 457.1010 States do have the option of applying for a variance to purchase family coverage through which a pregnant woman over the age of 19 could be determined SCHIP eligible.

States do have options available if they wish to expand eligibility to a pregnant woman over the age of 19 whose income is over the current Medicaid income guidelines rather than to the unborn child, which include: a title XIX expansion under one of their poverty groups; or a section 1115 waiver demonstration. However, absent a

waiver, eligibility can only be conferred to the targeted low-income child.

That being said, nothing in this rule is intended to affect the traditional relationship between the pregnant mother and the physician. Questions of medical treatment for the pregnant woman and/or her unborn are a decision between the pregnant woman and her physician and nothing in this rule would circumvent or alter that relationship.

Comment: Commenters were concerned that a woman could possibly be denied medical treatments such as prescription drugs, psychotropic medications to treat psychiatric illnesses, and life-saving radiation or chemotherapy treatments because of the effects they would have on the unborn child.

Commenters asked if the pregnant woman would be denied other care that might be harmful to the unborn child, thus effectively pitting her needs against those of the unborn child? One commenter asked whether the State would be subjecting women to drug and alcohol tests on the alleged ground that it is protecting its patient-beneficiary? Several commenters referred to this policy as medically unsound, ethically unacceptable, and/or poor public policy. Commenters questioned if physicians would be required to consult with the unborn child's father or another legal guardian if these types of issues exist. Several questioned what entities would have the authority to assert the rights of the unborn child (such as, State, Federal government, physician, pregnant woman, father?).

To illustrate their point, two commenters cited a court case (*In re A.C.*, 573 A.2d 1235, 1235 (D.C.1990) in which a woman was compelled by the court to undergo a caesarean section, following which both the mother and unborn child died (Veronica E. B. Kolder *et. al*, Court-Ordered Obstetrical Interventions, 316, *New Engl. J. Med.* 1192, 1195 (1987).

Several commenters also raised the question as to what happens in cases where continuing the pregnancy itself endangers the life of the mother, since the assumption made by the commenters is that the life of the unborn child would take precedence over the life of the mother or that both would be allowed to die.

Response: These comments extend beyond the scope of this regulation, which concerns only the ability of States to extend SCHIP eligibility to unborn children. As in Medicaid, nothing in this rule is intended to affect the traditional relationship between the pregnant mother and the physician.

Questions of medical treatment for the pregnant woman and/or her unborn are a decision between the pregnant woman and her physician and nothing in this rule would circumvent or alter that relationship.

Comment: Commenters expressed concern that certain benefits that would provide comfort for the pregnant woman would not be covered, such as epidurals or anesthesia during delivery.

Response: Within the options for benefit coverage selected by a State, as described at § 457.410, a State selecting this SCHIP option has the flexibility in defining its benefit package to provide benefits it deems necessary.

Regarding the specific question asked by the commenters, while analgesia given as an epidural and/or intramuscular intravenous injections of pain relievers, and/or anesthesia given as regional or general anesthesia is primarily provided during labor and delivery to relieve the mother's pain from uterine contractions or to perform surgery, that is, C-section, if a woman's pain during labor and delivery is not reduced or properly relieved, adverse and sometimes disastrous effects can occur for the unborn child. There is no question that analgesia/anesthesia is required in order to perform a C-section and such a procedure cannot even be considered if some form of pain relief is not provided. In terms of vaginal deliveries, without relieving the mother's pain from uterine contractions, the progress and labor may be interrupted and not efficient, which in turn can cause fetal complications, such as fetal distress and infection from prolonged labor and prolonged rupture of membranes and other complications. Therefore, we would expect that this coverage would be provided.

Comment: Several commenters were concerned about whether States would have the flexibility to use enhanced Federal funds to provide comprehensive benefits to pregnant women and stated that the failure to provide a comprehensive range of services for all of a pregnant woman's health care needs and treatment of some stated diseases, could compromise her health, as well as, that of the unborn child.

Although many commenters supported expanded access to prenatal care among low-income, uninsured women, many believed that the benefit should be given to the woman, in addition to or instead of her unborn child. One commenter stated that one cannot effectively treat an unborn child without treating the woman carrying it, believing that a healthy pregnancy resulting in the delivery of a healthy baby requires a healthy mother. One

commenter stated that low-income women deserve actual, not merely incidental, health insurance coverage that covers all of their health needs. Several commenters indicated that women deserve comprehensive care, not simply care related to the unborn child, and several referred to the proposal as "reducing women to vessels."

Commenters also felt that extending comprehensive care to the mother would result in women who are healthier and ultimately would result in better birth outcomes. One commenter felt that targeting coverage for the unborn child, not the mother raised ethical issues and puts the mother's health at risk by providing inadequate coverage.

Commenters expressed concern or questioned whether care would be extended to women for injury or disease not related to the pregnancy, such as skin melanoma, emergencies, accidents, broken bones, or mental illness. One commenter advocated for coverage of drug treatment programs for mothers who were addicted.

Several commenters indicated that the focus should be on addressing the health care needs of millions of uninsured women, and one advocated expanded access to uninsured women to "take care of those already here."

Response: The SCHIP statute provides States with broad flexibility in defining those services for which they choose to provide coverage under their State plan. States have the flexibility to define and provide comprehensive services that are related to the pregnancy or to conditions that could complicate the pregnancy. Under the regulation, States would define what services would be included. Services related to conditions that could complicate the pregnancy include those for diagnosis or treatment of illnesses or medical conditions that might threaten the carrying of the unborn child to full term or the safe delivery of the unborn child. Within these parameters, States have discretion in the services for which coverage can be provided.

However, SCHIP eligibility is limited by statute to targeted low-income children and there must be a connection between the benefits provided and the health of the unborn child.

We would point out that the regulation is intended to reach individuals who are currently uninsured and who therefore lack access to any services.

Comment: Commenters believe that, by permitting States to extend SCHIP coverage to unborn children, this rule would effectively deny women access to needed postpartum care. They felt that pregnancy-related care should be

viewed as a continuum comprising three distinctly important periods: prenatal, intrapartum (during labor and delivery), and postpartum care. Commenters stressed that a woman's pregnancy-related health care needs do not end the moment her child is born. The commenters stated that the woman still requires many pregnancy-related services and optimal maternal health is important for overall family health. Under the proposed regulation, covered care would be available only during "the period from conception to birth." These commenters are concerned that the moment after the birth of the child, a woman would lose any incidental covered care that she had received as a result of having an SCHIP-covered unborn child in utero. The commenters continued with their concern that woman would therefore not be eligible for any care during the postpartum period including but not limited to the treatment of hemorrhage, infection, episiotomy repair, C-section repair, family planning counseling, treatment of complications after delivery, and postpartum depression. Several cited this proposal as bad public policy that will ultimately result in increased health care costs.

One commenter questioned whether hospitals and practitioners would be compelled to release women immediately after delivery due to lack of maternal coverage. Others expressed concern that some women will leave the hospital immediately after birth to avoid expenses, against ACOG and AAP recommendations, while others will not attend the four to six week recommended follow-up visits (resulting in decreased maternal health).

Several commenters noted that if the mother is ill and does not get the care she needs, she may not be able to take care of her children, especially an infant, appropriately. This indirectly jeopardizes the health of women, children and families, and will inevitably result in compromised health outcomes for both the woman and the unborn child.

Commenters quoted ACOG and AAP's recommendation that four to six weeks after delivery the mother should receive a postpartum review and examination. Several commenters referenced Medicaid statute and regulations as an illustration of how public programs rely on established medical standards (§ 1902(1) of the Act as defined in § 1902(a)(10)(a) (clause VII).

One commenter also indicated that lack of family planning counseling creates greater risk of unintended pregnancy with serious social and economic costs to the woman, State, and

community. Others noted that maternal mortality represents a serious health problem, particularly for African-American women.

One commenter stated that coverage for postpartum care and assistance in enrollment in Medicaid or SCHIP should be a requirement for States electing to implement this rule, even in cases where the child is not born alive.

Commenters asked clarifying questions such as: would postpartum follow-up be covered; would emergencies arising to the mother following delivery be covered; and would benefits such as the 60 days postpartum care available through Medicaid be provided?

Response: Again, the intent of this rule is to extend access to individuals who are currently uninsured. We believe that the benefits that would be available to the mother and unborn child are indeed vital.

The SCHIP statute provides States with flexibility in defining those services for which they choose to provide coverage under their State plan. States have the flexibility to define and provide services that are related to the pregnancy or to conditions that could complicate the pregnancy. Within these parameters, States have significant flexibility in the services for which coverage can be provided.

Commenters are correct that care after delivery, such as postpartum services could not be covered as part of the title XXI State Plan, (unless the mother is under age 19 and eligible for SCHIP in her own right), because they are not services for an eligible child.

Comment: One commenter expressed concern that there are those who would define care to include abortion, which the commenter felt would be a complete twisting of the term "care." This commenter did not want abortions covered by the government.

Response: FFP is available in expenditures for abortions under SCHIP only as specifically authorized by the Congress in the statute and this will not change with this regulation. Section 2105(c)(1) and (c)(7) of the Act sets limitations on payment for abortion services under SCHIP. Section 457.475 of the January 2001 SCHIP final regulation, specifies that FFP is not available for expenditures for abortion, or for expenditures for the purchase of health benefits coverage that includes coverage of abortion services, unless the abortion is necessary to save the life of the mother or the abortion is performed to terminate a pregnancy resulting from an act of rape or incest. Additionally, FFP is not available to a State for expenditures of any amount under its

title XXI plan to assist in the purchase, in whole or in part, of health benefits coverage that includes coverage of abortion other than to save the life of the mother or resulting from an act of rape or incest.

Comment: Commenters asserted that fetal surgery saves lives, as in the case of spina bifida or repair of heart defects and asserted that this type of coverage should be offered to unborn children.

Response: We provided a discussion of "fetal medicine" or "fetology" in the preamble to this rule as an example of a distinct and important medical specialty that represents emerging opportunities for services specifically targeted to the care of the unborn child.

Consistent with section 2103 of the Act, States have flexibility in defining the benefits that are included as part of the health coverage provided to targeted low-income children. The specific prenatal and pregnancy related benefits included in a State's benefit package would be the decision of the State.

Comment: The commenters stated that the practices of "fetal surgery," as described in the March 5, 2002 proposed rule, have been deeply plagued by both clinical and ethical problems. The commenters wanted to make clear that there is no such thing as fetal surgery independent of the mother, and that surgery on the unborn child occurs only through the woman's body and can occur only with her consent. Commenters stated that surgery on the fetus presents significant risks to the pregnant woman's life and health and the impact this surgery can have on pregnant woman should be recognized and strongly considered. Commenters continued that modest improvements (or no improvements at all) in the outcomes for fetuses with neonatal operations often happen in conjunction with severe obstetrical complications for the woman.

In support of the medical and ethical controversy surrounding fetal surgery, one commenter cited several articles: Bruner *et al*, Fetal surgery for myelomeningocele and the incidence of shunt dependent hydrocephalus JAMA 1999;282:1819–25; Sutton *et al*, Improvement in hindbrain herniation demonstrated by serial fetal magnetic resonance imaging following fetal surgery for myelomeningocele JAMA 1999;282:1826–31; Simpson JL, Fetal surgery for myelomeningocele: Promise, progress, problems JAMA 1999;282:1873–4; Lysterly *et al*, Attitudes of maternal-fetal specialists concerning maternal-fetal surgery, American Journal of Obstetrics and Gynecology 2001;185:1052–8; Lysterly *et al*, Toward the ethical evaluation and use of

maternal-fetal surgery. Obstetrics and Gynecology 2001;98:689–97. This commenter also cited a National Institutes of Health conference examining the scientific, clinical, and ethical issues related to maternal-fetal surgery.

The commenters stressed that a review of the medical literature shows that maternal-fetal surgery is still considered experimental or investigational by such medical professional organizations as the American College of Obstetricians and Gynecologists. One commenter quoted a member survey of the Society for Maternal-Fetal Medicine, which found that 57 percent of respondents believed that a moratorium should be imposed on open fetal surgery for nonlethal conditions until a multicenter controlled trial is completed. The commenter noted that most of the conditions listed by the March 5, 2002 proposed rule are exceptionally rare and the mortality rates following surgery have been high. Another commenter indicated that current Medicaid programs and most private insurers do not cover experimental procedures.

In addition, the commenters expressed concern that there is no research or data to support the assertion that fetal surgery can ultimately lower postpartum medical care costs. They indicated that while long-term research in this field may someday produce such results, the March 5, 2002 proposed rule's claims that cost-savings currently exist is without support.

The commenters noted that despite the fact that fetal surgery is at this stage largely experimental, the March 5, 2002 proposed rule states that the "Secretary would like to permit the States the flexibility to pay for the medical expenses related to unborn children," suggesting a departure from longstanding State and Federal policy regarding denying coverage for experimental treatments. One commenter indicated that this rule seems to signal a radical shift in policy regarding experimental treatments, and if this is the case, there are many patients suffering from cancer and other diseases who might benefit from an overall change in policy regarding experimental treatments. The commenter refers to a May 26, 1993, letter to State Medicaid Directors and cites the following: *Miller by Miller v. Whitburn*, 10 F.3d 1315 (7th Cir. 1993); *Rush v. Parham*, 625 F.2d 1150, 1156 (5th Cir. 1980); *Weaver v. Reagan*, 886 F.2d 194 (8th Cir. 1989).

In addition, commenters are concerned that since fetal surgery is so new and lacking in proven benefits that

it really should be considered research. Commenters asserted that this would make it appear, then, that this rule is promoting unreviewed and unapproved research on pregnant human subjects, in conflict with statutes regarding human subjects of medical research (Anne E. Drapkin Lyster, MD *et al.* Toward the Ethical Evaluation and Use of Maternal-Fetal Surgery, 98 ACOG 689 (2001).) They also stated that fetal surgery is experimental and it is highly unlikely that this would be covered by Medicaid or any other insurance program (45 CFR 46.101 through 45 CFR 46.409, promulgated pursuant to the Health Research Extension Act, 42 U.S.C. 289.)

Response: As we have said previously, nothing in this rule is intended to affect the traditional relationship between the pregnant woman and her physician. Questions of medical treatment for the pregnant woman and/or her fetus are a decision between the pregnant woman and her physician and nothing in this rule would circumvent or alter that relationship.

Additionally, we are not saying that States that choose to extend coverage to the unborn child must provide fetal medicine or fetology. Consistent with section 2103 of the Act, States have flexibility in defining the benefits that are included as part of the health coverage provided to targeted low-income children. As such, States have always had the ability under SCHIP to provide treatments or surgery that may be considered investigational or experimental if they determine they are medically necessary. We note that States have the same option for providing such coverage under Medicaid. But, the specific prenatal and pregnancy related benefits included in a State's benefit package would be the decision of the State.

We do not have data that fetal surgery can ultimately lower postpartum medical care costs and did not make this assertion. In the preamble to the proposed rule we said that conditions in utero that can be medically or surgically corrected can have beneficial consequences that can include saving the life of the child; elimination of long neo-natal, post-partum medical care for the child and ultimately lower post-partum medical care costs for the child and therefore the SCHIP plan.

Comment: Commenters stated that according to this rule, the unborn child is the patient and the one eligible for services and, as such, they asked, "When the needs of the fetus and mother diverge, to whom is the medical professional's ethical duty owed?" They asked whether SCHIP or Medicaid

would still pay for surgery if the unborn child were endangered to save the life of the pregnant woman? Commenters stated that this proposal raises troubling ethical issues for physicians because ancillary health care potentially puts women's health at risk.

Response: We understand the commenters' concerns, and want to be very clear that nothing in this rule is intended to affect the traditional relationship between the pregnant woman and her physician. Questions of medical treatment for the pregnant woman and/or her unborn child are a decision between the woman and her physician and nothing in this rule would circumvent or alter that relationship.

Comment: Many commenters were also concerned that coverage would not be extended in the case of miscarriage or stillbirth since the SCHIP beneficiary would no longer exist. Many cited such a policy as disrespectful to women.

Response: Services provided under those circumstances would be allowable costs. We believe that providing uninsured women with access to health insurance coverage that benefits both mother and child contributes to the respect of women. This proposed regulation is one option that would become available to States and is one action out of many that the Secretary has taken to promote the health of women.

Comment: Another commenter indicated that the rule allows for unscrupulous providers to bill twice for some services—once on the mother's account and a second time on the unborn child's account.

Response: We believe that States with separate SCHIP programs have implemented sufficient safeguards to address the commenter's concerns. Specifically, § 457.980 of the June 25, 2001 SCHIP implementing rule requires States to establish and maintain systems to identify, report, and verify the accuracy of claims for those enrolled children who meet the requirements of section 2105(a) of the Act, where enhanced Federal medical assistance computations apply. Additionally, States are required by § 457.915 of the January 2001 SCHIP final rule to establish procedures for ensuring program integrity and detecting fraudulent or abusive activity.

Comment: The commenter questioned why prenatal care should be provided to an expectant mother and indicated care should wait until after delivery.

Response: Prenatal care has been clearly shown to reduce the likelihood of premature delivery or low birth weight, both of which are associated

with a wide range of congenital disabilities as well as infant mortality. Moreover, proper prenatal care can detect a great number of serious and even life-threatening disabilities, many of which can now be successfully treated in utero. Ensuring prenatal care for more children will significantly help reduce infant mortality and morbidity rates and will spare many infants from the burden of congenital disabilities and reduce the cost of treating those congenital disabilities after birth.

Comment: The commenter noted that States have the option under SCHIP to offer a benefit package that is equivalent to benchmark coverage, coverage under a State-based plan, or Secretary-approved coverage. The commenter questioned how a State would determine a comparable or actuarially equivalent benefit package for unborn children.

Response: Rather than carving out services and establishing a benefit package exclusively for unborn children as the commenter suggests, we would expect the prenatal benefits for unborn children to be part of the State's overall health benefits coverage package that is consistent with section 2103 of the Act and § 457.410 of the final regulation.

The definition of child health assistance at § 457.402 provides a comprehensive listing of services that includes prenatal care along with other services that would be pregnancy-related. These are services that many States already provide to SCHIP eligible children who become pregnant as part of their current benefit coverage.

Comment: One commenter asked whether Medicaid currently covers the types of services listed in the March 5, 2002 proposed rule. If so, the commenter asked how this could be so, since unborn children are not covered under Medicaid. If not, the commenter asked whether there are estimates of the cost of providing fetology services to Medicaid eligibles, since States cannot offer higher income children greater benefits than lower income children.

Response: Under Medicaid, coverage may include services for pregnant women that are related to pregnancy (including prenatal, delivery, postpartum, and family planning services) and to other conditions that may complicate pregnancy. Within those parameters, States have broad discretion in what services to cover in their Medicaid State plan. While these types of services are available to eligible pregnant women under Medicaid, this rule would authorize SCHIP coverage of these types of services to unborn children whose mothers are not eligible under Medicaid.

Medicaid and SCHIP are different programs, authorized through title XIX and title XXI respectively although States can expand their Medicaid program through the enhanced funding made available by title XXI. As in Medicaid, the specific prenatal services, which any given State will cover under SCHIP is left to the discretion of the State. Inasmuch as States are not required to cover the same package of benefits relating to prenatal care under Medicaid and SCHIP, States can cover the same, fewer or more services under SCHIP than Medicaid. In the event that a State decided to cover certain prenatal services provided to an unborn child under SCHIP, but not to pregnant women under Medicaid, the commenter seems concerned that the State would be in violation of section 2102(b)(1)(B)(i) of the Act.

Section 2102(b)(1)(B)(i) of the Act prohibits States from covering targeted low-income children at a higher income level without covering children at a lower-income level within any defined group of targeted low-income children. An unborn child who is eligible under SCHIP and a lower-income pregnant woman who is eligible under Medicaid are not within the same defined group of targeted low income children under SCHIP. Accordingly, the provisions of section 2102(b)(1)(B)(i) of the Act would not apply.

6. Maintenance of Effort

Comment: One commenter underscored that the Maintenance of Effort requirements under title XXI should apply to unborn children to the same extent that they apply to born children. Several other commenters opposed application of the maintenance of effort requirements to unborn children. These commenters felt that doing so punishes States that already have expanded Medicaid coverage to pregnant women beyond the minimum required and may discourage States from expanding coverage to new populations in the future. They also suggested revising the final rule to clarify that any State that expanded eligibility for pregnant women after June 1, 1997 be permitted to convert that expansion to SCHIP.

One commenter asked whether a proposal to convert optional coverage for pregnant women with incomes from 150 percent to 185 percent of the Federal poverty level (FPL) from title XIX to title XXI funding would be consistent with the March 5, 2002 proposed rule. This commenter asked specifically whether a State could shift the current optional coverage of pregnant women under Medicaid up to

185 percent of the FPL to SCHIP, expand the income limit to 200 percent of the FPL and use the savings to fund the expansion.

A final commenter felt that the purpose of the maintenance of effort provision in the March 5, 2002 proposed rule was unclear. This commenter advocated an interpretation that "SCHIP coverage for fetuses picks up where Medicaid coverage of pregnant women ends." However, the commenter was concerned that, through application of the maintenance of effort provisions of title XXI, we might be purporting to redefine a child for purposes of Medicaid.

Response: We agree with the first commenter that title XXI's maintenance of effort requirements apply equally to unborn and born children. We do not agree that such application is punitive. By including section 2105(d) in the SCHIP legislation, the Congress sought to ensure that title XXI funds were used by States to expand coverage to new populations, not to take the place of Medicaid expenditures for populations already covered. Application of this principle is no different when coverage of prenatal care for an unborn child is at issue, than when coverage of children post-birth is at issue.

Accordingly, in applying the maintenance of effort requirements in the case of unborn children, enhanced Federal Medical Assistance Percentages (FMAP) will not be available if a State adopts income and resource standards and methodologies for purposes of determining eligibility for Medicaid under a group for pregnant women that are more restrictive than those applied under the policies of the State plan in effect on June 1, 1997. We are applying the maintenance of effort requirements to the Medicaid eligibility groups for pregnant women because the unborn child of a pregnant woman who is eligible for Medicaid receives the benefits of the prenatal care covered by Medicaid. Thus, to allow States to cover this an unborn child under SCHIP would result in precisely the kind of cost shifting between Medicaid and SCHIP that the Congress intended to preclude in § 2105(d) of the Act. Application of the maintenance of effort requirements in this way does not in any way alter the definition of child for purposes of Medicaid.

We agree with the commenters that the maintenance of effort requirements do not apply with respect to expansions of coverage for pregnant women implemented after June 1, 1997 (just as they do not apply to expansions of Medicaid coverage of children implemented after June 1, 1997.)

However, we do not believe that revision of this rule is necessary, as this fact is clearly stated in section 2105(d) of the Act as well as the implementing regulations at 42 CFR 433.11(b)(1).

Thus, States generally will not be permitted to drop optional coverage of pregnant women under Medicaid and pick up coverage of unborn children in the same income range under SCHIP, because most States expanded Medicaid coverage of pregnant women prior to June 1, 1997. However, as stated above, expansions implemented after June 1, 1997 are not subject to the maintenance of effort requirements. Thus, a State could eliminate an optional expansion of Medicaid coverage for pregnant women implemented after June 1, 1997 and pick up coverage for the unborn children of the affected women under SCHIP. Similarly, if a State does not already cover pregnant women between 185 percent and 200 percent of the Federal poverty level under Medicaid, it could extend coverage to unborn children in that income range under this regulation.

To permit a State to eliminate coverage of pregnant women implemented on or before June 1, 1997, and pick up coverage of their unborn children under SCHIP, would require that the Secretary waive the maintenance of effort requirements found in section 2105(d) of the Act. The Secretary has never approved a waiver of these requirements in the past and we do not believe that doing so would be consistent with the objectives of title XXI, as required by section 1115 of the Act.

7. Budget Implications

Comment: Numerous commenters noted that this rule does not bring new funding to SCHIP. Some stated that this rule also would increase the financial burden on SCHIP by expanding eligibility and could potentially result in inadequate funds for SCHIP coverage. Others noted that some States already are having trouble maintaining their SCHIP programs and may be freezing enrollment of currently eligible children. Some also noted that the high costs of in utero treatments make expanding care under this regulation less likely. One commenter stated that the expansion in eligibility should be accompanied by additional funds to allow for an increase in enrollment, not just a shift in priorities of the "type" of uninsured child to be covered.

One commenter felt that the lack of funds for this rule means that States also would have access to less Federal funds to provide care to poor immigrant women. Another commenter cited

concern that because the current funding for SCHIP is not adequate to support comprehensive care, the rule could represent an unfunded mandate on States.

A number of these commenters argued that the Department should be making efforts to address the lack of funds to cover existing children. Some suggested that money should be added to other programs to provide prenatal care. One commenter noted in particular that the Administration's new budget contains no additional funding for the Maternal and Child Health grants, which could provide additional resources to pregnant women and their children. Some of the commenters noted that some bills currently pending before the Congress include additional funds for coverage of pregnant women, and that these funds would be available to States that already have expanded coverage to pregnant women under Medicaid.

Response: We recognize that States do not have access to unlimited Federal matching funds for SCHIP. As a result, each State will have to set its own priorities regarding the populations and services to be covered under its SCHIP program. This rule gives States an additional option—to cover prenatal care for unborn children under SCHIP. Some States may not choose to exercise this option, because they lack sufficient funds or for other reasons. This choice is left to each State.

Nearly all States still have unspent SCHIP funds and the President has proposed that the Congress extend the allotments from previous years that would otherwise be returned to the Federal treasury.

Finally, inasmuch as the regulation provides States with an option to extend coverage to unborn children under SCHIP, but does not mandate that they do so, it does not represent an unfunded mandate for States.

Comment: Some commenters mentioned that healthy babies are less expensive to care for than unhealthy babies, so that the cost of prenatal care can be recouped through reduced expenditures on subsequent intervention and surgeries. The commenters noted that this rule will prevent taxpayers from having to bear the burden of unhealthy babies, teens, and adults.

Response: We agree with the commenters. As explained in the March 5, 2002 proposed rule, it is well established that access to prenatal care can improve health outcomes during infancy as well as over a child's life. Since healthy babies and children require less medical care than babies

and children with health problems, provision of prenatal care will result in lower medical expenditures for the affected children in the long run.

Comment: One commenter noted that this rule is more costly than other options, since States will receive the enhanced match available for services provided under SCHIP instead of their regular Medicaid match. The commenter further notes that, with the strict budget neutrality requirements of Health Insurance Flexibility and Accountability (HIFA), States are cutting back benefits to provide coverage. The commenter argues that cost savings derived from providing prenatal services through Medicaid could be used to provide benefits under HIFA.

Response: We agree that States can accomplish the goal of this regulation—increased access to prenatal care—by expanding Medicaid coverage of pregnant women, just as States can expand coverage to children under Medicaid, and that FFP would be available for services provided under the expansion at the State's regular Medicaid match.

With the passage of title XXI, the Congress created a greater incentive for States to expand coverage of low-income children. By expanding the definition of targeted low-income child to include an unborn child, we are extending the increased incentive created by the Congress to include coverage of prenatal services for unborn children.

HIFA provides a vehicle for States seeking to expand Medicaid coverage to populations not typically covered under Medicaid. Nothing in this regulation would preclude States from incorporating the provision of prenatal care into a HIFA waiver proposal, and CMS staff is available to work with any State that may want to do so.

8. Miscellaneous

Comment: Several commenters noted that generally, an American citizen is only counted for taxation purposes after they are born. They asked if granting of legal personhood under this rule mean that unborn children could be taxed inside the womb? Alternatively, the commenters asked, could they be claimed as a deduction before they are born?

Response: The regulation does not purport, nor do we have the authority, to alter the definition of a child or individual for purposes of Federal or State tax statutes or regulations.

IV. Provisions of the Final Rule

In the preamble of the March 5, 2002 proposed rule, we noted an error that we have corrected. The preamble stated that we proposed to revise the definition at § 457.10 to clarify that “child” means an individual under the age of 19 and may include any period of time from conception to birth through age 19. This should have been stated as up to age 19 and has been corrected. In this final rule, we are adopting the provisions of the March 5, 2002 proposed rule, without change.

V. Collection of Information Requirements

States that opt to extend eligibility to unborn children must submit a State plan amendment in accordance with § 457.60. OMB has approved information collection requirements associated with SCHIP State plan amendments under OMB approval number OMB-0938-0841.

VI. Regulatory Impact Statement

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year).

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and

government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 to \$29 million in any 1 year. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications. The option for States to extend coverage to unborn children promulgated in this final rule does not meet the criteria for having Federalism implications. This provision does not impose direct costs on States or local governments, nor does it preempt State laws. This new option only increases State flexibility and, therefore, prior consultation is not required.

This final rule revises and clarifies the definition of “child” under the State Children’s Health Insurance Program (SCHIP) to provide that an unborn child may be considered a “targeted low-income child” by the State and therefore eligible for SCHIP if other applicable State eligibility requirements are met. We estimate that 13 States will elect to include this definition in their State

plans. We also estimate that an additional 30,000 unborn children will benefit by this change. In States that adopt this option, the health status of children will improve to the extent that their mothers receive prenatal care.

We developed cost estimates based on the following assumptions and calculations. We excluded from the calculations a few States that already have eligibility for pregnant women under SCHIP, as well as those that appear likely to exhaust their Federal SCHIP funding at some point. We assumed that each remaining State would have a one-third probability of taking the proposed option to cover unborn children. The increase in SCHIP spending for a State picking up the option was based on Current Population Survey data on the number of infants relative to the total population of children between 100 percent and 200 percent of poverty in the State. The infant count was used as a proxy for pregnant women. Per-person costs were assumed to be twice that of a child on SCHIP.

The costs also include an increase in Medicaid spending as a result of the rule. The reason for this is that, with more SCHIP allotments being spent on unborn children, less is available for redistribution to States that expend all their allotments. Some of these States will run short of funds, and those that are using Medicaid expansions in their SCHIPs will get FFP at the regular matching rate, thus increasing title XIX expenditures.

Regarding state take-up: The estimating model is based on iterative simulations using the one-third participation probability assumption, so there is not a specific set of States that we assume will take the option. Although on average the number of states participating is about a dozen.

Based on the assumptions, we estimate that the budget impact will be \$330 million over a 5-year period. Please see the table below.

NET MEDICAID AND SCHIP COSTS—WITH BUYOUT OF POST-BBA

	2003	2004	2005	2006	2007	2003–7
Federal cost	98	44	81	93	14	330

Therefore, the provisions set forth in this rule will not have an impact of \$110 million or more in any one year. Neither is this rule expected to impose an unfunded mandate on States exceeding \$110 million in any 1 year. Therefore, we have not prepared an analysis of cost

and benefits as required by E.O. 12866 and the Unfunded Mandates Act for rules with significant economic impacts or that impose significant unfunded mandates on States. Also, we believe the changes being promulgated in this document will have very little direct

impact on small entities as defined under the RFA or on small rural hospitals as defined under section 1102(b) of the Social Security Act. Therefore, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined,

and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

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

List of Subjects in 42 CFR Part 457

Administrative practice and procedure, Grant programs-health, Children's Health Insurance Program, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 42 CFR part 457 is amended as set forth below:

PART 457—ALLOTMENTS AND GRANTS TO STATES

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

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

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

2. In § 457.10, the definition of "child" is revised to read as follows:

§ 457.10 Definitions and use of terms.
* * * *

Child means an individual under the age of 19 including the period from conception to birth.
* * * *

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

3. Amend § 457.350 as follows:
A. Redesignate the text of paragraph (b) following the heading as (b)(1).
B. Add a new paragraph (b)(2) to read as follows:

§ 457.350 Eligibility screening and facilitation of Medicaid enrollment.
* * * *

(b) Screening objectives. (1) * * *
(2) Screening procedures must also identify any applicant or enrollee who would be potentially eligible for Medicaid services based on the eligibility of his or her mother under one of the poverty level groups described in section 1902(l) of the Act, section 1931 of the Act, or a Medicaid demonstration project approved under section 1115 of the Act.
* * * *

Subpart F—Payment to States

4. Revise § 457.622(c)(5) to read as follows:

§ 457.622 Rate of FFP for State expenditures.
* * * *
(c) * * *

(5) For States that elect to extend eligibility to unborn children under the approved Child Health Plan, the State does not adopt eligibility standards and methodologies for purposes of determining a child's eligibility under the Medicaid State plan that were more restrictive than those applied under policies of the State plan in effect on June 1, 1997. This limitation applies also to more restrictive standards and methodologies for determining eligibility for services for a child based on the eligibility of a pregnant woman.
* * * *

5. Amend § 457.626 by adding a new paragraph (a)(3) to read as follows:

§ 457.626 Prevention of duplicate payments.

(a) * * *
(3) Services are for an unborn child and are payable under Medicaid as a service to an eligible pregnant woman under that program.
* * * *
(Catalog of Federal Domestic Assistance Program No. 93.767, State Children's Health Insurance Program)

Dated: August 4, 2002.
Thomas A. Scully,
Administrator, Centers for Medicare & Medicaid Services.

Approved: August 8, 2002.
Tommy G. Thompson,
Secretary.
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