DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 440

[CMS–2232–F4]

RIN 0938–AP72

Medicaid Program; State Flexibility for Medicaid Benefit Packages

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

ACTION: Final rule.

SUMMARY: This rule revises the final rule published on December 3, 2008 to implement provisions of section 6044 of the Deficit Reduction Act of 2005, which amends the Social Security Act by adding a new section 1937 related to the coverage of medical assistance under approved State plans. That rule provides States increased flexibility under an approved State plan to define the scope of covered medical assistance by offering coverage of benchmark or benchmark-equivalent benefit packages to certain Medicaid-eligible individuals. In addition, this final rule responds to public comments on the February 22, 2008 proposed rule and comments received in response to rules published subsequently that delayed the effective date of the December 3, 2008 final rule until July 1, 2010.

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

FOR FURTHER INFORMATION CONTACT: Fran Crystal, (410) 786–1195.

SUPPLEMENTARY INFORMATION:

I. Background

A. Regulatory History

On December 3, 2008, we published a final rule in the **Federal Register** entitled "Medicaid Program; State Flexibility for Medicaid Benefit Packages" (73 FR 73694), hereafter referred to as the December 3, 2008 rule. The December 2008 rule was to implement provisions of section 6044 of the Deficit Reduction Act (DRA) of 2005, (Pub. L. 109–171), enacted on February 8, 2006, which amends the Social Security Act (the Act) by adding a new section 1937 related to the coverage of medical assistance under approved State plans.

Subsequent to the publication of the December 3, 2008 rule, and in accordance with the memorandum of January 20, 2009 from the Assistant to the President and the Chief of Staff, entitled "Regulatory Review," we published an interim final rule with comment period (74 FR 5808) on February 2, 2009 in the **Federal Register** to temporarily delay for 60 days the effective date of the December 3, 2008 rule entitled, "Medicaid Program; State Flexibility for Medicaid Benefit Packages." The February 2, 2009 interim final rule also reopened the comment period on the policies set out in the December 3, 2008 rule. We received nine timely items of correspondence in response to the February 2, 2009 interim final rule.

On April 3, 2009, we published a second interim final rule (74 FR 15221) in the **Federal Register** effectively delaying implementation of the December 3, 2008 rule until December 31, 2009. The second interim final rule was published in order to allow time to incorporate provisions of the Children's Health Insurance Program Reauthorization Act (CHIPRA) of 2009 (Pub. L. 111–3) enacted on February 4, 2009, which corrected language in the DRA as if these amendments were included in the DRA, and subsequently amended section 1937 of the Act "State Flexibility for Medicaid Benefit Packages". This delay also allowed for sufficient time to fully consider all of the public comments received on this regulation. In response to the April 3, 2009 interim final rule with a 30-day comment period, we received seven timely items of correspondence.

Upon further review and consideration of the new provisions of the American Recovery and Reinvestment Act (ARRA) of 2009 (Pub. L. 111–5), enacted on February 17, 2009), CHIPRA, and the public comments received during the reopened comment period, we believed it necessary to revise a substantial portion of the December 3, 2008 rule. Therefore, on October 30, 2009, we published a proposed rule in the **Federal Register** (74 FR 56151) to solicit public comments on further delaying the effective date of the December 3, 2008 rule until July 1, 2010. We proposed to further delay the effective date of the December 3, 2008 rule from December 31, 2009 to July 1, 2010 to allow us sufficient time to revise a substantial portion of the final rule based on our review and consideration of the new provisions of CHIPRA, ARRA, and the public comments received during the reopened comment periods. To allow time to make these revisions, the Department determined that several more months were needed to fully consider necessary changes to the rule.

In the proposed rule, we noted that the comments received during the reopened comment periods were complex and presented numerous policy issues which require extensive consultation, review and analysis. Additionally, because both CHIPRA and ARRA contain provisions that impact the American Indian and Alaska Native community, we stated that the development of the final rule required collaboration with other HHS agencies and the Tribal governments. We believed that this time period would allow sufficient time to further consider public comments, analyze the impact of the revisions on affected stakeholders, and develop appropriate revisions to the regulation.

We received one timely item of correspondence in response to the October 30, 2009 proposed rule. The comment did not directly address our proposal to delay the effective date of the December 3, 2008 rule until July 1, 2010. The comment was limited to the exemption of the benchmark and benchmark equivalent packages from the assurance of transportation requirements. Because the comment was outside the scope of the proposed rule on the delay of the effective date of the December 3, 2008 rule, but instead addresses the issue of revisions that are needed to comply with statutory changes, we have addressed the comment in the revisions to the final rule.

On November 30, 2009, we published a final rule in the **Federal Register** (74 FR 62501) delaying the effective date of the December 3, 2008 final rule until July 1, 2010.

B. General Provisions

Under title XIX of the Act, the Secretary is authorized to provide funds to assist States in furnishing medical assistance to needy individuals, whose income and resources are insufficient to meet the costs of necessary medical services, including families with dependent children and individuals who are aged, blind, or disabled. To be eligible for funds under this program, States must submit a State plan, which must be approved by the Secretary. Programs under title XIX are jointly financed by Federal and State governments. Within broad Federal guidelines, each State determines the design of its program, eligible groups, benefit packages, payment levels for coverage and administrative and operating procedures.

Before the passage of the DRA, States were required to offer at minimum a standard benefit package to eligible populations identified in section 1902(a)(10)(A) of the Act (with some specific exceptions, for example, for certain pregnant women, who could be

limited to pregnancy-related services). Under section 1902(a)(10)(A) of the Act, this standard benefit package had to include certain specific benefits identified in the definition of "medical assistance" at section 1905(a) of the Act. These identified benefits include inpatient and outpatient hospital services, physician services, medical and surgical services furnished by a dentist, rural health clinic services, federally qualified health center services, laboratory and X-ray services, nursing facility services, early and periodic screening, diagnostic and treatment (EPSDT)services for individuals under age 21, family planning services and supplies to individuals of child-bearing age, nurse-midwife services, certified pediatric nurse practitioner, and certified family nurse practitioner services. Under section 1902(a)(10)(D) of the Act, the standard benefit package is also required to include home health services.

Section 6044 of the DRA amended the Act by adding a new section 1937 that allows States to amend their Medicaid State plans to provide for the use of benefit packages other than the standard benefit package, namely benchmark benefit packages or benchmark-equivalent packages, for certain populations. The statute delineates what benefit packages qualify as benchmark packages and what would constitute a benchmark-equivalent package. The statute also specifies those exempt populations that may not be required to enroll in a benchmark coverage plan. To be eligible for funds under this new provision, States must submit a State plan amendment, which must be approved by the Secretary. On March 31, 2006, we issued a State Medicaid Director letter providing guidance on the implementation of section 6044 of the DRA.

C. CHIPRA Technical Corrections

On February 4, 2009, CHIPRA was enacted. Section 611 of CHIPRA made technical corrections to the Benchmark Benefit provisions in section 1937 of the Act, which were originally established under the DRA. The CHIPRA technical correction changes take effect as if included in the DRA.

Section 611(a)(1)(C) and section 611(a)(3) of CHIPRA require States to assure that children under the age of 21, rather than those under 19 as originally specified in the DRA, who are included in benchmark or benchmark-equivalent plans, have access to full EPSDT services (that is, those found in sections 1905(a)(4)(B), 1905(r), and 1902(a)(43) of the Act). These EPSDT services may be provided through a benchmark or benchmark-equivalent plan and/or as an additional benefit to those plans under section 1937 of the Act.

Section 611(a)(1)(A)(i) of CHIPRA changed the "Notwithstanding any other provision of this title * * *" language in section 1937(a)(1)(A) of the Act to "Notwithstanding section 1902(a)(1) (relating to statewideness), section 1902(a)(10)(B) (relating to comparability) and any other provision of this title which would be directly contrary to the authority under this section and subject to [subparagraph] (E)". One effect of this CHIPRA change is to clarify the requirement, under 42 CFR 431.53 and section 1902(a)(4) of the Act, to assure transportation for Medicaid beneficiaries in order for them to have access to covered State plan services is applicable, regardless of whether beneficiaries are or are not enrolled in benchmark or benchmark-equivalent plans.

These two sections in CHIPRA affect the implementation of benchmark and benchmark-equivalent plans and thus the "Analysis of and Responses to Public Comments" in section III of this final rule, as well as the regulation, reflect these changes.

Section 611(a)(2) of CHIPRA changed the heading of section 1937(a)(1)(C) of the Act to replace the term "Wrap-Around" with "Additional" and to accordingly strike the term "wrap-around" in the text of section 1937(a)(1)(C) of the Act.

Section 611(b) of CHIPRA clarifies the reference to children receiving foster care under section 1937(a)(2)(B)(viii) to apply to individuals receiving "child welfare services," not "aid" or "assistance".

Section 611(c) of CHIPRA requires the Secretary to post on the CMS Web site and publish in the **Federal Register,** with respect to benchmark and benchmark-equivalent plans approved by the Secretary, those provisions of title XIX of the Act which were determined by the Secretary as not applicable to the State's benchmark and/or benchmark-equivalent plan, as well as the reason for such determinations.

II. Provisions of the Proposed Regulations

We published a proposed rule in the **Federal Register** on February 22, 2008 (73 FR 9714) that implemented the provisions of the DRA of 2005, which amends the Act by adding a new section 1937 related to the coverage of medical assistance under approved State plans. Under this new provision, States have increased flexibility under an approved State plan to define the scope of covered medical assistance by offering coverage of benchmark or benchmark-equivalent benefit packages to certain Medicaid-eligible individuals. For a complete and full description of the States' Medicaid Benefit Packages provisions as required by the DRA, see the February 2008 State Flexibility for Medicaid Benefit Packages proposed rule. In the February 2008 proposed rule, we proposed to add a new subpart C beginning with § 440.300 as follows:

A. Subpart C—Benchmark Packages: General Provisions § 440.300, § 440.305, and § 440.310 Basis, Scope, and Applicability

At proposed § 440.300 (Basis), § 440.305 (Scope), and § 440.310 (Applicability), the regulations would reflect the statutory authority for States to provide medical assistance to individuals, within one or more groups of Medicaid eligible individuals specified by the State, through enrollment in benchmark coverage or benchmark-equivalent coverage. A State may only require that individuals obtain benefits by enrolling in that coverage if they are a "full benefit eligible" whose eligibility is based on an eligibility category under section 1905(a) of the Act that would have been covered under the State's plan on or before February 8, 2006, and are not within exempted categories under the statute. The proposed regulatory definition of full benefit eligible individuals would include individuals who would otherwise be eligible to receive the standard full Medicaid benefit package under the approved Medicaid State plan, but would not include individuals who are within the statutory exemptions, who are determined eligible by the State for medical assistance under section 1902(a)(10)(C) of the Act or by reason of section 1902(f) of the Act, or who are otherwise eligible based on a reduction of income due to costs incurred for medical or other remedial care (other medically needy and spend-down populations).

B. Section 440.315 Exempt Individuals

Proposed § 440.315 would reflect statutory limitations on mandatory enrollment of specified categories of individuals. A State may not require enrollment in a benchmark or benchmark-equivalent benefit plan by the following individuals:

- An individual who is a pregnant woman who is required to be covered under the State plan under section 1902(a)(10)(A)(i) of the Act.
- An individual who qualifies for medical assistance under the State plan

on the basis of being blind or disabled (or being treated as being blind or disabled) without regard to whether the individual is eligible for SSI benefits under title XVI on the basis of being blind or disabled and including an individual who is eligible for medical assistance on the basis of section 1902(e)(3) of the Act.

- An individual who is entitled to benefits under any part of Medicare.
- An individual who is terminally ill and is receiving benefits for hospice care under title XIX.
- An individual who is an inpatient in a hospital, nursing facility, intermediate care facility for the mentally retarded, or other medical institution, and is required, as a condition of receiving services in such institution under the State plan, to spend for costs of medical care all but a minimal amount of the individual's income required for personal needs.
- An individual who is medically frail or otherwise an individual with special medical needs (as described by the Secretary in section 440.315(f)). For purposes of this section, we proposed that individuals with special needs includes those groups defined by Federal regulations at § 438.50(d)(1) and § 438.50(d)(3) of the managed care regulations (that is, dual eligibles and certain children under age 19 who are eligible for SSI; eligible under section 1902(e)(3) of the Act, TEFRA children; children in foster care or other out of home placement; or children receiving foster care or adoption assistance). We did not propose a definition for medically frail populations but we invited public comments to assist us in defining this term in the final regulation.
- An individual who qualifies for Medicaid based on medical condition for medical assistance for long-term care services described in section 1917(c)(1)(C) of the Act.
- An individual who receives aid or assistance under part B of title IV for children in foster care or an individual with respect to whom adoption or foster care assistance is made available under part E of title IV, without regard to age.
- An individual who qualifies for medical assistance on the basis of eligibility to receive assistance under a State plan funded under part A of title IV (as in effect on or after the welfare reform effective date defined in section 1931(i) of the Act). This provision includes those individuals who qualify for Medicaid solely on the basis of qualification under the Temporary Assistance for Needy Families (TANF) rules (that is, the State links Medicaid eligibility to TANF eligibility).
- An individual who is a woman receiving medical assistance by virtue of the application of sections 1902(a)(10)(ii)(XVIII) and 1902(a) of the Act. This provision relates to those individuals who are eligible for Medicaid based on the breast or cervical cancer eligibility provisions.
- An individual who qualifies for medical assistance as a TB-infected individual on the basis of section 1902(a)(10)(A)(ii)(XII) of the Act.
- Individuals who are only eligible for Medicaid coverage of the care and services necessary for the treatment of an emergency medical condition in accordance with section 1903(v) of the Act.

C. Section 440.320 State Plan Requirements: Optional Enrollment for Exempt Individuals

At proposed § 440.320, we would allow States to offer exempt individuals specified in § 440.315 the option to enroll into a benchmark or benchmark-equivalent benefit plan. The State would identify in its State plan the exempt groups for which this coverage is available. There may be instances in which an exempt individual may benefit from enrolling in a benchmark or benchmark-equivalent benefit package. States would be permitted to elect in the State plan to offer exempt individuals a benchmark or benchmark-equivalent package, but States may not require them to enroll in one. For example, in some States the State employee benchmark coverage may be more generous than the State Medicaid plan. Secretary-approved coverage may offer the opportunity for disabled individuals to obtain integrated coverage for acute care and community-based long-term care services. Additionally, States may be able to improve the integration of disease management programs to provide better coordinated care that targets the specific needs of individuals with special health needs.

D. Section 440.325 State Plan Requirements: Coverage and Benefits

At proposed § 440.325, we set forth the conditions under which a State may offer enrollment to exempt individuals specified in § 440.315. When a State offers exempt individuals the option to enroll in a benchmark or benchmark-equivalent benefit package, the State would inform the individuals that enrollment is voluntary and that the individual may disenroll from the benchmark or benchmark-equivalent benefit package at any time and regain immediate eligibility for the standard full Medicaid program under the State plan. The State would inform the individual of the benefits available under the benchmark or benchmark-equivalent benefit package and provide a comparison of how they differ from the benefits available under the standard full Medicaid program. The State would document in the individual's eligibility file that the individual was informed in accordance with this paragraph and voluntarily chose to enroll in the benchmark or benchmark-equivalent benefit package.

At proposed § 440.325, a State would have the option to choose the benchmark or benchmark-equivalent coverage packages offered under the State's Medicaid plan. A State may select one or all of the benchmark plans described in § 440.330 or establish benchmark-equivalent plans described in § 440.335, respectively.

E. Section 440.330 Benchmark Health Benefits Coverage

At proposed § 440.330, benchmark coverage is described as any one of the following:

- Federal Employees Health Benefit Plan Equivalent Coverage (FEHBP—Equivalent Health Insurance Coverage). A benefit plan equivalent to the standard Blue Cross/Blue Shield preferred provider option service benefit plan that is described in and offered to Federal employees under 5 U.S.C. 8903(1).
- State employee coverage. A health benefits plan that is offered and generally available to State employees in the State involved.
- Health Maintenance Organization (HMO) plan. A health insurance plan that is offered through an HMO (as defined in section 2791(b)(3) of the Public Health Service Act) that has the largest insured commercial, non-Medicaid enrollment in the State.
- Secretary-approved coverage. Any other health benefits coverage that the Secretary determines, upon application by a State, provides appropriate coverage for the population proposed to be provided that coverage. As proposed, States wishing to opt for Secretarial-approved coverage should submit a full description of the proposed coverage and include a benefit-by-benefit comparison of the proposed plan to one or more of the three benchmark plans specified above or to the State's standard full Medicaid coverage package under section 1905(a) of the Act, as well as a full description of the population that would be receiving the coverage. In addition, the State should submit any other information that would be relevant to a determination that the proposed health benefits coverage would be appropriate for the

proposed population. The scope of a Secretary approved health benefits package will be limited to benefits within the scope of the categories available under a benchmark coverage package or the standard full Medicaid coverage package under section 1905(a) of the Act.

A State may select one or more benchmark coverage plan options. The State may also specify the benchmark plan for any specific individual. For example, one individual may be enrolled in the FEHBP-equivalent and another may be enrolled into State Employee Coverage at the option of the State.

F. Section 440.335 Benchmark-Equivalent Health Benefits Coverage

At proposed § 440.335, we proposed to provide that if a State designs or selects a benchmark plan other than those specified in § 440.330, the State must provide coverage that is equivalent to benchmark coverage. Coverage that meets the following requirements will be considered to be benchmark-equivalent coverage:

• Required Coverage. Benchmark-equivalent coverage includes benefits for items and services within each of the following categories of basic services and must include coverage for the following categories of basic services:

+ Inpatient and outpatient hospital services.

+ Physicians' surgical and medical services.

+ Laboratory and x-ray services.

+ "Well-baby" and "well-child" care, including age-appropriate immunizations.

+ Other appropriate preventive services, as designated by the Secretary.

• Aggregate actuarial value equivalent to benchmark coverage. Benchmark-equivalent coverage must have an aggregate actuarial value, determined in accordance with proposed § 440.340, that is at least equivalent to coverage under one of the benchmark packages outlined in § 440.330.

• Additional coverage. In addition to the categories of services set forth above, benchmark-equivalent coverage may include coverage for any additional services included in the benchmark plan or described in section 1905(a) of the Act.

• Application of actuarial value for benchmark-equivalent coverage that includes prescription drugs, mental health, vision, and hearing services. Where the benchmark coverage package used by the State as a basis for comparison in establishing the aggregate actuarial value of the benchmark-equivalent package includes any or all of the following four categories of services: Prescription drugs; mental health services; vision services; and hearing services; then the actuarial value of the coverage for each of these categories of service in the benchmark-equivalent coverage package must be at least 75 percent of the actuarial value of the coverage for that category of service in the benchmark plan used for comparison by the State.

If the benchmark coverage package does not cover one of the four categories of services mentioned above, then the benchmark-equivalent coverage package may, but is not required to, include coverage for that category of service.

G. Section 440.340 Actuarial Report for Benchmark-Equivalent Health Benefit Coverage

In accordance with 1937(a)(3) of the Act, at § 440.340, we proposed to require a State, as a condition of approval of benchmark-equivalent coverage, to provide an actuarial report, with an actuarial opinion that the benchmark-equivalent coverage meets the actuarial requirements of § 440.335.

At § 440.340, we proposed to require the actuarial report to obtain approval for benchmark-equivalent health benefit coverage and to meet all the provisions of the statute. The actuarial report must state the following:

• The actuary issuing the opinion is a member of the American Academy of Actuaries (AAA) (and meets Academy standards for issuing an opinion).

• The actuary used generally accepted actuarial principles and methodologies of the AAA, standard utilization and price factors and a standardized population representative of the population involved.

• The same principles and factors were used in analyzing the value of different coverage (or categories of services) without taking into account differences in coverage based on the method of delivery or means of cost control or utilization used.

• The report should also state if the analysis took into account the State's ability to reduce benefits because of the increase in actuarial value of health benefits coverage offered under the State plan that results from the limitations on cost sharing (with the exception of premiums) under that coverage.

• The actuary preparing the opinion must select and specify the standardized set of utilization and pricing factors as well as the standardized population.

• The actuary preparing the opinion must provide sufficient detail to explain the basis of the methodologies used to estimate the actuarial value or, if requested by CMS, to replicate the State's result.

H. Section 440.345 EPSDT Services Requirement

At § 440.345, we proposed to require States to make available EPSDT services as defined in section 1905(r) of the Act that are medically necessary for those individuals under age 19 who are covered under the State plan. We expected that most benchmark or benchmark-equivalent plans will offer the majority of EPSDT services. To the extent that any medically necessary EPSDT services are not covered through the benchmark or benchmark-equivalent plan, States are required to supplement the benchmark or benchmark-equivalent plan in order to ensure access to these services. As proposed, individuals mandated into a benchmark or benchmark-equivalent plan and entitled to have access to EPSDT services cannot disenroll from the benchmark or benchmark-equivalent plan just to receive these services. While, as proposed, individuals are required to have access to such medically necessary services first under the benchmark or benchmark-equivalent plan, the State may provide wrap-around or additional coverage for medically necessary services not covered under such plan. Any wrap-around benefits must be sufficient so that, in combination with the benchmark or benchmark-equivalent benefits package, an individual would have coverage for his or her medically necessary services consistent with the requirements under section 1905(r) of the Act. The State plan would include a description of how wrap-around benefits or additional services will be provided to ensure that these individuals have access to full EPSDT services under section 1905(r) of the Act.

In addition, as proposed, individuals would need to first seek coverage of EPSDT services through the benchmark or benchmark-equivalent plan before seeking coverage of such services through other options established by the State for receiving wrap-around benefits under section 1937 of the Act.

I. Section 440.350 Employer Sponsored Insurance Health Plans

At § 440.350, we proposed that the use of benchmark or benchmark-equivalent benefit coverage would be at the discretion of the State and may be used in conjunction with employer sponsored health plans as a coverage option for individuals with access to private health insurance. Additionally, the use of benchmark or benchmark-equivalent coverage may be used for

individuals with access to private health insurance coverage. For example, if an individual has access to employer sponsored coverage and that coverage is determined by the State to be benchmark or benchmark-equivalent, a State may, at its option, provide premium payments on behalf of the individual to purchase the employer coverage. Additionally, a State could create a benchmark or benchmark-equivalent plan combining employer sponsored insurance and wrap-around benefits to that employer sponsored insurance benefit package. The premium payments would be considered medical assistance and the State could require the non-exempt individual to enroll in the group health plan.

J. Section 440.355 Payment of Premiums

At § 440.355, we proposed that payment of premiums by the State, net of beneficiary contributions, to obtain benchmark or benchmark-equivalent benefit coverage on behalf of beneficiaries under this section will be treated as medical assistance under section 1905(a) of the Act.

K. Section 440.360 State Plan Requirement for Providing Additional Wrap-Around Services

At § 440.360, we proposed that a State may at its option provide additional wrap-around services to the benchmark or benchmark-equivalent plans. The wrap-around services do not need to include all State plan services. However, the State plan would be required to describe the populations covered and the payment methodology for assuring those services. Such additional or wrap-around services must be within the scope of categories of services covered under the benchmark plan, or described in section 1905(a) of the Act.

L. Section 440.365 Coverage of Rural Health Clinic and Federally Qualified Health Center (FQHC) Services

At § 440.365, we proposed that a State that provides benchmark or benchmark-equivalent coverage to individuals must assure that the individual has access, through that coverage or otherwise, to rural health clinic services and FQHC services as defined in subparagraphs (B) and (C) of section 1905(a)(2) of the Act. Payment for these services must be made in accordance with the payment provisions of section 1902(bb) of the Act.

M. Section 440.370 Cost Effectiveness

At § 440.370, we proposed that benchmark or benchmark-equivalent coverage and any additional benefits must be provided in accordance with Federal upper payment limits, procurement requirements and other economy and efficiency principles that would otherwise be applicable to the services or delivery system through which the coverage and benefits are obtained.

N. Section 440.375 Comparability

At § 440.375, we proposed that a State may at its option amend its State plan to provide benchmark or benchmark-equivalent coverage to individuals without regard to comparability.

O. Section 440.380 Statewideness

At § 440.380, we proposed that a State may at its option amend its State plan to provide benchmark or benchmark-equivalent coverage to individuals without regard to statewideness.

P. Section 440.385 Freedom of Choice

At § 440.385, we proposed that a State may at its option amend its State plan to provide benchmark or benchmark-equivalent coverage to individuals without regard to freedom of choice. States may restrict individuals to obtaining services from (or through) selectively procured provider plans or practitioners that meet, accept, and comply with reimbursement, quality and utilization standards under the State Plan, to the extent that the restrictions imposed meet the following requirements:

(+) Do not discriminate among classes of providers on grounds unrelated to their demonstrated effectiveness and efficiency in providing the benchmark benefit package.

(+) Do not apply in emergency circumstances.

(+) Require that all provider plans are paid on a timely basis in the same manner as health care practitioners must be paid under § 447.45 of the chapter.

Q. Section 440.390 Assurance of Transportation

At § 440.390, we proposed that a State may at its option amend its State plan to provide benchmark or benchmark-equivalent coverage to individuals without regard to the assurance of transportation to medically necessary services requirement specified in § 431.53.

III. Analysis of and Responses to Public Comments

In response to the February 2008 proposed rule, we received over 1,100 timely items of correspondence. In response to the February 2, 2009 interim final rule with a 30-day comment period (the first temporary delay of the December 3, 2008 final rule), we received nine timely items of correspondence. In response to the April 3, 2009 interim final rule with a 30-day comment period (the second temporary delay of the December 3, 2008 final rule), we received seven timely items of correspondence. In response to the October 30, 2009 proposed rule on delaying the effective date of the final rule to July 1, 2010, we received one timely item of correspondence.

The majority of the comments received on the proposed rule represented transportation providers, medical providers, and Medicaid beneficiaries, particularly Medicaid beneficiaries who rely on dialysis treatments. Other comments represented State and local advocacy groups, national associations that represent various beneficiary sub-groups, State Medicaid agency senior officials, and human services agencies. In this section, we provide a discussion of the public comments we received on the February 22, 2008 proposed rule, the February 2, 2009 interim final rule with a 30-day comment period (the first temporary delay of the December 3, 2008 final rule) and the April 2, 2009 final rule with a 30-day comment period (the second temporary delay of the December 3, 2009 final rule), as well as the one comment that we received in response to our October 30, 2009 proposed rule delaying the effective date of the December 3, 2008 final rule, which addressed the issue of revisions required to comply with statutory changes. Comments related to the impact of this rule are addressed in the "Collection of Information Requirements" section of this regulation.

Additionally, we published a proposed rule in the **Federal Register** on February 22, 2008 (73 FR 9727) titled, "Medicaid Program: Premiums and Cost Sharing" (CMS–2244–P). Comments on CMS–2244–P were also due March 24, 2008 similar to this rule. Some comments for CMS–2244–P were forwarded as comments to this rule (CMS–2232–P). Consistent with the Administrative Procedures Act, CMS is not responding to those comments in this regulation, but we addressed the issues raised by otherwise timely

comments in our publication of CMS–2244–F.

A. General Comments

Comments: A few commenters supported the proposed rule and a few commenters strongly supported certain provisions of the December 3, 2008 rule. However, most commenters oppose either the February 22, 2008 proposed rule or certain sections of the December 3, 2008 rule. Many commenters are concerned that the benchmark or benchmark-equivalent benefit packages are inadequate benefit packages for, among others, individuals with mental illness, children with serious emotional disturbance, the disabled and elderly, individuals with end stage renal disease, and American Indians. Many of the commenters believe that to enroll Medicaid beneficiaries in benchmark or benchmark-equivalent benefit packages without the assurance of transportation could lead to poorer health outcomes, costlier care because individuals will be forced into hospital emergency rooms, and shifts in costs to the Emergency Medical Services.

Response: We acknowledge and appreciate the views of the commenters who both supported and opposed the February 22, 2008 proposed rule and the December 3, 2008 rule. Those who opposed the rule generally raised concerns about the underlying wisdom of the statutory provision at section 1937 of the Act, which this final rule implements. CMS is charged with implementing the statute. We address comments relating to restrictive interpretations below in the discussion of specific proposed provisions that arguably were not required by the statutory provision.

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

Some commenters stated that the 30-day comment period in the proposed rule was not sufficient for Tribes to comment on a regulation that could potentially have a significant impact on Tribal communities.

Other commenters noted that while the Department views the proposed rule as merely formalizing its earlier policy statements delivered only to State Medicaid Directors, a 30-day public comment period is too short for meaningful public review, analysis, and comment. Some commenters believe that the 30-day comment period is discouraging of full review and consideration by States.

One commenter requests that the public comment period be extended by 60 days for a total of a 90-day comment period. Additional time is needed to provide sufficient time for stakeholders to be able to adequately assess the potential effects of the proposed rule.

Response: As described in the "Background" in section I of this regulation under "Regulatory History," in section I.A. of this regulation a 30-day public comment period on the February 22, 2008 proposed rule was provided and two additional 30-day public comment periods were provided on the December 3, 2008 rule. We believe that these comment periods allowed sufficient time for public comment.

B. Section 440.300 Basis

Comment: One commenter believed that the proposed limitations on eligibility groups who can be provided alternative benefit packages are overly restrictive. The commenter suggested that the rule should allow application to any eligibility category the State had the option to implement on or before the date of enactment of section 1937 (February 8, 2006). The commenter reasoned that States are continually adding and changing eligibility requirements and these program changes are inherent in Medicaid programs. The commenter asserted that, if the rule is considered beneficial for individuals in eligibility categories that existed before February 8, 2006, it is logical to suppose it would also be beneficial for those created after that date.

Response: The language in section 1937(a)(1)(B) of the Act specifies that the State may only exercise the option to offer benchmark or benchmark-equivalent coverage for an individual eligible under an eligibility category that had been established under the State plan on or before February 8, 2006. We have interpreted this statutory term to mean any eligibility category listed under section 1905(a) of the Act. Thus, all individuals within a category covered or potentially covered under the State's Medicaid plan could be eligible to participate in a benchmark or benchmark-equivalent plan at the State's option, unless specifically excluded by statute, even when the State makes modifications to the income and resource eligibility levels or methodologies, ages covered, etc. for a group or category after February 8, 2006.

C. Section 440.305 Scope

Comment: Numerous commenters believed that offering benchmark and benchmark-equivalent benefit packages to certain Medicaid individuals will deter those individuals, including children, from receiving appropriate care. Commenters indicated that individuals with low incomes are likely to forego needed treatment if all medically necessary services and transportation are not included in the benchmark program. Most commenters believed that our most vulnerable populations, those with chronic medical needs, will be required to choose to provide for their basic needs like food and shelter rather than obtain necessary medical health care because of the rigor created by following a private health insurance model of benefits and the need to provide their own method of transportation.

Response: The benchmark and benchmark-equivalent coverage was authorized by the statute. Under the statute, the benchmark flexibility is an option that States can choose to use in redesigning their current Medicaid benefit program. It should be noted that as a result of the CHIPRA changes to the DRA, this option is not as broad as it had been and we have revised the regulations to comply with CHIPRA by stating that States must comply with all requirements of title XIX other than sections 1902(a)(1) and 1902(a)(10(B) of the Act, unless such requirement can be shown to be directly contrary to the authority under section 1937 of the Act. For example, under the CHIPRA changes transportation is a required service and benchmark plans utilizing managed care delivery systems must meet managed care rules.

Comment: Other commenters indicated that the DRA does not require that States offer the same Medicaid benefits statewide, meaning States could design different benefit packages for rural and urban areas. States may also "tailor" packages for different populations, although the commenter acknowledges, certain groups are exempt from mandatory changes to their Medicaid benefits package. In States where this has already been done, there have been some reports that the changes have been unsatisfactory. Several commenters believed that allowing States to "tailor" benefit packages would mean that individuals may not have access to the services they need. Benefit packages designed outside the important consumer protections in

traditional Medicaid may fail to meet beneficiaries' needs, and will not save money if these individuals experience significant unmet needs that escalate into problems that require treatment in emergency rooms.

One commenter mentioned that private health plans, such as those listed as benchmarks under the law, frequently have limited coverage of mental health services. The commenter asserted that few cover any of the intensive community services that are covered by Medicaid under the rehabilitation category or the home and community-based services option. The commenter noted that, under the DRA, these limited mental health benefits can be further reduced by 25 percent of their actuarial value. Other commenters expressed concern that the reliance on commercial benefit plans is inappropriate for Medicaid individuals. Those commenters are concerned that many private insurance plans do not provide adequate mental health services. Other commenters noted that benchmark coverage is likely to prove entirely inadequate for individuals who need mental health services. The commenters noted that children with serious mental and/or physical disorders often qualify for Medicaid on a basis of family income and are not, for various reasons, receiving Supplemental Security Income (SSI) benefits or otherwise recognized as children with disabilities and would not be exempt from mandatory enrollment. In addition, the commenters noted that many low-income parents on Medicaid have been found to have serious depression, which could not be adequately treated with a very limited mental health benefit.

Similarly, many commenters believed that the proposed rule has the potential to become the behavioral healthcare Medicaid "Trojan horse": It appears harmless but it will reverse hard fought progress won over years of struggle that brought about equitable, decent care for Medicaid-eligible individuals experiencing mental illness or who have a developmental disability. The commenters asserted that, in the end, these rules will have costlier results and not the desired economizing while also negatively impacting peoples' lives, their well-being and care, and our society.

Another commenter believed that it is critical for beneficiaries with life-threatening conditions such as HIV/AIDS to maintain access to the comprehensive range of medical and support services required to effectively manage HIV disease. The commenter stated that allowing States to "tailor" benefit packages in ways that essentially eliminate coverage for critical health services places the health of Medicaid beneficiaries with HIV/AIDS in serious jeopardy.

Response: The DRA created section 1937 in response to States' desire for more flexibility in designing their Medicaid programs and adopting benefit programs tailored to the needs of the varied populations they serve. The DRA provides that States can provide alternative benchmark or benchmark-equivalent benefit packages at their option; that is, States are not required to implement these provisions. We have incorporated elements in this regulation that are designed to protect vulnerable populations and to help assure that individuals enrolled in a benchmark benefit plan will have access to services that are appropriate to their individual needs to the extent permitted by the statute.

To protect individuals with disabilities we have included in this rule a basic minimum definition of medically frail and special medical needs to insure that people with disabilities and special health care needs are not mandatorily enrolled in benchmark benefit plans. Rather, they can only be voluntarily enrolled after being fully informed of the differences between the benchmark benefit plan and the traditional State plan. We have added language at § 440.305(b)(2) that requires States electing to offer benchmark benefit plans or wishing to substantively change an approved benchmark benefit plan to provide advance public notice with an opportunity to comment. Before submitting to CMS a State plan amendment to implement a benchmark benefit plan or an amendment to substantially modify the benefits or eligibility provisions of an approved benchmark benefit plan, the State must first provide the public the opportunity to review the proposed change and comment on it.

We acknowledge and agree with the commenters on the importance of providing adequate mental health benefits and will be separately addressing how post DRA-enactments, specifically the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 relate to benchmark benefits.

The new benefit option provides States with additional tools to provide care to maximize health outcomes for certain individuals. These tools may be used in conjunction with other Medicaid and Children's Health Insurance Program (CHIP) authorities to strategically align the Medicaid program with the current health care environment and expand access to care by leveraging existing benefit and coverage options to improve quality and coordination of care.

States seeking to use benchmark and benchmark-equivalent plans to provide coverage for children and adults with special medical needs, individuals with HIV/AIDS, and long-term care and community-based service options, must design a benchmark benefit package that is appropriate to meet the health care needs of the population being served, including coverage that may be more generous than a State's Medicaid plan.

We think it is important to note that States are required to provide children under the age of 21 with EPSDT services either as an additional service and or as part of the benchmark or benchmark-equivalent benefit plan. States are required to inform families about how and where to access these services particularly if the benchmark or benchmark-equivalent benefit does not identify the full range of EPSDT services needed by the beneficiary as being covered. States must assure that these services are provided in the most seamless way possible and the families understand how to access such services through the Medicaid State plan.

Moreover, certain groups cannot be included in a mandatory enrollment for an alternative benefit package—among others, pregnant women, dual eligibles, terminally ill individuals receiving hospice, inpatients in institutional settings, and individuals who are medically frail or have special medical needs. These individuals may be offered a choice to enroll and, in considering the choice, must be provided a comparison of benchmark benefits versus the traditional Medicaid State plan benefit. Their decision to enroll is voluntary and individuals must be provided the opportunity to revert back to traditional Medicaid at any time.

Comment: One commenter noted that the preamble language refers to meeting the "* * * needs of today's Medicaid populations and the health care environment." The commenter believed the preamble should describe these needs in some detail so that there is a shared understanding of the types of needs this new flexibility is intended to address.

Response: We agree that it is important to understand the needs of today's Medicaid populations and the health care environment. Congress has provided States with the flexibility to align Medicaid benefit packages for certain populations with commercial insurance plans. States now have the ability to provide additional services that are uniquely designed to meet the

needs of targeted populations. For example, individuals with asthma and chronic obstructive pulmonary disease who reside in a certain area of the State may be offered disease management services which are not otherwise available under the traditional State plan to all individuals with asthma and chronic obstructive pulmonary disease. A State may elect to provide beneficiaries with incentives for healthy behavior by offering additional services. For example, a State could offer certain (enhanced) preventive services not available under the regular State plan, such as smoking cessation counseling or nutritional/dietary management, to beneficiaries with certain medical conditions and/or in certain parts of the State. Prior to the enactment of the DRA, a State that wanted to tailor its Medicaid program to meet the unique needs of its beneficiaries would have to utilize a demonstration or waiver program.

Comment: One commenter stated that the proposed rule, read together with other CMS rules like the citizenship documentation requirement and CMS's Children's Health Insurance Program (CHIP) crowd-out directive of August 17, 2007, create major barriers to access to appropriate health care, and that the proposed rule has a devastating impact on the low income populations. In particular, some commenters raised concerns about requirements for American Indians and Alaska Natives to prove both citizenship and identity in order to obtain Medicaid services. Commenters also raised concerns about the CHIP review strategy outlined in an August 17, 2007 letter sent to State Health Officials. Commenters also asserted that other proposed rules released by CMS like the Rehabilitation Rule and the Targeted Case Management Rule coupled with this rule will have a devastating effect on individuals in need of transportation since these rules also eliminate non-emergency medical transportation services.

Response: We agree that the DRA benchmark rules can create some risk that beneficiaries may not be able to access needed care, and we will implement the rules mindful of this possibility and consistent with the Federal law. Additionally, CHIPRA included two significant technical changes to the DRA that amended section 1937 of the Act. In order to reflect these changes, we modified the regulation at § 440.390 to clarify that States must assure necessary transportation to and from providers and at § 440.345 to clarify that States must assure that children under the age of 21 who are enrolled in alternative benefit plans must have full access to EPSDT services. Additionally, we expanded paragraph (b)(5) in § 440.335, which lists the mandatory services that benchmark-equivalent plans must provide, to include family planning services and supplies as a required preventive service.

Citizenship documentation requirements and the rehabilitation and case management requirements are not part of this rule and we do not address them here. This regulation implements the statutory provisions of section 1937 of the Act. However, it should be noted that the August 17, 2007 State Health Officials letter on CHIP eligibility levels and crowd out was withdrawn on February 4, 2009, at the direction of President Obama. The CHIPRA, signed into law on that same day, provides new flexibility to States for streamlining citizenship documentation. CHIPRA also includes technical amendments to the DRA which clarify documentation requirements, provide for a reasonable opportunity period for individuals to submit such documentation, and expand the list of documents that are acceptable for verifying citizenship.

Comment: Several comments were provided by organizations that have an interest in how the benchmark and benchmark-equivalent benefit packages impact American Indians/Alaska Natives. The commenters believed that alternative benefit packages serve as a substantial barrier to American Indians/Alaska Natives enrollment in the Medicaid program. They noted that, because of the Federal government's trust responsibility to provide health care to American Indians/Alaska Natives, implementing benchmark and benchmark-equivalent benefit packages have specific tribal implications that were not addressed in the proposed rule. Several commenters believed that American Indians/Alaska Natives should be exempt from mandatory enrollment in benchmark and benchmark-equivalent benefit programs entirely.

Response: In Medicaid, there is no statutory basis to exempt American Indians/Alaska Natives from Medicaid alternative benefit provisions. Section 1937 of the Act does not provide for such an exemption. Section 1937 does provide some specific exemptions from mandatory enrollment in benchmark or benchmark-equivalent benefit packages and it is possible that some American Indians/Alaska Natives would fit into one of these exempt groups. Section 1937 does not however give CMS authority to identify additional exempt groups.

To address the unique needs of the American Indians/Alaska Natives population, we expect States to ensure that alternative benefit packages recognize the unique services offered by IHS and tribal providers, and the unique health needs of the American Indians/Alaska Natives population. To ensure this, section 5006 of ARRA requires States to consult with Indian Health Programs or Urban Indian Organizations that furnish health care services on matters that are likely to have a direct effect on these health programs. It also requires that services provided to Indians through managed care organizations provide access to IHS providers.

Comment: One commenter contended that there are no provisions to require States to ensure that American Indians/Alaska Natives continue to have access to culturally competent health services through the Indian Health Service (IHS) or tribally operated health programs. The commenter stated that the proposed rules allow States to offer coverage without regard to comparability, statewideness, freedom of choice, the assurance of transportation to medically necessary services, and other requirements. There are large disparities between American Indians/Alaska Natives' health care status and the health care status of the rest of the country. The commenter added that for American Indians/Alaska Natives, the patient should always have the option of the provider being an Indian Health Service or tribal health program.

Response: State Medicaid programs provide health care services to many diverse populations including American Indians/Alaska Natives individuals. We believe that culturally competent services are important for all Medicaid beneficiaries and access to care and facilities in remote parts of the country, where it is especially difficult to find providers who will agree to participate in the Medicaid program, is paramount. Section 1937 of the Act does not provide any special protections for benefit packages applicable to American Indians/Alaska Natives individuals, but this does not mean that benefit packages will be deficient.

Section 5006(e) of the ARRA, which was signed on February 17, 2009 and became effective July 1, 2009, requires that in the case of any State in which one or more Indian Health Program or Urban Indian Organization furnishes health care services, the Medicaid State plan specify a process under which the State seeks advice from designees of such programs or organizations on matters that are likely to have a direct effect on these health programs.

As noted previously, to address the unique needs of the American Indians/

Alaska Natives population, we expect States to work with Indian Health Programs or Urban Indian Organizations that furnish health care services to ensure that alternative benefit packages recognize the unique services offered by IHS and tribal providers, and the unique health needs of the American Indians/Alaska Natives population.

With regard to the assurance of transportation and freedom of choice of providers, CHIPRA amended the "notwithstanding any other provisions of this title" language. This change in the law clarifies that the authority under section 1937 of the Act to deviate from otherwise applicable Medicaid requirements is limited. Therefore, we revised the regulation at § 440.390 to require States to assure necessary transportation to and from providers for individuals enrolled in benchmark and benchmark-equivalent plans and at § 440.385 by removing the option to provide benchmark and benchmark-equivalent coverage without regard to freedom of choice of providers. While we do not anticipate that there will be many requirements of title XIX that would be contrary to implementing a benchmark benefit plan, States may request an exemption from a provision of title XIX if they can demonstrate how the provision would be directly contrary to section 1937 of the Act.

Comment: Another commenter stated on behalf of American Indians/Alaska Natives, the Indian and tribal health care system is woefully under-funded and tribal providers rely on Medicaid revenues to supplement that meager funding. Forcing American Indians/Alaska Natives into benchmark plans, which may have dramatically reduced coverage or payments, would thus jeopardize Indian health, injure tribal health systems, and thereby violate the Federal trust obligation to care for the health needs of Indian people.

Response: We acknowledge that benchmark plans could reduce covered benefits. To date, however, CMS has approved ten benchmark benefit programs, and most offer State plan services plus additional services like preventive care, personal assistance services, or disease management services. For individuals under the age of 21, section 1937 of the Act ensures that all needed services will be available through the requirement that EPSDT services must be provided either in addition to, or as part of, the benchmark or benchmark-equivalent plan.

Section 1937 of the Act does not provide a basis to exclude IHS or tribal health providers from participation in the delivery system for alternative benefits. Futhermore, CMS does not determine IHS funding levels.

In an effort to reach out to Tribes we held several discussions with Tribes about the changes made to the DRA and section 1937 of the Act by section 611 of CHIPRA. These discussions took place during the All Tribes call on July 2, 2009, and during two face to face open consultation meetings held with Tribes on July 8th and July 10th, 2009. We covered all CHIPRA related issues, including the changes made to section 1937 of the Act during all of these meetings. Also, on June 29, 2009 we covered section 611 of CHIPRA during the Tribal Technical Advisory Group (T–TAG) meeting CMSO had with the T–TAG policy advisors. CMS is committed to enhancing communication with Tribes and to assuring that the obligation of States to consult with American Indians/Alaska Natives on all issues affecting Indian health services are followed by State Medicaid agencies.

Comment: Some commenters believed that the proposed rule did not comply with the Department of Health and Human Services' Tribal Consultation policy, since CMS did not consult with Tribes in the development of these regulations before they were promulgated.

These commenters noted that CMS did not obtain advice and input from the CMS Tribal Technical Advisory Group (TTAG), even though the TTAG meets on a monthly basis through conference calls and holds quarterly face to face meetings in Washington, DC. They also noted that CMS did not utilize the CMS TTAG Policy Subcommittee, which was specifically established by CMS for the purpose of obtaining advice and input in the development of policy guidance and regulations.

These commenters also noted that the proposed rule does not contain a Tribal summary impact statement describing the extent of the tribal consultation or lack thereof, nor an explanation of how the concerns of Tribal officials have been met. Several commenters request that these regulations not be made applicable to American Indians/Alaska Natives Medicaid beneficiaries until Tribal consultation is conducted, or be modified to specifically require State Medicaid programs to consult with Indian Tribes before the development of any policy which would require mandatory enrollment of American Indians/Alaska Natives in benchmark or benchmark-equivalent plans. One commenter suggested that this consultation should be similar to the way in which consultation takes place with Indian Tribes in the development of waiver proposals. And, a commenter urged that, after appropriate tribal consultation and revision reflecting these and other comments, the rule be republished with a longer public comment period.

One Tribe commented that the proposed rule does not honor treaty obligations for health services that are required by the Federal government's unique legal relationship with Tribal governments.

Response: CMS currently operates under the Department of Health and Human Services' Tribal Consultation Policy. The Departmental guidelines provide information as to the regulatory activities that rise to the level that require consultation (include prior notification of rulemaking). We have considered the Departmental guidelines. Though the effect on American Indians/Alaska Natives individuals results from the statute itself, and not this rule, CMS did consult with the Tribes about the changes made to the DRA and section 1937 of the Act by section 611 of CHIPRA as described in the previous response.

Section 5006(e) of ARRA, which was signed on February 17, 2009 and became effective July 1, 2009, provides American Indians/Alaska Natives individuals with new protections because it requires that Medicaid State plans specify a process under which the State seeks advice from designees of Indian Health Programs or Urban Indian Organizations that furnish health care services on matters that are likely to have a direct effect on these health programs. States that elect to implement alternative benefit packages must consult with Tribes and notify them about State plan amendments that will directly affect the Tribes. These regulations implement section 1937 of the Act, as enacted by Congress, and do not address treaty rights of American Indians. These regulations neither diminish nor increase such treaty rights. Questions about the Indian Health Services budget should be directed to Indian Health Services.

Comment: Several commenters believed that States should not have the ability to create benchmarks that allow for increases in cost sharing. Specifically, States can establish a benchmark coverage package that requires co-pays for health care access, whereby the cost sharing will actually be a limitation on coverage. However, if the selected benchmark plan indicates that it provides coverage for only half of the cost of mental health services, CMS views that as a coinsurance requirement rather than as a limitation on coverage.

Premiums and cost sharing act as a deterrent to those receiving health care and may cause low income populations to choose between healthcare and basic needs such as food. The commenter indicated that American Indians/Alaska Natives and other low-income groups should be exempt from premiums and cost-sharing requirements.

Response: States have the option to impose cost sharing in Medicaid but are limited by the requirements of sections 1916 and 1916A of the Act. To the extent that these benchmark packages impose premiums or cost sharing, this final regulation stipulates that any cost sharing and premiums for individuals may not exceed cost sharing limits applicable under sections 1916 and 1916A of the Act. In a State that imposes cost sharing under either 1916 or 1916A the State would be permitted to apply different cost sharing requirements for individuals enrolled in the benchmark or benchmark-equivalent plan than it imposes for those not enrolled in such plans. In some cases individuals enrolled in benchmark or benchmark-equivalent plans may actually have lower cost sharing than is required of individuals enrolled in the traditional State plan benefit package. Under section 1916A of the Act, there are tiered individual service limits based on family income, and an aggregate cap of five percent of family income. These limits apply to all individuals enrolled in benchmark plans.

Section 5006 of ARRA added new protections for American Indians/Alaska Native related to: premiums and cost sharing; exclusion of certain American Indians/Alaska Natives specific property from estate recovery in Medicaid; new rules regarding American Indians/Alaska Natives, Indian Health Providers and Indian Managed Care entities in Medicaid; and new consultation requirements for Medicaid, CHIP and other health care programs funded under the Act involving Indian Health programs and Urban Indian organizations.

It is important to note that alternative benefit package programs are provided at the State's option. However, we recognize the concerns raised by these commenters.

Numerous Medicaid eligibility categories are exempt from mandatory enrollment in alternative benefit packages and can only select the alternative benefit package voluntarily. Such individuals must be provided a comparison of the benchmark option versus the State plan option before they choose to enroll. That comparison must include information on the cost-sharing obligations of beneficiaries. In choosing the benchmark option over the State plan option, these individuals would thus have actively made an informed choice. Finally, exempt individuals must be able to revert back to traditional Medicaid at any time. States electing to offer an alternative benefit package and choosing to allow voluntary enrollment for exempt populations must demonstrate how the State will operationalize the disenrollment provisions as well as provide detailed information on how informed choice will occur.

Comment: One commenter urged CMS to add provisions to provide special protections for individuals with disabilities, dual eligibles, and persons with other chronic medical conditions to ensure access to benchmark packages that are uniquely designed to address physical impairments and rehabilitation needs.

Another commenter believed CMS should require State Medicaid agencies to provide access to care management and care coordination services to Medicaid individuals who are incapable of managing their benchmark plan services. The commenter further believed that home health services should be included in all benchmark plan packages.

Several commenters recommended that all State programs include prevention services and promote health, wellness, and fitness. Physical therapists are involved in prevention by promoting health, wellness and fitness, and in performing screening activities.

One commenter is concerned that the managed care model is better suited for a "well" population as opposed to children with chronic special health care needs and adults with disabilities.

Response: To the extent that the commenter is concerned that alternative benefit packages will result in a reduction in services, we acknowledge that this is a possibility. However, for the benchmark State plan amendments implemented to date, most offer traditional State plan services as well as additional services like prevention and disease management.

States can consider benchmark-equivalent coverage as long as the coverage includes mandatory services such as inpatient and outpatient hospital services, physicians' surgical and medical services, laboratory and x-ray services, emergency services, well-baby and well-child care including age-appropriate immunizations, and other appropriate preventive services. We have determined that other appropriate preventive services must include family planning services and supplies.

Benchmark-equivalent plans may also include care management, care coordination, and/or home health services, but it is possible that some plans will not include these services. We do not agree that a requirement that States include these specific services would be consistent with the statute.

An important protection for children enrolled in alternative benefit packages is the requirement to ensure full access to the EPSDT benefit for children under the age of 21. If services are not provided as part of the benchmark or benchmark-equivalent plan, these services must be provided by the State as additional benefits. States electing the benchmark benefit option must provide CMS with information describing how it will inform families of the availability of such services and how the State will coordinate access to those services when they must be provided outside of the benchmark plan. Furthermore, States, at their option, can provide for additional services to benchmark or benchmark-equivalent programs.

Additionally, exempt individuals must make an informed choice before they elect to voluntarily enroll in benchmark or benchmark-equivalent plans. This includes the requirement that States must provide exempt individuals with a comparison of the benefits included in the benchmark or benchmark-equivalent plan versus the benefits included in traditional State plan coverage. The exempt individual has the right to return to State plan coverage at any time. For example, if the exempt individual is in need of services not offered in the benchmark plan, the individual can return to the regular Medicaid benefit package immediately. In order to assure that exempt individuals voluntarily choose to enroll in a benchmark benefit plan, we revised § 440.320 to require States to track the number of voluntary enrollments and disenrollments in benchmark benefit plans by exempt individuals. Section 440.320 also requires States to act promptly on requests from exempt individuals for disenrollment and to ensure that these individuals have full access to standard State plan services while disenrollment requests are being processed.

Comment: One commenter said the provisions of the regulation on exempting populations and covering benefits should be consistent with the Americans with Disabilities Act (ADA).

Response: While exempt populations under this regulation are specified in section 1937 of the Act and CMS does not have authority under the statute to expand the definition of exempt

populations through the regulatory process, we would consider any implications of the ADA when reviewing a benchmark plan amendment and in monitoring implementation of the option by a State.

Comment: One commenter believed current regulations governing managed care in Medicaid that describe the information States must provide and how that information should be provided should be incorporated in the rule governing benchmark benefit plans. The information should include a comparison of features between Medicaid and the benchmark plan, whenever they differ.

Other commenters urged CMS to allow States to deviate from the lock-in provisions of Medicaid managed care regulations at 42 CFR part 438. They assert that, if beneficiaries covered by an alternative benefit package, rather than full Medicaid benefits, can pick and choose benefits during an enrollment period by plan-hopping, plans will have no way to establish cost-effective premiums tied to the limited benefit package. The commenters requested that CMS allow States providing alternate benefit packages to offer as little as a 30-day change period after initial assignment, and differences in covered benefits be excluded as a justifiable cause for beneficiaries to switch health plans after the change period.

Response: In light of the statutory changes made by CHIPRA, we revised the regulation at § 440.305 to incorporate compliance with Medicaid managed care requirements at section 1932 of the Act and at 42 CFR part 438 of Federal regulations. Thus, in providing information to beneficiaries who are offered managed care plans to obtain alternate benefit coverage, States are required to comply with the requirements at 42 CFR 438.10, and therefore must provide all enrollment notices, informational materials, and instructional materials relating to the enrollees and potential enrollees in a manner and format that may be easily understood. This informational material must include, among other things, information concerning enrollment rights and protections; any restrictions on freedom of choice among providers; procedures for obtaining benefits including prior authorization requirements; information on grievances and fair hearings procedures; information on physicians, the amount, duration, and scope of benefits; cost sharing, if any, and the process and procedures for obtaining emergency services.

With regard to deviating from the lock-in provisions of Medicaid managed care regulations at 42 CFR part 438, we believe that the disenrollment provisions of § 438.56, which provide for a 90-day period after initial enrollment in which a managed care enrollee may change plans is consistent with the requirements of section 1932(a)(4) of the Act and represents a reasonable time period for enrollees to decide whether the plan in which they are enrolled will best meet their needs. This trial period of enrollment is even more critical when the plan is offering a benchmark or benchmark-equivalent benefit package. We are not convinced that this limited period of time provides an incentive for enrollees to plan-hop in order to access specific benchmark benefits.

Further, CMS has specified three circumstances where cause for disenrollment exists and permitted States to develop other reasons, including but not limited to, the examples in § 438.56(d)(iv). Beyond these requirements, States have the flexibility to create additional causes for disenrollment as best serves their beneficiaries and the Medicaid Program.

Comment: Some commenters believed that CMS should require that all non-managed care plans ensure adequate access to providers that accept assignment of benefits and bill benchmark plans directly.

Response: Access standards apply to all aspects of the Medicaid program, including benchmark and benchmark-equivalent plans. If States choose to offer benchmark or benchmark-equivalent plans to Medicaid beneficiaries, States must assure that access to providers and claims payment are in compliance with current Federal regulations.

Comment: One commenter raised the potential problems of billing alternate benefit insurers. The commenter believed CMS should ensure that benchmark plan options should impose no additional administrative burdens on participating Medicaid providers. Providers should not be depended upon to refund payments and re-bill plans in the event that a plan is billed for a Medicaid individual who is retroactively enrolled into a different plan. Individual plan requirements should be streamlined into the existing system to minimize complexity to the already complex billing requirements.

Response: Provider billing procedures will vary among the States based on the particular health care delivery system in the State at issue. We do not anticipate that provider billing under an alternative benefit program will necessarily differ from the way in which providers currently bill for Medicaid services, or that providers will have to establish new processes and systems to calculate, track, bill, and report benchmark services. Moreover, because most States already offer managed care enrollment, they already have experience ensuring coordination of provider claims among different managed care entities. Thus, we do not believe that the offering of alternate benefit packages will impose significant administrative burdens on providers.

Comment: One commenter stated the regulation should require plan to plan reconciliations of payment in instances where beneficiaries have switched from one benefit plan to another, and in order to minimize confusion about plan enrollment and benefits, benchmark plans should be required to coordinate the receipt of beneficiary ID cards with the beneficiary's effective date of enrollment.

Response: We acknowledge the commenter's concern regarding coordination of beneficiary enrollment in a plan and reconciliation of payment to providers. These are implementation and administrative issues that are, at least initially, best addressed by the State. We expect the State to appropriately coordinate enrollment and payment processes in a fashion that minimizes confusion and we expect the State to ameliorate coordination of payment issues so that providers are paid appropriately and in a timely fashion. However, we believe that these issues need not be addressed in regulation at this time, and that most States already have systems in place to coordinate enrollment and provider payments between managed care plans. Should there be evidence of problems CMS will revisit this issue.

Comment: One commenter asserted that the final rule should require States to provide an exceptions process in which beneficiaries can obtain services not covered by a benchmark plan when they are medically necessary, and to educate beneficiaries about how to pursue this essential safeguard.

Similarly, States should also be required to provide hardship exemptions if beneficiaries are unable to meet cost sharing requirements in benchmark plans and should review each beneficiary's eligibility category to ensure they meet statutory requirements for assignment to benchmark plans.

Response: CMS agrees with the commenter that States should review each beneficiary's eligibility category to ensure they meet statutory requirements for assignment to benchmark plans. The requirements for when mandatory enrollment can occur are outlined in § 440.431 and specify that only certain

groups of full benefit eligibles can be mandatorily enrolled in benchmark benefit packages. We are requiring in § 440.320 that exempt individuals be fully informed regarding the choice for enrollment in benchmark or benchmark-equivalent plans and that they affirmatively enroll in benchmark and benchmark-equivalent plans. We are also requiring that States comply with the Medicaid managed care regulations including the information requirements for enrollees and potential enrollees.

We are not requiring that States provide a process for beneficiaries to obtain services not covered by a benchmark plan when they are medically necessary, except with respect to children, because such a process is not authorized by section 1937 of the Act. Benchmark or benchmark-equivalent plans offered to beneficiaries constitute the individual's medical assistance health care coverage. Children must be provided access to the full range of EPSDT services, as defined in section 1905(r). While section 1905(r) of the Act specifically requires that States provide children necessary health care, diagnostic services, treatment and other measures described in section 1905(a) related to conditions discovered by a screening service, we believe that any encounter with a health professional practicing within the scope of his or her practice should be considered to be a screening service for the purpose of the EPSDT requirement.

It is important to note that for those who voluntarily enroll in benchmark or benchmark-equivalent plans, such individuals must be permitted to revert to traditional Medicaid coverage at any time. Requests by individuals to disenroll must be acted upon promptly. Furthermore, we included at § 440.320 a requirement for States to have a process in place to ensure that any disenrollment request is processed promptly and the individual is immediately able to access services described in the standard Medicaid State plan while the State is processing the individual's disenrollment request.

In terms of cost sharing, States are required to ensure that benchmark or benchmark-equivalent plans comply with the cost-sharing requirements at sections 1916 and 1916A of the Act, which includes the provision that premiums and/or cost sharing not exceed 5 percent of the family's income. Consistent with section 5006 of the ARRA, States are required to ensure that eligible Indians are neither charged premiums nor required to participate in cost sharing for services provided by IHS providers or through contract health services through IHS providers. The Act also provides that States may implement undue hardship provisions for premiums and may permit providers to waive cost sharing on a case-by-case basis.

Comment: One commenter believed alternative plans should include a provision for mandatory cost sharing, where applicable, in return for treatment or services. Uncollected cost-sharing places an unfair financial burden on providers.

Response: States are required to ensure that benchmark or benchmark-equivalent plans comply with the cost-sharing requirements at sections 1916 and 1916A of the Act. These sections provide that States can impose premiums and cost sharing on certain Medicaid beneficiaries, and Section 1916A provides for enforcement of such premiums and cost sharing on certain Medicaid beneficiaries (certain limitations do apply). The enforcement of premiums and cost sharing through the denial of medically necessary services is at a State's option. CMS is not requiring that cost sharing be mandated in return for treatment or services, since this would be inconsistent with the statutory language provided by Congress in the DRA and could impose considerable hardship and result in the denial of necessary health service for beneficiaries.

Comment: One commenter mentioned that because of the potential for harm to beneficiaries, this rule should mandate strong requirements for meaningful public input at both the Federal and State level when States propose use of alternative benefit packages. Only a full open process in which all stakeholders can participate will provide the thorough, thoughtful analysis needed to determine whether specific changes will foster genuine efficiency or threaten beneficiaries' access to appropriate care.

These commenters noted that the State plan amendment process provides almost no meaningful opportunity for public input. They noted that States can implement changes the day after publishing a notice, with no requirement to acknowledge or address comments.

The commenter suggested that meaningful opportunities for public comment could include well-publicized and easily accessible public hearings, ample opportunity for stakeholders to provide written comments, and a requirement that State and Federal officials provide written responses to comments.

Response: We agree that States must seek public input concerning plans to offer alternative benefit packages. Thus, we are requiring in § 440.305 "Scope" that States secure public input prior to any submission to CMS of a proposed State plan amendment that would provide for an alternative benefit package. We are not requiring any specific process to secure public input, in order to permit States flexibility to design and use a public input process that meets State needs, but we intend these processes to be meaningful and will be reviewing how they are conducted to assure compliance with the law.

Comment: One commenter suggested that CMS require States to include in Medicaid contracts with alternative benefit packages provisions that require fair reimbursement for providers at rates no less than rates paid under the traditional Medicaid program, including a reasonable dispensing fee for pharmacy providers.

Further, the commenter believed that CMS should prohibit States from procuring contracts that contain mail order prescription requirements for Medicaid-eligible individuals. The commenter asserts that Medicaid-eligible individuals who are required to enroll in benchmark plans should have the option of receiving pharmacy services in a retail pharmacy setting. CMS should also require that contracts contain an assurance that allows extended quantities of medications from retail pharmacies for Medicaid-eligible individuals receiving treatment for chronic illnesses.

Response: States are required to submit State plan amendments to establish rates and rate methodologies for all fee-for-service institutional and non-institutional services as part of their approved Medicaid State plan. Benchmark plans that utilize fee-for-service delivery systems must follow the State plan reimbursement process. This process is detailed at § 447.200 and § 447.201 and includes a public notice requirement detailed at § 447.205. We published general rate setting regulations for drugs at 42 CFR part 447 subpart I and for managed care entities at § 438.6(c), and we expect States to follow these rules when setting rates for benchmark and benchmark-equivalent plans.

With regard to benchmark benefit plans that use managed care as the delivery system, the requirements for actuarial soundness at part 438 apply in the same way they apply to any Medicaid managed care entity, but we do not have statutory authority to review or approve reimbursement rates to contracted providers under managed care arrangements once the premium has been certified as actuarially appropriate for the populations and

services in the contract. We do however, have the authority and responsibility to review the provider network to determine that individuals have adequate access to all medically necessary services.

With regard to mail order prescriptions, section 1937 did not address or limit the use of mail order prescription requirements, or otherwise address or limit the coverage of, or payment for, prescription drugs.

Comment: One commenter recommended that CMS include in its rule an evaluation of the impact on beneficiaries of the benchmark benefit packages.

Response: CMS points the commenter to the "Regulatory Impact Analysis" in section VI.B "Anticipated Effects" of this regulation.

D. 440.310 Applicability

Comment: One commenter disagreed that the medically needy population should be exempt from participating in benchmark plans. The commenter believed the rule should permit voluntary enrollment of medically needy into benchmark plans in States such as Minnesota which provide full benefits across the board to both categorically and medically needy. Section 1937 of the Act only expressly prohibits required participation by the medically needy but is silent as to whether they can be voluntarily enrolled. It is illogical for CMS to interpret Congressional intent to permit scaled back benefit coverage for the categorically needy, while shielding the medically needy from scaled back benefit packages.

Response: We agree with the commenter's suggestion that medically needy populations may be offered voluntary enrollment in an alternative benefit package. Thus, we revised the rule at § 440.315 "Exempt Individuals" to indicate that benchmark and benchmark-equivalent benefits can be offered as a voluntary option to medically needy or those eligible as a result of a reduction of countable income based on costs incurred for medical care. We recognize that applying benchmark benefit plans to medically needy individuals can be cumbersome depending on the arrangements for benchmark coverage. If the State administers its own benchmark benefit plan, enrolling and disenrolling these individuals would be no more problematic than standard Medicaid enrollment.

E. Section 440.315 Exempt Individuals

Comment: One commenter believed that these alternative benefit packages should provide exemptions to additional Medicaid coverage groups. Other commenters suggested that CMS use its discretion to expand the categories of exempt individuals to include adults with serious mental illness and children with serious emotional disturbances.

Some commenters believed that all people with mental illness should be exempt.

Response: The statute does not authorize CMS to exempt additional categories of individuals from mandatory enrollment in alternate benefit package. We have included the medically needy with the list of exempt populations because the medically needy population is effectively exempted from mandatory enrollment by exclusion from the definition of "full benefit eligible".

We have defined "medically frail" and "special medical needs" individuals who are exempt from mandatory enrollment. At a minimum, States must include children with serious emotional disturbances, individuals with disabling mental disorders, individuals with serious and complex medical conditions, and individuals with physical and or mental disabilities that significantly prevent them from performing one or more activities of daily living. Accordingly, we revised the regulation at § 440.315(f) to reflect this change. These are minimum standards and States have the flexibility to expand this definition.

Comment: One commenter requested a definition for exempt individuals "who qualify for Medicaid solely on the basis of qualification under the State's TANF rules." The commenter noted that no individual can qualify to receive Medicaid benefits solely on the basis of their TANF eligibility, since TANF is not linked to Medicaid.

Response: In the proposed rule we published on February 22, 2008, we stated that we interpreted the exemption from mandatory enrollment in section 1937(a)(2)(B)(ix) of the Act to apply only to those individuals who qualify for Medicaid because the State has elected to link Medicaid eligibility to TANF eligibility. Under the law, since passage of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA), Medicaid eligibility is not tied to TANF eligibility. While many States automatically enroll people receiving TANF in Medicaid they do so because the design of the TANF and Medicaid rules means that, in fact, all TANF individuals qualify under the Medicaid rules. There is no direct eligibility link under law, however, between TANF and Medicaid.

We have determined that our proposed regulation did not adequately take into account the references in section 1937 to title IV–A, and section 1931 of the Act. Section 1902(a)(10)(A)(i)(I) of the Act still requires States to cover, in their Medicaid programs, individuals receiving cash assistance under part A of title IV. However, section 1931 of the Act provides the rules for determining whether an individual is treated as a recipient of title IV–A assistance for purposes of Medicaid eligibility. Under section 1931 of the Act, references to title IV–A must be considered to be references to the IV–A State plan that was in effect prior to the date that title I of PRWORA took effect. In other words, the AFDC cash assistance rules are carried over to Medicaid eligibility under section 1931, (States may adopt less restrictive rules under section 1931(b)(2) of the Act), but actual eligibility for or receipt of cash assistance is not a requirement under section 1931. Accordingly, we are revising our regulation at § 440.315(i) to provide that parents or caretakers who qualify for medical assistance on the basis of eligibility to receive assistance under a State plan funded under part A of title IV, as determined under section 1931 of the Act, are exempt from the requirement to enroll in benchmark or benchmark-equivalent coverage. These are the parents who, at a minimum, States must cover under section 1931. We are also clarifying that we interpret the reference to "parents" in section 1937(a)(2)(B)(ix) to include caretakers, as defined in section 1931. We are not requiring that parents or caregivers who qualify for Medicaid on the basis of more liberal income or resource methodologies which a State uses pursuant to the option available under section 1931(b)(2)(C) be exempt from mandatory enrollment in benchmark or benchmark-benefit plans, although States may, at their option, exempt some or all such individuals.

Comment: A commenter stated the proposed rule defines the exempt "special medical needs" group to include two of the three groups that are also exempt from mandatory enrollment in managed care plans under section 1932(a)(2) of the Act: "Dual eligibles" and certain children. However, the proposed rule does not exempt the third group that is exempt from mandatory enrollment in managed care plans, American Indians/Alaska Natives. Several commenters believed that the same compelling policy reasons for excluding American Indians/Alaska Natives from mandatory managed care

support excluding them from mandatory enrollment in benchmark plans, and requested that we revise the rule to be consistent with current policy described in the Medicaid managed care rule of 2002.

Response: In the proposed rule we mistakenly confused two distinct groups in our definition of "individuals with special needs" and included individuals eligible for Medicare as a special needs population when it is identified in section 1937 as a separate exempt population. We have therefore deleted that reference. Section 1937(a)(2)(iii) of the Act exempts individuals entitled to Medicare benefits (dual eligibles), regardless of medical need, from mandatory enrollment in an alternative benefit package. There is a separate statutorily exempt category at section 1937(a)(2)(vi) of the Act for individuals who are medically frail or have special medical needs. This final regulation includes both of these groups separately.

Specifically, in the proposed rule, we specified that "individuals with special needs" means the populations identified in § 438.50(d)(1) and § 438.50(d)(3). The reference to § 438.50(d)(1) was an erroneous reference to the dual eligible population discussed above. The reference to § 438.50(d)(3) was made because that population was a pre-existing definition of the statutory term "children with special medical needs" contained at section 1932(a)(2)(A) of the Act. We did not include a separate definition of adults with special medical needs in the proposed rule.

After reviewing public comment, we have determined that States should be allowed flexibility to adopt reasonable definitions of "individuals with special medical needs" as long as that definition includes, at a minimum, the children specified in § 438.50(d)(3), children with serious emotional disturbances, individuals with disabling mental disorders, individuals with serious and complex medical conditions and individuals with physical, and/or mental disabilities that significantly impair their ability to perform one or more activities of daily living.

We recognize that Congress included special protections for American Indians under the managed care provisions at section 1932(a)(2)(C) of the Act, but those special protections were not included under section 1937 of the Act. It is possible that the managed care protections were based on the fact that American Indians have access to the IHS and tribal health care delivery system, and there was concern about mandating enrollment in a managed care plan that would not be consistent with that health care delivery system.

While American Indians/Alaska Natives are not a statutory group that is exempt from enrollment in an alternative benefit package, they remain exempt from mandatory enrollment in managed care when such an option is utilized under section 1932 of the Act. As a result, a State that operates an alternative benefit package through managed care providers must provide American Indians/Alaska Natives with a health care delivery system that is consistent with the special protections related to managed care enrollment contained in section 1932(a)(2)(C) of the Act as well as section 1932(h) of the Act, added by ARRA, that addresses the requirement that American Indians/Alaska Natives enrolled in managed care have access to IHS providers.

Comment: One commenter believed that States may be discouraged from pursuing the benchmark option because of the extra work required for determining eligibility, along with the fact that potential savings may be limited. The commenter asked that CMS not impose any additional definition of sub-groups that must be identified and carved out of benchmark plans.

Response: The benchmark benefit is an option that States may elect to utilize within their Medicaid State plan when the State determines its value for a defined population. The additional steps needed in determining eligibility are necessary to assure that the benefit plan is targeted appropriately. The ultimate value of a benchmark benefit plan to both the State and beneficiaries is dependent upon the clear definition of eligibility for the defined benefit package. The exempt categories were established by statute and must be evaluated as a condition of providing a benchmark or benchmark-equivalent benefit.

Comment: One commenter asked for additional clarification of the phrase "or being treated as being blind or disabled" in § 440.315 of this regulation.

Response: This phrase needs to be interpreted in light of the particular eligibility conditions in that State. For example, the phrase could refer to States that qualify under section 209(b) of the Act, since States with this classification can have a more restrictive definition of blindness or disability. The term could also refer to one of the working disabled groups, since one group has a categorical requirement that the person have a medically determinable severe impairment, which does not exactly match the criteria for a determination of "disabled." Additionally, Territories operate on a different definition of blindness and disability than the 50 States.

Comment: Some commenters stated that the proposed rule exempts from mandatory enrollment the "medically frail." Several commenters suggested this term be given specific meaning in the rule. They suggested it include anyone who is eligible for or is receiving Medicare or Medicaid services for home health, hospice, personal care, rehabilitation or home and community-based waivers, or who is at imminent risk of need for these types of services.

Another commenter suggested this group be defined as individuals with multiple medical conditions and/or a chronic illness.

Response: After considering public comment on the issue, we have included in the text at § 440.315(f) guidance on how States must, at a minimum, define "medically frail." Additionally, we will require that States offering alternative benefit packages inform CMS as to their definition of "medically frail." States will be required to include information regarding which population groups will be mandatorily enrolled in the benchmark program and will need to ensure that enrollment is optional for exempt populations, including individuals defined by the State as "medically frail." Additionally, the required public input process should include informing interested parties of the State's proposed definition of "medically frail."

Comment: Another commenter suggested CMS use the existing definition of children with special health care needs which is defined by the Department of Health and Human Services, Health Resources and Services Administration, Maternal and Child Health Bureau (MCHB) as: "Children with special health care needs:" "Children who have or are at increased risk for a chronic physical, developmental, behavioral, or emotional condition and who also require health and related services of a type or amount beyond that required by children generally."

Other commenters believed the definition of "special medical needs individuals" should include adults who meet the Federal definition of an individual with serious mental illness and children who meet the Federal definition of children with serious emotional disturbance, as promulgated by the Substance Abuse and Mental Health Services Administration (SAMHSA). The SAMHSA definition would include some individuals who, for one reason or another, are not eligible as persons with a disability, but

nevertheless are significantly impaired by their mental disorder.

Response: In the February 22, 2008 proposed rule, we defined "individuals with special medical needs" to be consistent with § 438.50(d)(3), which implements and interprets the term "children with special medical needs" used in section 1932(a)(2)(A) of the Act. This definition refers to children under age 19 who are eligible for SSI, section 1902(e)(3) of the Act, TEFRA children, children in foster care or receiving other out of home placement, children receiving foster care or adoption assistance services or who are receiving services through a community based coordinated care system.

We appreciate commenters' suggestions of additional populations of children and adults for inclusion in the definition of special medical needs. In this final rule, we are allowing States the flexibility to adopt a reasonable definition of the term "special medical needs" and we expect States to consider, at a minimum, all of these individuals for inclusion in the definition of "individuals with special medical needs."

To maintain State flexibility, we have provided guidance to States in our discussion of these terms and in the regulation at § 440.315(f) and we are requiring that the exempt population include, at a minimum, those children identified in § 438.50(d)(3), children with serious emotional disturbances, individuals with disabling mental disorders, individuals with serious and complex medical conditions and individuals with physical and or mental disabilities that significantly impair their ability to perform one or more activities of daily living.

Also, as stated previously, CMS will require that States offering alternative benefit packages inform CMS as to their definition of "medically frail" and "special medical needs." States will be required to ensure that exempt populations, including individuals with "special medical needs" or who are "medically frail" are not mandatorily enrolled in alternative benefit packages, but are instead offered an informed choice. Additionally, CMS will interpret the required public input process to include informing interested parties as to the proposed definition of "special medical needs."

F. Section 440.320 State Plan Requirements—Optional Enrollment for Exempt Individuals

Comment: One commenter supported our regulation at § 440.320 and appreciated the willingness of CMS to provide for optional enrollment of otherwise exempt individuals. Several other commenters urged CMS to require States to provide more information and assistance to exempt individuals who are given the option to enroll in alternative coverage.

Response: We agree with the commenter that if States plan to offer enrollment in a benchmark plan to exempt individuals, the State must provide information and assistance to exempt individuals or their legal guardians/caregivers who are given the option to enroll in alternative coverage plans so they can make an informed choice. We proposed in § 440.320 that States must inform the individuals that enrollment is voluntary and that the individual may disenroll from the benchmark or benchmark-equivalent benefit package at any time and regain immediate access to the standard full Medicaid program under the State plan while the State processes their disenrollment request. We also proposed that States must inform the individual of the benefits available under the benchmark or benchmark-equivalent benefit package and provide a comparison of how the benefits, and if relevant, the cost share differ from the benefits and cost share available under the standard full Medicaid program. We also required that the State document in the individual's eligibility file that the individual was informed and voluntarily chose to enroll in the benchmark or benchmark-equivalent benefit package.

After considering public concerns as to the importance of the informed choice process, we revised the regulation at § 440.320(a) to require the State to effectively inform exempt individuals about the voluntary nature of their enrollment, and that they may choose to disenroll at any time from the benchmark or benchmark-equivalent plan in order to have immediate and full access to the standard Medicaid benefits, the benefits available under the benchmark benefit plan, the cost associated with the benchmark benefit plan, and to provide a comparison between the benefits available under the benchmark benefit plan and cost share, to the benefits and cost share provided by the standard, full Medicaid program. To support these requirements we have also included the requirement that the State document in the individual's eligibility file that the individual elected to enroll in the benchmark plan after receiving such information regarding benefits and disenrollment rights.

As part of the State Plan Amendment (SPA) approval process whereby States receive approval from CMS to implement new benefits under their State plan, States must define their disenrollment process and include a specific time period for disenrolling a beneficiary and assuring full access to standard Medicaid coverage. To the extent that the informed choice process continues to raise concerns, we will consider the development of additional guidance as to what processes are necessary to insure that the informed choice process is effective.

Comment: One commenter said that "exempt" populations should not be allowed to enroll in an alternative benefit plan at all.

Response: The statute states that exempt individuals may not be required to enroll in an alternative benefit plan, and with the protections noted, it is reasonable to give such individuals the opportunity to enroll in such plans. Alternative benefit plans may in fact have richer benefits than traditional State plan services and be targeted to the specific needs of exempt individuals. We are aware, however, that the benchmark plan may not provide all the services as the traditional plan and that exempt groups should not in any way be enrolled in such plans involuntarily, or without full knowledge of the consequences. Accordingly, this regulation provides new protections to assure that exempted individuals are fully informed about their options for enrolling and disenrolling from an alternative benefit plan.

Comment: One commenter believed the proposed rule was silent on the requirement that the State provide information in plain language that is understood by the individual, parent, or guardian including clear instructions on how to access EPSDT services not provided by the benchmark plan and how to disenroll from the benchmark plan. One commenter suggested that CMS establish literacy and translation standards for benefit information sheets and another commenter requested that at a minimum, information should be provided in the beneficiary's spoken language and at an appropriate reading level.

Response: We agree that it is important to provide information in plain language and individuals should be provided clear instructions on how to access EPSDT services not provided by benchmark plans. Furthermore, individuals should also receive information on how to disenroll from benchmark plans. We are requiring in § 440.320 that States effectively inform exempt individuals of the choice, and provide sufficient information in order to make an informed choice, including a comparison of benefits and any cost

sharing. Exempt individuals must be afforded the opportunity to disenroll from benchmark or benchmark-equivalent coverage promptly and without any loss of access to the full standard Medicaid benefits, if they determine that the coverage is not meeting their health care needs.

Comment: Some commenters stated that the rules should provide for immediate revocation of any voluntary election at the discretion of those exempt individuals who elect an alternative plan. These commenters urged that revocation be permitted through telephone, in writing, in person, by electronic communication, or by a designee, so as to make revocation as simple as possible and as quick as possible for beneficiaries. The commenters also asserted that the State should be required to provide immediate notification to such individuals of the right to revoke their election if they fall into an excluded category. The commenters urged that coverage and payment should not be interrupted during changes in election and marketing should not be permitted by alternate plans to excluded groups.

These commenters asked that the disenrollment process from benchmark plans allow a seamless transition to and from the selected program and minimize the administrative burden on the provider while ensuring care delivery is not interrupted.

Response: We agree that coverage and payment should not be interrupted during changes in election. It is important that coordination of care continue during any time of transition either from one Medicaid eligibility group to another or from one benefit program to another. Thus, in considering the commenters' suggestions, we have provided in § 440.320 that, for individuals who voluntarily enroll and later determine they want to return to traditional Medicaid and/or for individuals who are later determined eligible for an exempted group, disenrollment requests must be acted upon promptly and States must have a process in place to ensure full access to standard Medicaid State plan services while disenrollment requests are being processed. Furthermore, we expect that for individuals who voluntarily enroll and later decide to return to traditional Medicaid and/or for individuals who are later determined eligible for an exempted group, the State will process disenrollment requests consistent with the managed care regulations at § 438.56(e), and the effective date of disenrollment must be no later than the first day of the second month following the month in which the enrollee files the request.

Comment: Some commenters recommended that CMS enhance the proposed rule to include a section on CMS oversight containing a requirement that CMS approve State informational materials that provide comparative information and information on choice. Other commenters were concerned that inappropriate marketing activities such as those they believe are being used by some Medicare Advantage plans, may be adopted by benchmark plans. These commenters urged CMS to be aware of the potential for inappropriate marketing tactics, require States to oversee marketing activities, and impose limits on marketing to ensure individuals are not enrolled under false pretenses.

Response: To the extent that benchmark and benchmark-equivalent benefit packages are provided through managed care plans, States must comply with the Medicaid managed care rules at 42 CFR part 438. Marketing requirements for managed care plans are described in § 438.104. States must consider these requirements in contracting with these entities.

We will monitor implementation to determine if additional measures are needed.

Comment: Other commenters indicated that CMS should require strong beneficiary protections for people, including frail older and disabled beneficiaries, who have the opportunity to voluntarily enroll in benchmark plans. The commenters indicated that these protections should include objective counseling to make sure they understand the potential for higher costs and make truly informed decisions, a ban on aggressive and coercive marketing such as door-to-door sales, a requirement to document network adequacy for additional populations, and ongoing monitoring to ensure that these beneficiaries are getting the care they need. Some commenters indicated that, even with full information, individuals who voluntarily enroll may be likely to make an inappropriate election. They suggested a professional counselor independent of the plan be available to review their plan selection.

Response: We believe a professional counselor or enrollment broker would be a reasonable administrative protection that could be adopted by a State, but we are not requiring it. This is an operational issue that may depend on the circumstances of a particular State's program. States who contract with an enrollment broker can receive administrative match from CMS at the 50 percent match rate. To the extent that the State offers alternative benefits through managed care plans, enrollment brokers must operate consistently with the requirements at § 438.810. Consistent with the managed care rules at § 438.10, States are encouraged to provide information at least annually as to an individual's enrollment choice under the benchmark option or the traditional State plan option. This could be accomplished at the point of re-determining eligibility for enrollees.

Additionally, if a change in eligibility status has occurred (for example, non-pregnant female mandatorily enrolled in the benchmark plan becomes pregnant and is no longer eligible for mandatory enrollment), the State will have to provide such individuals with information about their benefit options as soon as the State becomes aware of the change in eligibility. If the individual chooses to disenroll, the individual must have full access to standard Medicaid State plan services that may not be available in the benchmark plan while the State implements the disenrollment process.

Comment: Several commenters believed exempt individuals will be automatically enrolled without their expressed consent and wanted an assurance that this will not occur. These commenters urged CMS to safeguard exempt individuals from being enrolled in benchmark or benchmark-equivalent plans without their prior informed consent by more expressly prohibiting States from taking an automatic enrollment or default enrollment approach to their enrollment. They suggested that the proposed language could allow or even encourage States to adopt an automatic or default enrollment approach without further clarification because the language could be read to allow States to initially enroll all exempt persons who do not affirmatively choose not to enroll. These commenters indicated that failure to clarify this point would be construed as approval of opt-out practices and would not protect against any form of automatic or "presumed voluntary" enrollment.

Response: Section 1937 of the Act provides that exempt individuals cannot be mandatorily enrolled in benchmark or benchmark-equivalent plans. We proposed to permit States to offer exempt individuals a voluntary option to enroll, based on informed choice. In order for exempt individuals not to be mandatorily enrolled and to have made an "informed choice" about enrollment, the choice must take place before enrollment in the benchmark or benchmark-equivalent plan. We have

amended the final rule to make this clear and to require the State to inform the exempt individual of the benefits available under the benchmark or benchmark-equivalent package and the cost of such a package. Furthermore, these actions should occur before the receipt of services in a benchmark or benchmark-equivalent plan. We mentioned earlier that we require that the individual's file be documented to reflect that an exempt individual is fully informed and has chosen to be enrolled in a benchmark or benchmark-equivalent plan. CMS, in response to these comments, has made it clear that individuals cannot be enrolled until an informed election is made.

In terms of CMS monitoring, we provide in Federal regulations at § 430.32 for program reviews of State and local administration of the Medicaid program. In order to determine whether the State is complying with the Federal requirements and the provisions of its Medicaid plan, we may conduct reviews that include analysis of the State's policies and procedures, on-site review of selected aspects of agency operation, and examination of individual case records. We also require in § 440.320 that the State track and maintain the total number of individuals that have voluntarily enrolled in a benchmark benefit plan and the total number of individuals that have elected to disenroll from the benchmark benefit plan.

Comment: One commenter believed that the rule should describe the level of detail required in the State's description of the difference between State Plan benefits and benchmark-equivalent plan benefits because the commenter believed it is important that there be a detailed, written comparison.

Response: We agree with the commenter on the importance of the benefit comparison. We have required that if the State chooses to offer benchmark or benchmark-equivalent benefit options to individuals exempt from mandatory enrollment such individuals must be given, prior to benchmark enrollment, a comparison of traditional State plan benefits and the benefits offered in the benchmark or benchmark-equivalent benefit package, as well as any differences in cost sharing. In order for exempt individuals to make an informed choice, the information must be fully detailed by the State in a format that is understandable by the beneficiary.

Comment: A commenter believed CMS should prohibit States from implementing procedures that make it more difficult for beneficiaries to stay in the regular Medicaid program than to enroll in benchmark benefit plans. Beneficiaries should not be asked to make a choice without being afforded a reasonable time to evaluate the options. Another commenter was concerned that a State could reduce its standard Medicaid State plan services in order to force exempt beneficiaries to enroll in a benchmark or benchmark-equivalent plan.

Response: We agree that individuals should be given a reasonable time to evaluate the options in considering traditional Medicaid benefits versus benchmark or benchmark-equivalent options. In order for individuals to make an informed choice, individuals must have ample time to consider the options available. Therefore, we have revised the regulatory provision at § 440.320(a)(3) to require that the State document that the individual had ample time for an informed choice. We are not prescribing standards for what constitutes "ample time" because we believe this may vary based on the circumstances and/or individual involved. With regard to States reducing their standard Medicaid State plan services, section 1937 of the Act does not change State flexibility to reduce or add optional 1905(a) medical services. However, if such changes are done for the purpose of coercing exempt individuals to enroll in benchmark plans, such action may not be consistent with the requirement that exempt individuals must be permitted to make a fully voluntary decision to enroll in a benchmark plan.

Comment: Another commenter believed CMS should require States to institute expedited processes to transition out of benchmark plans those individuals who become eligible for exempted categories.

Response: We agree with the commenter that States should provide for timely transition of individuals if they become eligible for exempt categories and thus are not required to be mandatorily enrolled in a benchmark plan. Congress clearly identified individuals who are exempt from mandatory enrollment in benchmark or benchmark-equivalent plans.

As mentioned previously, we have revised the final rule at § 440.320 to require that States inform exempt individuals that they may disenroll at any time and provide them with information about the disenrollment process. We have also revised § 440.320 to require that disenrollment requests be acted upon promptly and that States have a process in place to ensure full access to standard Medicaid State plan services while any disenrollment requests are being processed. We further revised § 440.320 to include a requirement for States to maintain data that tracks the number of voluntary enrollments in benchmark and benchmark-equivalent benefit plans and the number of disenrollments from these plans.

These requirements also apply to individuals who become part of an exempt population for which no mandatory enrollment can occur. It is incumbent upon the State to ensure that procedures are in place to notify these individuals of their change in status and to provide them with information explaining their right to disenroll from the benchmark or benchmark-equivalent benefit plan and return to the traditional Medicaid State plan. We believe that States should not rely on the individual's ability to recognize that their change in status permits them to revert back to traditional Medicaid and that they are entitled to the full range of Medicaid benefits. It is therefore the responsibility of the State to assure that these individuals have the choice to receive benchmark plan benefits, or the benefits available under the traditional Medicaid State plan.

Comment: One commenter asked for clarification on whether the benchmark or benchmark-equivalent benefit packages would apply to "unqualified individuals" who fall under the "exempt category" and who could be offered optional enrollment in a benchmark benefit package.

Response: We wish to clarify that unqualified individuals (aliens who are not lawfully admitted for permanent residence in the United States or otherwise do not meet the Medicaid eligibility requirements for aliens) for example, aliens who are residing in the U.S. illegally, are exempt individuals who cannot be mandatorily enrolled in benchmark plans because in most cases they are only eligible for emergency services under Medicaid.

Unqualified or undocumented individuals who are otherwise eligible for Medicaid (for example, meet income or residency requirements) are only covered for emergency medical services under section 1903(v) of the Act. Generally, the determination that such an individual has received an emergency medical service is made retrospectively by the State. Therefore, it is unlikely that a State would decide to offer the benchmark or benchmark-equivalent benefit option for these individuals, even if enrollment were voluntary.

G. Section 440.330 Benchmark Health Benefits Coverage

Comment: A few commenters questioned the coverage standards of a Secretary approved benefit package. They contended that under this option, CMS could approve coverage of any kind, one that may include or exclude any benefits the State chooses. They asserted that this failure to recognize any minimum set of required benefits in Medicaid could limit access to critical health care services. They argued that allowing States even greater flexibility, by not requiring that coverage meet benchmark levels, is inappropriate and is likely to result in more beneficiaries going without health care services until they become sick and require emergency treatment.

Another commenter agreed and stated that the proposed rule says, "Secretary-approved coverage is any other health benefits coverage that the Secretary determines * * * provides appropriate coverage for the population proposed to be provided this coverage." The commenter finds this statement troublesome. This provision gives the Secretary the wide discretion to approve a number of plans that are more flexible than the benchmark plan requirements as articulated in this rule. This provision would give States the option to craft qualifying plans that include or exclude any benefits that the State chooses.

The commenters urged CMS to remove this fourth option for Secretary-approved benchmark packages from the proposed rule.

Response: The statute provides States with the option of Secretary-approved coverage, and we believe we have provided for sufficient protections to ensure that this option will be consistent with the statutory purpose of meaningful health benefits coverage while also allowing State flexibility. In this final rule, we have articulated the general standard that Secretary-approved coverage must be appropriate coverage to meet the needs of the population provided that coverage. The regulations also provide a number of documentation requirements so that CMS can determine that this standard has been met. States are required to submit a full description of the proposed coverage. The State must include a benefit-by-benefit comparison of the proposed plan to one or more of the three benchmark plans specified in § 440.330 or to the State's standard full Medicaid coverage package under section 1905(a) of the Act, as well as a full description of the population that would receive the coverage. Additionally, States will be providing to CMS any other information that would be relevant in making a determination that the proposed coverage would be appropriate for the proposed population. In considering Secretary-approved coverage, we will review individual State designs on a case-by-case basis. To the extent that State designs deviate from the other options for benchmark coverage (for example, State employees coverage, etc.) or traditional Medicaid State plan coverage, we will consider the information provided as a result of the public input process and any other information States submit that would be relevant to a determination that the proposed coverage would be appropriate for the proposed population.

We believe that Secretary-approved coverage can be appropriate to meet the needs of the targeted population provided that coverage. To date, the majority of the approved benchmark plans are Secretary-approved benchmark plans and most of these include not only all regular Medicaid State plan services but provide for additional services like disease management and/or preventive services.

Comment: Some commenters believed that to allow States to establish alternative health benefit programs that do not include family planning services is counter-productive to ensuring the health of Americans and maintaining the sustainability of the Medicaid program. Also, a benchmark or benchmark-equivalent plan would not be appropriate for individuals of childbearing age if it did not include access to family planning services. The commenter believed that no health benefits package would be "appropriate" for individuals of childbearing age if it did not include access to family planning services and supplies, and asked CMS to revise the proposed rule to clarify that, in order to be considered "appropriate," a benchmark or benchmark-equivalent plan must include coverage of family planning services and supplies.

The commenter also urged CMS to amend the rule to allow beneficiaries to disenroll from any such alternative benefit plan and reenroll in traditional Medicaid if the plan does not cover family planning services and supplies.

Several commenters noted that family planning is basic preventive health care for women and that ensuring a woman's freedom of choice is critical in the delivery of these services. The commenters stated that birth control, the main component of family planning coverage, is the most effective way to: (1) Prevent unwanted pregnancies, (2) safely space pregnancies in the interest of the mother and child's health, and (3) keep women in the workforce. Furthermore, the commenters believed that birth control enables preventive behaviors and allows for the early detection of disease by getting women into doctor's offices for regular health screenings.

One commenter believed that the legislation authorizes the Secretary to approve benchmark plans that provide "appropriate coverage for the population proposed to be provided that coverage." Similarly, the legislation requires benchmark-equivalent coverage to include "other appropriate preventive services, as designated by the Secretary." Coverage offered to women of reproductive age cannot be considered "appropriate" if it excludes coverage of family planning services and supplies.

Some commenters asserted that permitting some plans to exclude coverage of family planning runs directly counter to three of the major goals articulated by the legislation's supporters: reducing Medicaid costs, promoting personal responsibility and improving enrollees' health.

Other commenters believed that approximately half of all pregnancies in the United States are unplanned and there is a strong correlation between unintended pregnancies and failure to obtain timely prenatal care. They stated that guaranteeing coverage of family planning services for women enrolled in Medicaid benchmark plans increases the likelihood that these women will be under the care of a health professional before pregnancy, and that when they do become pregnant they will obtain timely prenatal care as recommended by the American College of Obstetricians and Gynecologists.

The commenters urged the Department to revise § 440.330 to clarify that in order for Secretary-approved coverage to be considered appropriate coverage for women of reproductive age, it must include family planning services and supplies. In addition, the commenters urged the Department to modify § 440.335 to designate family planning services and supplies as a required preventive service that must be included in all benchmark-equivalent plans offered to women of reproductive age.

Response: If one of the statutorily-specified benchmark packages (that is, FEHB, State Employees plan, and commercial HMO plan) did not contain family planning services and supplies, the statute permitted States to base an alternative benefit package on that

specific benchmark plan. CMS had no authority to disapprove the use of a statutorily-specified benchmark plan as the basis for an alternative benefit package. However, at the time that this regulation was being revised the Patient Protection and Affordable Care Act (PPACA), (Pub. L. 111–148), had not yet been enacted. That law has now amended section 1937(b) of the Act to add additional requirements affecting benchmark and benchmark-equivalent coverage, including the requirements for coverage of family planning services and supplies. We intend to issue a second final rule implementing the changes made by PPACA with a shortened effective date to bring the provisions of this regulation into conformity with the statute.

Consequently, we are revising § 440.375 to update the title and revise the regulation at this section to indicate that States can provide benchmark or benchmark-equivalent coverage to individuals without regard to the requirements relating to the scope of coverage that would otherwise apply under traditional Medicaid benefit packages. The scope of coverage would still need to be consistent with the requirements for the scope of coverage contained in this subpart, which are based on the statutory benchmark or benchmark-equivalent coverage provisions.

With respect to Secretary-approved coverage, we agree with the commenters that if such a benchmark benefit plan is provided to individuals of child bearing age that does not include family planning services and supplies, it would not be appropriate to meet the needs of the population it serves and would have to therefore include these services. Additionally, if a non-Secretary approved benchmark plan such as a commercial HMO plan does not include family planning services and supplies, States have the option of adding family planning services to the benchmark, at the enhanced FMAP rate established for these services.

With respect to benchmark-equivalent coverage in § 440.335, we have added family planning services and supplies as required services. In addition we have added emergency services as other required appropriate preventive services designated by the Secretary, consistent with the strong emphases the Medicaid statute places on these preventive services.

Comment: Other commenters believed that one reason States may wish to design a plan under the option for benchmark-equivalent or Secretary-approved plans is to offer beneficiaries important services that are not otherwise covered by Medicaid or a standard benchmark plan. The commenters stated that this rule does not permit this. CMS should allow States to submit proposals that include other services and judge the overall plan proposed by the State to assess its efficiency.

Response: Section 1937 provides that benchmark-equivalent or Secretary-approved plans can be offered as benchmark plans, so long as the identified basic services are provided as part of the benchmark-equivalent benefits and the benefit package is appropriate to meet the needs of the population it serves for Secretary-approved coverage. The rule is consistent with the statute. The rule provides that the scope of a Secretary approved health benefits package or any additional benefits will be limited to benefits within the scope of the categories available under a benchmark coverage package or the standard full Medicaid coverage under section 1905(a) of the Act. This provision allows States flexibility to offer additional health care services that would not otherwise be offered. Additional services are limited to those in categories offered under a benchmark plan or section 1905(a) of the Act because section 1937 of the Act did not expressly authorize coverage beyond the defined scope of medical assistance, and these limits ensure that additional services will be of the type generally considered as health care services.

H. Section 440.335 Benchmark-Equivalent Health Benefits Coverage

Comment: One commenter urged CMS to clarify that plans cannot use actuarial methods that further reduce benefits because of cost-sharing limits.

Another commenter noted that the preamble of the proposed rule indicates that even if the benchmark plan has 50 percent coinsurance, the State would have to ensure that cost sharing does not exceed the applicable limits in Medicaid, which are substantially lower.

However, § 440.340 specifies that the actuarial report "should also state if the analysis took into account the state's ability to reduce benefits because of the increase in actuarial value of health benefits coverage offered under the State plan that results from the limitations on cost sharing * * * under that coverage." The commenter strongly urged CMS to clarify that this language does not allow States to reduce mental health benefits below 75 percent of the value of the benchmark benefits because there are lower co-payments in the benchmark-equivalent plan. Congress intended that individuals would get 75 percent of the value of the benefit; they did not intend to reduce the value of this benefit through cost-sharing limitations.

Response: We agree that clarification is needed in terms of using actuarial methods to further reduce benefits because of cost-sharing limits. We have specified in § 440.340 that, as a condition of approval of benchmark-equivalent coverage, States must provide an actuarial report with an actuarial opinion that the benchmark-equivalent coverage meets the actuarial requirements for coverage specified in § 440.335. We have also specified in § 440.340 that the actuarial report must—

- Be prepared by a member of the American Academy of Actuaries and must meet the standards of this Academy;
- Use generally accepted actuarial principles and methodologies of the Academy, standard utilization and price factors, and a standardized population representative of the population involved;
- Use the same principles and factors in analyzing the value of different coverage (or categories of services) without taking into account differences in coverage based on the method of delivery or means of cost control or utilization use;
- Indicate if the analysis took into account the state's ability to reduce benefits because of the increase in actuarial value of health benefits coverage offered under the State plan that results from the limitations on cost sharing under that coverage;
- Select and specify the standardized set of utilization and pricing factors as well as the standardized population; and
- Provide sufficient detail to explain the basis of the methodologies used to estimate the actuarial value.

In considering the actuarial value, we expect that the States and the actuaries making the determination of actuarial equivalence will account for changes in cost sharing between the benchmark-equivalent plan and the benchmark plan as well as account for any differences in income and assets between Medicaid beneficiaries and the enrollees in the benchmark plan. Cost sharing for the Medicaid benchmark-equivalent plan is still subject to the limitations set forth in this rule and in sections 1916 and 1916A of the Act. The determination of actuarial equivalence should provide an aggregate actuarial value that is at least equal to the value of one of the benchmark benefit packages, or if prescription drugs, mental health services, vision and/or hearing services

are included in the benchmark plan, an aggregate actuarial value that is at least 75 percent of the actuarial value of prescription drugs, mental health services, vision and/or hearing services of one of the benchmark benefit packages. Changes to the benchmark-equivalent plans, including changes in the cost-sharing structure that would result in expected benefit amounts less than under the benchmark plan or less than 75 percent of the actuarial value of prescription drugs, mental health services, vision and/or hearing services, would not be allowed under this rule.

Comment: Several commenters note that the standard for adopting a benchmark-equivalent coverage package is set at 75 percent of the actuarial value of that category of services in the benchmark plan and wants to understand if the percentage is set in statute. The commenters believe that if this percentage is not a statutory provision, it would be important to describe the basis for this standard.

Response: The DRA provides for this standard. Section 1937(b)(2)(C) of the Act specifies that the benchmark-equivalent coverage with respect to prescription drugs, mental health services, vision services, and/or hearing services must have an actuarial value equal to at least 75 percent of the actuarial value of the coverage of that category of services in the benchmark plan. We have maintained this standard in the rule consistent with the statutory provision.

Comment: One commenter requested that benchmark-equivalent plans be required to provide the full continuum of care including the care required by individuals with cancer.

Another commenter pointed out that the benchmark-equivalent plans are allowed to provide 75 percent of the actuarial value of mental health and prescription drugs. The commenter is concerned that if the plan used as a benchmark does not cover mental health treatment or prescription drugs, the new Medicaid benefit package does not have to provide this coverage.

Other commenters are concerned about language indicating that a benchmark-equivalent coverage package is not required to include coverage for prescription drugs, mental health services, vision services, or hearing services. The commenter believed all of these services are necessary medical services.

Response: Section 1937 of the Act does not specifically require that benchmark or benchmark-equivalent plans provide a full continuum of care, nor does it guarantee all services that might be considered medically necessary.

Furthermore, while all services described under section 1905(a) of the Act are provided based on medical necessity, not all of those services are considered mandatory Medicaid services that States must include in the standard Medicaid plan. Prescription drugs, certain mental health services, vision services, and hearing services are not mandatory services under the State plan for adults. The DRA specifies that if coverage for prescription drugs, mental health, vision and/or hearing is provided in the benchmark plan, the benchmark-equivalent plan must provide at least 75 percent of the actuarial value of the coverage. If coverage is not provided under the benchmark plan, the benchmark-equivalent plan is also not required to provide the coverage. In calculating the actuarial value of the benchmark-equivalent, the actuarial value would be calculated based only on the services included in the specified benchmark plan and not calculated based on services that are not included in that plan. This rule is consistent with the statutory provision.

Comment: Some commenters questioned how the State will assure the aggregate actuarial value is equivalent if there is lesser coverage in prescription drugs, mental health, vision, and/or hearing services.

Response: Section 1937(b)(2)(C) of the Act specifies that, in considering a benchmark-equivalent benefit, if prescription drugs, mental health, vision, and/or hearing are provided in the benchmark plan, the benchmark-equivalent must provide at least 75 percent of the actuarial value of that coverage. This section specifies the minimum coverage levels but does not specify the maximum level. Thus, States have the option to cover these services at higher than 75 percent of the actuarial value. To assure that the aggregate actuarial value is equivalent, we required in § 440.340 that, as a condition of approval of benchmark-equivalent coverage, States must provide an actuarial report that provides, among other things, sufficient detail as to the basis of the methodologies used to estimate the actuarial value of the benchmark-equivalent coverage.

Comment: Another commenter suggested that rehabilitation services should be added to the list of services included at § 440.335.

Response: The DRA specifies that benchmark-equivalent coverage must include certain basic services; that is, inpatient and outpatient hospital services; physicians' surgical and medical services; laboratory and x-ray services; well-baby and well-child care including age-appropriate immunizations; and other appropriate preventive services. We have also specified the inclusion of emergency services, and within the context of preventive services, family planning services and supplies, but have left States with the flexibility to define other appropriate preventive services.

It is important to note, however, that States, at their option, can provide additional services to benchmark or benchmark-equivalent plans. The inclusion of rehabilitation services may be appropriate for some populations as determined by the State based on the requirements of the population utilizing the benchmark plan. Additional services are discussed in § 440.360 of this rule.

We did not receive any additional comments to § 440.340, Actuarial report. Therefore, in this final rule, § 440.340 will be adopted as written in the proposed rule of February 22, 2008.

I. Section 440.345 EPSDT Services Requirement

Comment: Some commenters supported the proposed regulation that would require individuals to first seek coverage of EPSDT services through the benchmark or benchmark-equivalent plan before seeking coverage of services through wrap-around benefits. Some commenters believed that when individuals need to access additional services as a wrap-around either for children or adults, States should be required to ensure they continue to be able to receive services from the same provider.

Response: It is important for individuals to receive services from the same provider whenever possible and we believe that an individual's physician is in the best position to "manage" an individual's care. If an individual is entitled to additional services, the treating physician should be responsible for providing and/or coordinating the individual's care and should be aware of any additional services the individual needs. To ensure that individuals under the age of 21 receive full EPSDT services we revised § 440.345 to require States to not only include a description of how additional benefits will be provided, but also how access to additional benefits will be coordinated and how beneficiaries and providers will be informed of these processes.

Comment: Some commenters objected to the provision in the proposed rule that stipulates that individuals must first seek coverage of EPSDT services

through the benchmark plan before seeking coverage of these services through wrap-around benefits. These commenters asserted that Congress intended to allow States the option of providing these benefits directly to Medicaid beneficiaries or to provide benefits in whole or in part by the benchmark provider. They indicated that CMS provides no justification as to why children must first wrestle with the administrators of the benchmark benefit package before accessing EPSDT services. One commenter asked that the rule be amended to eliminate the requirement that a family first seek coverage of EPSDT services through the benchmark plans.

Response: We believe that children enrolled in a benchmark benefit plan should have a medical provider that serves as the "medical home" for the child and that this medical provider will coordinate the child's care and facilitate access to specialists and necessary support services.

It is the responsibility of the State Medicaid program to assure that individuals enrolled in benchmark and benchmark-equivalent benefit plans receive EPSDT services that can be accessed in the most beneficial and seamless manner possible, and that individuals under 21 and their parent, guardian or care giver are informed and understand how and where to gain access to these services. We therefore revised § 440.345 by removing the requirement that individuals must first seek coverage of EPSDT services through the benchmark plan before seeking coverage of these services through additional benefits. Additionally, to further ensure that these individuals have access to the full EPSDT benefit, we revised the requirement to include a description of how the additional benefits will be provided, how access to additional benefits will be coordinated and how beneficiaries and providers will be informed of these processes. States must ensure that information is given to the providers either through the State or through the managed care entity in order to ensure that providers are aware of the child's right to additional services, as necessary, through the EPSDT benefit so that they can assist individuals with accessing necessary care.

Comment: One commenter believed that families are unlikely to realize that their children have access to more coverage than that provided through the benchmark. Even if they understood, they may not know how to request such a service. The commenter suggested that this section be strengthened by requiring States to explain, in detail, how a family will be informed of their rights under EPSDT once they are enrolled in a benchmark plan and to explain the specific process the State will then go through to approve or disapprove these services. States should also explain timelines for consideration of EPSDT requests in emergency, urgent and routine cases.

The commenter goes on further to say the preamble to the proposed rule stated, "the State may provide wrap-around * * * under such plan." The commenter urged that CMS clarify that the word "may" should be replaced with "must" because the word "may" inaccurately suggested that States are not required to provide these services. The commenter noted that, in other areas of the proposed rule, CMS correctly stated that EPSDT services must wrap-around benchmark plans.

Response: We agree that States should be required to inform families of their rights under EPSDT. The commenter is correct that children enrolled in benchmark or benchmark-equivalent plans may be entitled to additional services. It should be noted that CHIPRA underscored that full EPSDT services must be provided. Therefore, we are clarifying that States must ensure that information is provided to all EPSDT eligibles and/or their families about the benefits of preventive health care, what services are available under the EPSDT benefit, where and how to access those services, that transportation and scheduling assistance are available, and that services are available at no cost. This is consistent with the requirements of section 1902(a)(43)(A) of the Act and current policy outlined in Section 5121 of the State Medicaid Manual. Information must be given to individuals no later than within 60 days of the individual's initial Medicaid eligibility determination, and annually thereafter if they have not utilized EPSDT services. We believe most States have booklets to inform individuals of their benefits, rights, responsibilities, etc. This information is typically presented to families by the eligibility worker at the time of application and/or sent to individuals as part of an enrollment packet from the managed care plan. These types of documents must clearly explain the benchmark and additional benefits available to EPSDT eligibles under the age of 21.

Additionally, we agree with the commenter that the word "may" was inaccurate in the preamble to the proposed rule. The law specifically requires States to provide additional services (if the full range of EPSDT services is not provided as part of the benchmark or benchmark-equivalent plan) to assure that all EPSDT services are available to eligible individuals. We are providing clarification here in response to the comment; however, we are not revising the regulation text, since the language in § 440.345 clearly indicates that this is a requirement rather than a choice.

Comment: One commenter stated that the rule was silent on the requirement that the state provide information in plain language that is understood by the individual, parent or guardian including clear instructions on how to access EPSDT services not provided by the benchmark plan and how to disenroll.

Response: We agree that it is important that individuals be provided with clear instructions in plain language on how to access EPSDT services not provided by the benchmark plan and how to disenroll. This is already required by the EPSDT outreach provisions of section 1902(a)(43) of the Act, which are applicable to alternative benefit packages. To the extent that alternative benefit packages are delivered through managed care plans, States must also comply with managed care rules at 42 CFR part 438. According to § 438.10, information provided must be in an easily understood language and format.

Comment: One commenter noted that proposed § 440.350 failed to specify that under the employer-sponsored insurance plan option States must still ensure that children have access to the wrap-around EPSDT benefit. This section should be amended to note this requirement.

Response: The requirement to provide EPSDT benefits to children under the age of 21 applies to benchmark and benchmark-equivalent coverage. We have provided that States can offer premium assistance for employer sponsored insurance if the insurance is considered a benchmark or benchmark-equivalent plan. Additionally, we have indicated in § 440.350(b) that the State must assure that employer sponsored plans meet the requirements of benchmark or benchmark-equivalent coverage, including the economy and efficiency requirements at § 440.370. By requiring that employer sponsored plans meet the requirements of benchmark or benchmark-equivalent coverage, and given that benchmark or benchmark-equivalent coverage must provide EPSDT to children under the age of 21 either as part of or in addition to the benchmark or benchmark-equivalent plan, we are requiring that any employer sponsored insurance coverage provide EPSDT services to children under the age of 21. We believe this is

clear in the regulation, so we have not revised the regulation text in this regard.

Comment: Another commenter believed that limiting the mandatory EPSDT benefit to children under age 19 rather than under age 21 denies 19 and 20 years olds access to critical health care services. The commenter stated that this provision is inconsistent with the title XIX definition of EPSDT. Removing EPSDT for 19 and 20 years olds may exacerbate existing health disparities for minority adolescents, compromise 19 and 20 years olds' ability to transition successfully into adulthood, and impede identification of physical and mental conditions.

Response: Section 611 of CHIPRA raised the age for mandatory EPSDT coverage from 19 to 21 years of age. We have changed the regulation text accordingly.

Comment: One State Medicaid official suggested, instead of the current language in the published proposed rule on (73 FR 9727) of the **Federal Register** regarding EPSDT, the following amendment be made to be consistent with Federal laws: "(a) The State must ensure access to EPSDT services, through benchmark * * * for any child under 19 years of age eligible under the State plan in a category under section 1902(a)(10)(A) of the Act."

Response: We have revised the rule to effectuate the clarification provided by section 611(a)(1)(C) and 611(a)(3) of CHIPRA which requires States to assure that children under the age of 21, rather than those under 19 as originally specified in the DRA, have access to the full range of EPSDT services.

I. Section 440.350 Employer-Sponsored Insurance Health Plans

Comment: One commenter requested information about enrollment in commercial plans and suggested a discussion of how such arrangements might actually be operationalized; that is, how premiums would be paid and tracked, and the level of Medicaid contribution to such plans.

Response: Benchmark or benchmark-equivalent benefit coverage may be offered through employer sponsored insurance health plans for individuals with access to private health insurance. If an individual has access to employer sponsored coverage and that coverage is determined by the State to offer a benchmark or benchmark-equivalent benefit package (either alone or in addition to services covered separately under Medicaid), a State may elect to provide premium payments on behalf of the individual to purchase the employer coverage. Non-exempt individuals can be required to enroll in employer sponsored insurance, and the premium payments would be considered medical assistance. The requirement for children under the age of 21 to receive EPSDT either as an additional service or as part of the benchmark coverage would still be applicable. The premium payments and any other cost-sharing obligations by beneficiaries would be subject to the premium and cost-sharing requirements outlined in sections 1916 and 1916A of the Act, including the requirement that cost sharing not exceed the aggregate limit of 5 percent of the family's income, as applied on a monthly or quarterly basis specified by the state.

If the employer plan is economical and efficient, States have the flexibility to take advantage of the coverage, without requiring a uniform employer contribution. It is likely that a substantial employer contribution would be necessary in order to meet the economy and efficiency requirement. States must identify the specific minimum contribution level that they are requiring of participating employers.

We have not approved any Medicaid benchmark programs at this time that provide for employer sponsored coverage; however, we have approved section 1115 demonstrations in which States have provided premium assistance payments and employer sponsored insurance coverage to Medicaid beneficiaries. For these section 1115 demonstration programs, some States have required beneficiaries to provide proof of premium assistance payments. Then, after such proof is received, the state reimburses the beneficiary directly. Some States use a voucher system in which they provide a monthly voucher directly to the beneficiary for the premium payment in purchasing the employer sponsored insurance. We are not specifying the way in which States operationalize employer sponsored insurance benchmark plans; however, we provide this information for consideration.

Comment: One commenter supported the inclusion of wrap-around services in general and wrap-around services for employer sponsored insurance plans as an option available to States, but did not support a requirement for additional wrap-around services. The commenter requested that language be added to describe the permissibility of various types of market innovations in coverage such as high deductible plans, health savings accounts, consumer-directed plans and wellness plans or that there be language added indicating such market innovations are acceptable as "Secretary-approved coverage" through a State plan amendment.

Response: Section 1937(a)(1)(C) of the Act provides that additional benefits are options that can be added by the State to benchmark or benchmark-equivalent coverage. Any services that are added do not need to include all State plan services; however, these additional services must be coverable under the benefit categories under the benchmark plan or under section 1905(a) of the Act.

The only requirement for additional services is at section 1937(a)(1)(A)(ii) of the Act, which provides that if children under the age of 21 are receiving services in a benchmark or benchmark-equivalent benefit plan, they are entitled to EPSDT services as defined in section 1905(r) of the Act and so must receive medically necessary services consistent with EPSDT either as services provided in the benchmark or as additional services to the benchmark plan.

We have further provided in § 440.330 that Secretary-approved coverage can be offered as benchmark coverage, consistent with the DRA. This coverage must be appropriate to meet the needs of the targeted population. We have required that States wishing to opt for Secretary-approved coverage should submit a full description of the proposed coverage and include a benefit-by-benefit comparison of the proposed plan to one or more of the other benchmark options listed in this section or to the State's standard full Medicaid coverage package under section 1905(a) of the Act, as well as a full description of the population that would be receiving the coverage. In addition, the State should submit any other information that would be relevant to a determination that the proposed health benefits coverage would be appropriate for the proposed population. The scope of the Secretary-approved health benefits package will be limited to benefits within the benefit categories available under a benchmark coverage package or under the standard full Medicaid coverage package under section 1905(a) of the Act.

To the extent that a benchmark coverage plan that is used as the comparison for the Secretary-approved benchmark plan provides for market innovations such as high deductible health plans, health savings accounts, consumer-directed plans, and/or wellness plans, we would consider these on a case by case basis as components included in a Secretary-approved benchmark option. It should be noted that CMS has approved ten State benchmark programs. Of these ten, eight have been approved as Secretary-approved programs. We did not receive any additional comments related to § 440.355 "Payment of premiums."

Therefore, in this final rule, § 440.355 will be adopted as written in the proposed rule of February 22, 2008.

J. Section 440.360 State Plan Requirement for Providing Additional Services

Comment: A dental provider indicated that the proposed rules give States the ability to create new benefit packages tailored to different populations and that States have the flexibility to provide "wrap-around" and "additional benefits." The commenter noted that CMS cited in a press release "dental coverage" as an example of "additional benefits" but, in the actual language of the proposed rule there are no examples or reference to "dental coverage." Further, the commenter noted that the conference report to the DRA includes guidance to States by explaining that both benchmark and benchmark-equivalent coverage would include "qualifying child benchmark dental coverage." The commenter also noted that in the context of employer group health plans, stand-alone dental arrangements are very often offered as a supplemental coverage that is separate from medical care coverage. The commenter indicated that this option would align Medicaid more closely with private market insurance options and give States more control over their Medicaid benefit packages.

The commenter requested that CMS provide guidance to the States with respect to "additional benefits" such as "dental coverage." The commenter recommended the rule be amended to include an additional paragraph that would provide that States have the option to provide additional benefits that specifically include dental benefits that may be offered as a supplement to medical care coverage.

Response: The DRA House Conference Report 109–362 provided for the language that benchmark or benchmark-equivalent coverage would include "qualifying child benchmark dental coverage." The conference agreement removed this reference. Thus, the final provisions of section 1937 of the Act include no such requirement for the inclusion of dental coverage as additional services nor does section 1937 of the Act provide examples of additional coverage. The rule provides that additional services do not need to include all State plan services but would be health benefits that are of the same type as those covered under the benchmark plan or considered to be health benefits under section 1905(a) of the Medicaid statute.

We do agree that dental coverage could be added to benchmark or benchmark-equivalent benefit plans. Further, it is possible that, because of the plan options that have been identified by Congress as benchmark coverage, dental services may already be covered services in these plans.

If the commenter is concerned that children will not receive dental coverage, we wish to point out that children under the age of 21 must receive EPSDT services, including all medically necessary dental services, consistent with section 1905(r) of the Act either as part of, or as additional services to, the benchmark or benchmark-equivalent plan. Therefore, medically necessary dental coverage must be provided to children under the age of 21 enrolled in benchmark plans regardless of whether or not the actual benchmark plan includes such coverage.

K. Section 440.365 Coverage of Rural Health Clinic and Federally Qualified Health Center (FQHC) Services

Comment: One commenter was concerned that the proposed rule stipulated that States with benchmark plans need only assure that these individuals have access through such coverage and that FQHCs are to be reimbursed for such services as provided under the FQHC reimbursement requirements found in section 1902(bb) of the Act. The commenter indicated further concern that CMS did not elaborate further on these requirements, and particularly, that it did not lay out minimum steps a State must take to assure that these patient and health center protections are effectively implemented. The commenter believed it is important that the final rule and preamble make clear that there are minimum steps a State must take to be in compliance with these FQHC statutory requirements.

Specifically, the commenter asked that it should be clear that individuals who are mandatorily or voluntarily enrolled in a benchmark plan: (1) Remain eligible to receive from an FQHC all of the services included in the definition of the services of an FQHC, as provided in section 1902(a)(2)(C); and (2) must be informed that one or several of the providers by whom they may choose to be treated under this coverage is (or are) an FQHC. The commenter asserted that, to the extent these same individuals receive benchmark coverage, both the State and the benchmark plans must be encouraged to contract with FQHCs as providers of services to these enrolled Medicaid populations. These FQHC(s) must be identified by name. The commenter further stated that, in the event the benchmark plans identified do not contract with an FQHC, enrollees must be informed that they still may receive Medicaid covered services from FQHCs. In the preamble and final rule, the commenter provided that CMS should underline to the States the importance of full compliance with the FQHC reimbursement requirements of section 1937(b)(4) of the Act and § 440.365. The commenter added that adoption of these recommendations is important to assure that the requirements of section 1937(b)(4) of the Act are met.

Response: We agree with the commenters and we have required in § 447.365 that if a State provides benchmark or benchmark-equivalent coverage to individuals, it must assure that the individual has access, through that coverage or otherwise, to rural health clinic services and FQHC services and that payment for these services must be made in accordance with the payment provisions of section 1902(bb) of the Act. We also agree that individuals always have access to FQHC services, even if the State does not contract with an FQHC to provide such services, and we encourage States to contract with FQHCs as providers.

We did not receive any comments to § 440.370. Therefore, we will adopt § 440.370 as written in the proposed rule of February 22, 2008 with the change of the title to "Economy and Efficiency" which more appropriately reflects Medicaid payment principles.

L. Section 440.375 Comparability

Comment: One commenter encouraged CMS to require comparability across traditional Medicaid and Medicaid benchmark alternatives.

Response: The language included in the rule allowing States to offer benchmark or benchmark-equivalent health care coverage without regard to comparability is based on the DRA language providing that "notwithstanding any other provision of Title XIX" States can offer medical assistance to certain Medicaid beneficiaries through benchmark or benchmark-equivalent benefit packages. Section 611 of CHIPRA clarified and narrowed the "notwithstanding" provision but did specifically mention comparability." Therefore, it is clear that States may offer benchmark or benchmark-equivalent coverage to certain specified Medicaid populations. This regulation provision gives meaning to the statutory language permitting States to offer benchmark or benchmark-equivalent coverage to certain, but not all, Medicaid populations.

We would note that States can design disease management services without

relying on DRA benchmark or benchmark-equivalent plans, as outlined in the March 31, 2006 State Medicaid Director letter, which provided guidance on the implementation of section 6044 of the DRA but this benchmark option offers another way for States to meet the needs of their Medicaid populations.

M. Section 440.380 Statewideness

Comment: One commenter is concerned that States are given the option to amend their State plan to provide benchmark plan coverage to Medicaid individuals without regard to statewideness. This proposed regulation would likely result in health care disparities among individuals living in different parts of the State, has no basis in the statute, and should therefore be excluded from the final regulations. The commenter stated that the proposed § 440.380 should be revised to ensure that beneficiaries across the State are not subject to disparities in health care services.

Response: The language included in the rule allowing for States to offer benchmark or benchmark-equivalent health care coverage without regard to statewideness is based on the DRA language providing that "notwithstanding any other provision of title XIX" and the more narrow and explicit language in CHIPRA which specifically states "Notwithstanding statewideness * * *". It is therefore clear that States could offer different benchmark or benchmark-equivalent coverage to Medicaid individuals in different regions within the State. This provision also gives meaning to the language permitting States to offer benchmark or benchmark-equivalent coverage to certain, but not all, Medicaid populations.

For example, States can test new benefit concepts in pilot areas before expanding the benchmark program to the entire State. We believe that this is consistent with Congressional intent in allowing flexibility regarding statewideness for benchmark benefit options.

N. Section 440.385 Freedom of Choice

Comment: One commenter noted that CMS protects the free choice of emergency services providers but failed to do so for family planning services providers. The commenter urged CMS to preserve the free choice of family planning services providers by amending the rule to include a provision preserving the free choice of family planning providers. The commenter believes that this has been a long-standing policy of the Congress and the Medicaid program.

The commenter added that the proposed rules would permit States to deny freedom of choice of a provider for managed care enrollees seeking family planning services and supplies. The commenter argued that this provision lacks any basis in the statute and is contrary to the clear, repeated articulated intent of Congress.

The commenter asserted that provider freedom of choice is critical because of the potentially sensitive nature of the service. The commenter argued that, if unable to obtain confidential services from the provider of their choice, some managed care enrollees may forgo obtaining family planning services entirely. This would threaten beneficiaries' access to high quality, confidential reproductive health care and set a precedent of inequity between beneficiaries in fee-for-service programs and beneficiaries in managed care plans.

The commenter noted that Congress has clearly indicated that while States may require Medicaid beneficiaries to enroll in managed care plans and obtain care from providers affiliated with those plans, an exception should be made for individuals seeking family planning. The commenter also noted that Federal regulations at § 431.51 state, "A recipient enrolled in a primary care case management system, a Medicaid MCO, or other similar entity will not be restricted in freedom of choice of providers of family planning services." The commenters urged the Department to revise § 440.385 to reflect that provider freedom of choice for family planning should be retained.

Response: Section 1937(a)(1) of the Act, as amended by section 611 of CHIPRA, narrowed the flexibility States have and we amended § 440.385 by removing the option to provide benchmark benefit plans without regard to the requirements for free choice of providers at § 431.51 of this chapter.

CHIPRA also made it clear that benchmark benefit programs may vary only from the requirements for statewideness, comparability, and "any other provision of this title which would be directly contrary to the authority under this section and subject to subsection (E)." Title XIX permits States the option to offer Medicaid through managed care entities. Thus, requiring States to comply with Medicaid managed care statutes and regulations would not be directly contrary to the authority of section 1937 of the Act. We have therefore revised the regulation at § 440.385 to clarify that States wishing to deliver benchmark and benchmark-equivalent packages through a managed care entity may do so but must comply with the requirements of section 1932 of the Act, 42 CFR part 438, and any other provisions of title XIX or the regulations pertaining to managed care.

Comment: One commenter requested that CMS explain the concept of "selective contracting" and provide more detail as to how this would be operationalized under benchmark plans.

Response: Selective contracting is a term usually referred to in the context of section 1915(b)(4) waiver programs or 1932(a) under the State plan. Selective contracting provides States with the opportunity to contract with certain providers, practitioners or managed care entities so long as certain other criteria are maintained. Specifically, the State must ensure that in order to selectively contract with providers, practitioners or managed care entities the selective process does not restrict providers in emergency situations or providers of family planning services and supplies; is based on reimbursement, quality and utilization standards under the State plan; and does not discriminate among classes of providers on grounds unrelated to their demonstrated effectiveness and efficiency in providing benchmark benefit packages.

Section 1937(a)(1) of the Act as amended by section 611 of CHIPRA allows selective contracting through benchmark or benchmark-equivalent plans when provision of free choice of providers would be directly contrary to efficient and effective operation of the proposed benchmark benefit program.

Comment: One commenter noted that CMS should include an "any willing provider" provision in Medicaid contracts for alternate plans that allow Medicaid participating providers the opportunity to continue serving those who are required by the State to enroll in a benchmark plan.

Response: Based on changes made by CHIPRA to section 1937 of the Act States must comply with all freedom of choice requirements under title XIX except to the extent the State can demonstrate that freedom of choice would be contrary to the effective and efficient implementation of a benchmark or benchmark-equivalent plan. We therefore revised § 440.385 by striking the option for States to provide benchmark benefit plans without regard to the requirements for freedom of choice. This revision eliminates the need to include an "any willing provider" provision.

O. Section 440.390 Assurance of Transportation

In responding in this final rule to all of the comments received we took into consideration the numerous remarks on the subject of transportation which generally disagreed with the provision in the proposed rule and the rule published December 3, 2008 that would allow States the option to exclude non-emergency medical transportation (NEMT) as a benefit under benchmark and benchmark-equivalent plans. In addition to considering these comments we now must also consider the new CHIPRA legislation which clarifies that the authority under section 1937 to deviate from otherwise applicable Medicaid requirements is limited.

It is true that benchmark benefit packages such as Federal Employees Health Benefit Plan coverage, State Employees Health Benefit coverage, and coverage offered by an HMO in the State with the largest insured commercial non-Medicaid population, generally do not cover non-emergency medical transportation (NEMT) to and from medical providers. However, pursuant to section 1902(a)(4) of the Act and 42 CFR 431.53 there is a general requirement that the State plan assure necessary transportation to and from providers for beneficiaries when needed to access Medicaid covered services. The CHIPRA amendment to the DRA made it clear that Medicaid provisions that are not directly contrary to the provision of services under benchmark or benchmark-equivalent plans continue to apply under the DRA benchmark provisions. Therefore, in accordance with the changes made to the DRA by CHIPRA, and since this assurance of NEMT would not directly conflict with the offering of benchmark or benchmark-equivalent benefit packages as authorized by section 1937 of the Act, the assurance of necessary transportation to and from providers remains applicable when a State elects the 1937 option, and regardless of whether it is or is not a covered benefit under a benchmark or benchmark-equivalent benefit plan.

Thus, we have revised the regulation at § 440.390 to require States to assure necessary transportation to and from providers for beneficiaries enrolled in benchmark and benchmark-equivalent plans, even if the plans themselves do not include transportation.

States have several options when assuring necessary transportation for beneficiaries enrolled in a benchmark or benchmark-equivalent plan. States may provide transportation and transportation-related services under a benchmark plan as provided at § 440.330 (FEHB plan, State Employees plan, Commercial HMO plan or Secretary-approved plan); under a benchmark-equivalent plan as an additional service as provided at § 440.335; or as an additional service as provided at § 440.360, and receive Federal financial participation (FFP) at the Federal matching rate designated for that State for covered Medicaid services (FMAP rate).

If transportation and transportation-related services or some portion of the transportation provided for beneficiaries enrolled in a benchmark or benchmark-equivalent plan is not covered under section 1937 of the Act, then such transportation and transportation-related services must be claimed as an administrative expense at the 50 percent Federal matching rate. If transportation and transportation-related services are claimed as a medical service under section 1937 of the Act, the State must adhere to the general Medicaid requirements which pertain to claiming transportation as a medical service, such as only claiming direct vendor payments.

Our responses to the following comments received on transportation reflect the changes made by section 611 of CHIPRA, which clarifies that the authority under section 1937 to deviate from otherwise applicable Medicaid requirements is limited and therefore the assurance of transportation remains applicable even when the State has elected the section 1937 option.

Comment: One commenter agreed with the interpretation of the "notwithstanding" language to "bypass" the assurance of transportation, including the elimination of non-emergency medical transportation (NEMT). The commenter noted that the ability of States to exclude NEMT services in their benchmark benefits is evident not only from the broad language of the statute but also from Congressional intent. The commenter noted that one of the stated purposes of section 6044 of the DRA is to allow States to offer benefit packages that mirror commercial packages.

Response: The benchmark options that Congress specified, Federal Employees Health Benefit Plan equivalent coverage, State employees coverage, and coverage offered by an HMO in the State with the largest insured commercial non-Medicaid population, generally do not pay for NEMT to and from medical providers in all instances. However, section 611(a)(1)(A)(i) of CHIPRA changed the "notwithstanding any other provision of this title" language and this change in the law clarifies that the authority under section 1937 to deviate from otherwise applicable Medicaid requirements such as those specified in section 1902(a)(4) of the Act and 42 CFR 431.53, which require States to assure that beneficiaries have access to covered medical services, is limited. Accordingly, we have revised the regulation at § 440.390 to require States to assure necessary transportation to and from providers.

Comment: A preponderance of commenters disagreed with the provision in the rule that would allow States the option to exclude NEMT as a benefit under a benchmark and benchmark-equivalent plan. Generally, these comments were submitted by transportation providers, medical providers, and Medicaid beneficiaries, particularly Medicaid beneficiaries who rely on dialysis treatments.

Most of the commenters believed that the goals of the Medicaid program would be undermined if needy individuals were unable to get to and from healthcare services and such an option would create a barrier to care. They asserted that assurance of transportation is a vital component of the Medicaid program and is of particular importance to mentally and physically disabled and elderly patients. They expressed concern that vulnerable populations might not receive medically necessary and often life sustaining services because of the difficulty in accessing needed care and provided examples of the negative impact on the Medicaid program that would be created by not assuring transportation. For example, patients with End-Stage Renal Disease (ESRD), would be unable to access dialysis services.

Many of the commenters focused on the impact that the proposed regulation would have on dialysis patients who require 3 weekly trips to and from dialysis facilities in order to survive. They noted that effective care of ESRD patients requires meticulous coordination of dialysis treatment and drug therapy with frequent and specialized care. Dialysis patients often have multiple co-morbidities and, therefore, require frequent transportation to multiple services. The severity of the complications that develop due to missed treatments is often life threatening. Elimination of transportation services would make it very difficult and often impossible for beneficiaries with ESRD to consistently access the frequent dialysis services that sustain their lives.

Many commenters stated that individuals with physical or mental disabilities have difficulty using public

transportation and require specialized transportation that would otherwise not be available should State Medicaid programs be allowed to stop providing transportation. For many beneficiaries, the cost of frequent trips in specialized vehicles would be unaffordable. Often beneficiaries live in rural areas where the only available transportation to and from medical appointments is provided through the Medicaid program. Without Medicaid transportation services, many beneficiaries would be unable to access needed care and ultimately would require more costly services, costly emergency care, and expensive emergency ambulance services and/or expensive non-medical wheelchair van care.

Other commenters indicated that co-occurring physical health conditions such as diabetes or heart disease, as well as mental health conditions such as depression and anxiety affect an individual's ability to drive.

Several commenters indicated that people suffering with HIV/AIDS, some in wheelchairs, others who are extremely fragile or elderly, have monthly office visits where they are assessed and treated. To remove their only means of free transportation will take away their compliance with medical office treatment.

Response: In light of these comments and because CHIPRA amended section 1937 of the Act by clarifying that the authority to deviate from otherwise applicable Medicaid requirements is limited, we have revised the regulation at § 440.390 to require States to assure necessary transportation to and from providers. Thus, the frail, elderly, disabled and those with ESRD will be entitled to receive transportation to and from medical providers.

Comment: Several commenters noted that elimination of the requirement to provide transportation would actually drive up Medicaid costs because medical visits would become less frequent, resulting in a higher incidence of more serious and costly medical problems, an increase in the use of emergency medical services, and an increase in long term nursing home admissions. A number of these commenters cited a 2006 Cost Benefit Analysis conducted by the Marketing Institute of Florida State University College of Business as proof of the cost effectiveness of providing NEMT to Medicaid beneficiaries. Another commenter cited several studies that compared Medicaid individuals residing in States that do provide access to NEMT. The commenter stated that these studies found that access to non-emergency transportation produces cost savings and increased health care results. For many beneficiaries, the cost of frequent trips in specialized vehicles would be unaffordable. Often beneficiaries live in rural areas where the only available transportation to and from medical appointments is provided through the Medicaid program. Without Medicaid transportation services, many beneficiaries would be unable to access needed care and ultimately would require more costly services, costly emergency care, and expensive emergency ambulance services and/or expensive non-medical wheelchair van care.

One commenter indicated that coordinating transportation would reduce the cost of providing transportation. Another commenter indicated that CMS requires States to comply with economy and efficiency principles in offering benchmark or benchmark-equivalent benefit packages to Medicaid beneficiaries, but does not require non-emergency medical transportation in benchmark or benchmark-equivalent plans, when according to several studies it has been proven that providing this service is cheaper overall and leads to better health outcomes for Medicaid beneficiaries.

Response: CHIPRA amended section 1937 of the Act by clarifying that the authority to deviate from otherwise applicable Medicaid requirements is limited and we have therefore revised the regulation at § 440.390 to require States to assure necessary transportation to and from providers.

Comment: One commenter suggested that this rule sets up a system that would limit mileage payments to drivers for non-emergency doctor visits. The commenter indicated that medical mileage is funded in part to drivers who transport people for medical care on a non-emergency basis.

Response: We do not understand the relevance of this comment to the provision of benchmark and benchmark-equivalent benefit plans and are therefore unable to respond.

Comment: One commenter stated that the number one reason that dentists and doctors do not wish to accept Medicaid patients is that Medicaid beneficiaries do not show-up for appointments or are late for appointments. If CMS does not require transportation benefits, no-shows will increase and the result will be that fewer providers will participate in Medicaid.

Response: As we previously stated, CHIPRA amended section 1937 of the Act by clarifying that the authority to deviate from otherwise applicable Medicaid requirements is limited and we have revised the regulation at § 440.390 to require States to assure necessary transportation to and from providers. Therefore, the commenter's concern about the lack of transportation contributing to missed appointments and late appointments has been addressed.

Comment: Many commenters stated that the possible elimination of transportation will not only decrease access to healthcare but would imperil the financial stability of ambulance services across the Emergency Medical Services (EMS) community. EMS providers depend on reimbursement from non-emergency transports to sustain operational costs and maintain optimal readiness standards for emergency transports. Without adequate reimbursement from Medicaid for non-emergency transports, many ambulance providers, especially those in rural areas, would cease to stay in business, causing a serious reduction in the overall availability of ambulance services. Many commenters stated the provision would likely cause over-utilization of emergency ambulance services, since beneficiaries would need to rely more frequently on more expensive emergency ambulance transport.

One commenter suggested that CMS implement the same "medically necessary transportation" guidelines for the Medicaid program that already exist and govern non-emergency ambulance transportation for Medicare patients, because commercial insurance almost universally uses these guidelines as the benchmark for reimbursement for non-emergency ambulance transportation.

One commenter noted that the GAO has found that the current Medicare rates for ambulance transportation is on average 6 percent below the cost of providing care. Medicaid rates are currently even less. Ambulance transportation is a vital service for Medicaid beneficiaries, and ambulance companies are currently operating under a fee schedule that does not compensate them for the cost of providing that care. To further reduce the overall reimbursement to the ambulance providers while leaving benefits intact for hospitals, physicians, and labs is unfair. Ambulance transport is a vital link between the patient and these other services, and should not be relegated to non-payment.

Response: CHIPRA clarified that the requirement to assure necessary transportation applies to benchmark and benchmark-equivalent benefit plans.

With regard to the comment that CMS require for benchmark and benchmark-equivalent benefit plans the same

ambulance transportation guidelines used by commercial insurance, we disagree with this comment because there is no authority under section 1937 of the Act to do so.

Comment: Many commenters indicated that the proposed rule would shift financial responsibility for Medicaid non-emergency transportation to non-profit and municipal fire service-based emergency medical systems (EMS), ADA paratransit programs, beneficiaries, beneficiaries' families, and other segments of the population who often do not have sufficient funds to pay for trips to and from providers. The commenters believed that the proposed cuts in transportation conflict with the protections afforded to the disabled under the Americans with Disabilities Act. Some commenters stated the shifting of the financial burden for Medicaid non-emergency transportation to ADA paratransit services and local transit programs without any additional funding constitutes an unfunded mandate.

Response: Because CHIPRA clarified that the assurance of necessary transportation is applicable to benchmark and benchmark-equivalent benefit plans, we revised the regulation in § 440.390 to require States to assure necessary transportation. Therefore, we do not believe that the responsibility for Medicaid NEMT will be shifted to municipal EMS systems, ADA paratransit programs, or beneficiaries. Consistent with Federal regulations, States are required to assure non-emergency transportation when the beneficiary has no other means of transportation.

Comment: Several commenters stated that under section 1937 of the Act, a benchmark-equivalent package must offer a specific range of services set forth in § 440.335(b)(1)–(5) of the proposed regulation and that the majority of qualifying benchmark plans cover emergency ambulance services. To ensure that enrollees in benchmark-equivalent plans receive coverage that is qualitatively equivalent to benchmark plans that provide emergency ambulance transportation, CMS should require benchmark-equivalent plans to cover emergency ambulance transportation.

Response: CHIPRA clarified that the assurance of necessary transportation is applicable to benchmark and benchmark-equivalent plans. We therefore revised the regulation at § 440.390 to require States to assure all necessary transportation.

Comment: One commenter noted that instead of saving money by eliminating non-emergency transportation, CMS should do a better job of policing the system to reduce fraud and abuse.

Response: The reduction of fraud and abuse should always be considered by States when designing or implementing their State Medicaid program and we expect States to implement policies that reduce fraud and abuse. CMS will review the provision of these services consistent with our responsibility to work with States to reduce fraud and abuse in the program.

Comment: One commenter believed that during the DRA process CMS attempted to end the Medicaid transportation service. This attempt was turned back by Congress with the clear intention that transportation was essential for adequate access to health services and it is clear that the proposed rule is contrary to the intent of Congress.

Response: CMS did not attempt to end the requirement for States to assure Medicaid non-emergency transportation. On August 23, 2007, CMS published a rule on the "State Option to Establish a Non-Emergency Medical Transportation Program" which intended to enhance the ability of States to provide NEMT by offering an additional option for providing more cost effective non-emergency transportation as a medical service through a brokerage program. Furthermore, we have revised the regulation at § 440.390 to require States to assure necessary transportation for beneficiaries enrolled in benchmark and benchmark-equivalent plans.

Comment: One commenter noted the proposed rule on the "State Option to Establish a Non-Emergency Medical Transportation Program" providing guidance on section 6083 of the DRA and wonders how CMS on one hand is providing guidance regarding non-emergency medical transportation and encouraging use of a brokerage program, while on the other hand proposing elimination of non-emergency medical transportation in benchmark or benchmark-equivalent plans.

Additionally, the commenter believed that the transportation benefit currently operates in a fiscally sound manner. As currently structured, the commenter asserted that the transportation benefit is cost effective in most States. The commenter noted that States generally limit reimbursement for transportation to the least costly form of transport that is medically appropriate based on the beneficiary's condition. Moreover, Medicaid beneficiaries are generally required to use free transportation resources before the program will provide reimbursement for transportation. The commenter stated that, consequently, patients who receive transportation under state Medicaid programs are required, as a condition of coverage, to have no other means of getting to or from providers of medical care.

Response: Because CHIPRA clarified that the requirement for States to assure necessary transportation is applicable to section 1937 of the Act, we revised the regulation in § 440.390 to require States to assure necessary transportation for beneficiaries enrolled in alternative benefit plans. Therefore, the brokerage program option for delivering non-emergency medical transportation and the benchmark or benchmark-equivalent benefits option do not contravene each other as the commenter suggests.

Comment: A few commenters stated that in the proposed rule CMS proposed to create more "flexibility" for States by allowing them to craft more mainstream packages like those found in the private health insurance market, and private health plans do not offer transportation as a covered benefit for enrollees. These commenters disagreed with this assumption because it presumes that Medicaid patients are of equal financial standing with enrollees of private health care plans in their ability to assume the cost of transportation to and from health care services and that private health plans do not provide non-emergency ambulance transportation, when in fact they do.

Response: The changes made to section 1937 of the Act by the CHIPRA legislation make it clear that regardless of whether NEMT and emergency ambulance services are included in the benchmark or benchmark-equivalent plan the State has chosen to offer Medicaid beneficiaries, the requirement to assure necessary transportation for eligible Medicaid beneficiaries remains applicable.

Comment: One commenter stated that CMS did not conduct an analysis of the impact that excluding the transportation benefit would have on the populations affected or on the States. The commenter also noted that in the "Regulatory Impact Analysis," CMS states that they are under no obligation to assess anticipated costs and benefits of this rule, even if the rule may result in expenditures by the State, local, or tribal governments of the private sector, because States are not mandated to participate in the benchmark plans. This precludes any discussion of the shift in costs to other agencies that may result from the exclusion of transportation benefits. The commenter stated that in the proposed rule CMS says that shifting the financial burden to the vulnerable Medicaid populations is simply a matter

of personal responsibility. The commenter believed that the elimination of transportation is a scenario for less effective, more expensive health care because fewer people will seek preventive care since they won't have transportation and will therefore end up needing more expensive medical services.

Response: We revised the regulation in § 440.390 to require States to assure necessary transportation for beneficiaries enrolled in benchmark and benchmark-equivalent benefit plans and have therefore revised the "Regulatory Impact Analysis," to account for the impact of providing transportation.

Comment: Several commenters noted the lack of definition addressing the difference between emergency and non-emergency transportation. Several other commenters requested that CMS provide a universal definition of non-emergency transportation, because without this guidance there would be chaos and an inability to adjudicate issues and disputes over what is and is not non-emergency transportation.

One commenter urged CMS to require that benchmark and benchmark-equivalent plans cover emergency ambulance transportation and do so by clarifying that the reference to "emergency services" in proposed § 440.335 include emergency ambulance services. Several commenters stated the regulation fails to make a distinction between emergency and non-emergency transport and CMS assumes that "to and from providers" means non-emergency medical transportation however this may not always be the case. According to the commenter, transport is often required for Medicaid patients who develop critical conditions that require immediate care beyond the scope of the initial facility, resulting in the patient being transported to another facility for care. If States are no longer required to ensure necessary transportation for individuals to and from providers, the State will likely not cover this type of transport under a benchmark or benchmark-equivalent plan. This type of transport fits the parameters of the regulation because it is from one provider to another, but the regulation does not make the distinction that it must be a non-emergency transport.

Other commenters believed ambulance service, whether considered non-emergency or emergency transportation should be required in all benchmark or benchmark-equivalent plans.

Response: Since CHIPRA clarified that the assurance of necessary transportation is a mandatory State plan requirement that applies to section 1937 of the Act, we have revised the regulation at § 440.390 to require States to assure necessary transportation. Therefore, the commenter's concerns regarding the provision of emergency transportation services and the need for States to properly distinguish between emergency and non-emergency transportation services have been addressed.

Comment: A number of commenters disagreed with the assumption that non-emergency transportation is not covered by private health insurance. They stated that many private health insurance plans do provide coverage for non-emergency ambulance transportation when medically necessary. One commenter stated that CMS is ignoring the fact that many commercial plans have provided services to Medicaid beneficiaries and are thus equipped to provide the transportation benefit. The same commenter requested that if the provision on non-emergency transportation remains in the final regulation, CMS should require that no benchmark or benchmark-equivalent plan be allowed to require emergency ambulance services to join a network as a condition of obtaining necessary information for billing or as a condition of prompt payment, and that benchmark and benchmark-equivalent plans be required to pay for emergency ambulance transportation at a rate not less than the State Medicaid approved rate. One commenter noted that if CMS intends to make this a rationale for the elimination of Medicaid benefits, it should first study this issue and release its findings.

Response: In accordance with changes made by CHIPRA to section 1937 of the Act and the clarification these changes provided we revised the regulation at § 440.390 to require States to assure necessary transportation.

Comment: Many of the commenters voiced concerns that CMS has overreached in its rationale for allowing States to opt-out of the transportation requirements, and that CMS did not support its rationale. Several commenters stated that CMS did not have the legal authority to allow States to choose not to provide non-emergency transportation. One commenter stated that § 440.390 exceeds the Department's administrative authority, results in an impermissible legislative action by the agency, and violates the separation of powers doctrine of the Constitution. Generally, an executive agency's authority is limited to implementing laws and to clarifying ambiguities in statutes passed by Congress. The commenter cites *Chevron U.S.A.* v. *Natural Resources Defense Council,* 467 U.S. 837 (1984).

A number of commenters noted that CMS's interpretation of the language in section 1937 of the Act is "overbroad" because it permits CMS too much discretion. Several commenters also stated that in believing that it could change a long standing Medicaid policy on the assurance of transportation, CMS wrongly interpreted the statute and had not supported its rationale for allowing States to waive the provider-to-provider transportation requirement. A number of commenters believed that allowing States to choose not to provide transportation was inconsistent with Medicaid's mission of increasing access to healthcare. Many commenters indicated that exempting States from the transportation requirement set forth in § 431.53 "renders those provisions to mere surplusage" and that CMS's interpretation affords CMS the unfettered ability to make ad hoc determinations about what laws and regulations will apply to benchmark and benchmark-equivalent plans. Many commenters stated that the requirements in § 431.53 exist to protect beneficiaries and to ensure that they receive access to healthcare. Also, CMS should not be permitted to allow States to deprive Medicaid individuals of necessary transportation based upon an illogical interpretation of a provision of the Act.

Several commenters stated that CMS is providing sufficient flexibility to States through the option to provide benchmark or benchmark-equivalent coverage without regard to comparability, statewideness, and freedom of choice. The commenter did not see how relieving the State of the requirement to assure transportation to and from providers offers any additional flexibility.

Response: Section 611(a)(1)(C) of CHIPRA amended the "notwithstanding any other provision of this title * * *" language. This change in the law clarifies that the authority under section 1937 to deviate from otherwise applicable Medicaid requirements is limited. Therefore, we have revised the regulation at § 440.390 to require States to assure necessary transportation to and from providers.

Comment: Several commenters mentioned earlier that CMS offered a definition of "special medical needs" but pointed out that CMS did not offer a definition of "medically frail." The commenters urged CMS, in considering transportation, to include in any definition of "medically frail" an individual who might require medically necessary ambulance transportation due

to their physical or mental condition, illness, injury, disability, in a bed confined or wheelchair confined state, such that transportation by any means other than ambulance would likely jeopardize the patient's health or safety.

Response: As stated earlier, while CMS wishes to maintain some State flexibility in defining the term medically frail we have provided further guidance on the characteristics of medically frail and special needs individuals. We expect States to take this guidance into consideration when determining what type of transportation is needed by these individuals.

Comment: Several commenters stated the proposed elimination of transportation was discriminatory because individuals with special needs are not able to access transportation services and will be de facto denied the medical services that other Medicaid individuals receive. Also, the commenters asserted that the statutory provision authorizing use of benchmark and benchmark-equivalent plans, "notwithstanding any other provision of this title" will not pass a challenge in the court system because it discriminates against disabled individuals.

Response: Section 611(a)(1)(C) of CHIPRA amended the "notwithstanding any other provision of this title" language. This change in the law clarifies that the authority under section 1937 to deviate from otherwise applicable Medicaid requirements is limited. Accordingly, we revised the regulation at § 440.390 to require States to assure necessary transportation to and from providers for individuals, including those with special needs, who are enrolled in benchmark and benchmark-equivalent benefit plans.

Comment: Several commenters noted that Executive Order 13330 requires coordination for elderly and handicapped transportation programs among Federal agencies. Creating Federal DHHS standards for appropriate service levels would promote this coordination effort and in the interests of quality services, lower costs and enhanced coordination, DHHS should develop parallel standards that would drive cost savings derived by competitive procurement instead of denying services to those who need it the most. Removing an essential element such as transportation in order to save money will ultimately result in greater reliance on institutional care at a much higher cost. One commenter believed that CMS should withdraw the regulation and allow the Coordinating Council on Access and Mobility, which was established by Executive Order 13330, to develop the benchmark policy on non-emergency transportation.

Response: Section 611(a)(1)(C) of CHIPRA amended the "notwithstanding any other provision of this title" language. This change in the law clarifies that the authority under section 1937 to deviate from otherwise applicable Medicaid requirements is limited. Accordingly, we revised the regulation at § 440.390 to require States to assure necessary transportation to and from providers. We do not believe that Executive Order 13330, which relates to the coordination of transportation among Federal agencies, is relevant to this rule as this rule pertains to the provision of transportation by States under State Medicaid programs.

Comment: One commenter, submitting on behalf of the Alaska Natives (ANs) Tribal Health Consortium, wrote that in Alaska nearly 40 percent of the Medicaid eligible populations are ANs. The vast majority of AN villages are accessible only by plane, boat, snow-machine, or dog-sled. Due to the extreme poverty found in AN villages, Congress authorized tribal health programs to bill the Medicare and Medicaid programs for covered services. Tribal health services rely heavily on Medicaid and Medicare payments. The commenter is profoundly concerned that the proposed rule would allow States to curtail Medicaid coverage of crucial health services currently provided to ANs and would eliminate coverage of transportation needed by ANs to access medical services.

Response: We recognize the important value of Medicaid transportation services to the AN population. As stated previously CHIPRA amended the "notwithstanding any other provision of this title * * *" language and this change in the law clarifies that the authority under section 1937 to deviate from otherwise applicable Medicaid requirements is limited. Therefore, we have revised the regulation at § 440.390 to require States to assure necessary transportation to and from providers for those enrolled in benchmark and benchmark-equivalent benefit plans.

IV. Provisions of the Final Regulations

In general, this final rule incorporates the provisions of the February 2008 proposed rule and the changes made by CHIPRA. The provisions of this final rule that differ from the February 2008 proposed rule are as follows:

Scope (§ 440.305)

We added a new paragraph (d) at § 440.305 to require public input before States submit a State plan amendment under this section of the law. We removed the exception at § 440.305(e) to the managed care rules that existed in the February 22, 2008 proposed rule because section 611(a) of CHIPRA required adherence to all rules except those directly contrary to the authority under this section. By removing this exception to the managed care rules all benchmark and benchmark-equivalent benefit plans that are delivered through a managed care entity must comply with managed care rules.

Exempt Individuals (§ 440.315)

We revised paragraph (f) at § 440.315 to indicate that States will have flexibility in adopting definitions of individuals who are "medically frail" and/or individuals with special medical needs, but that these definitions must at least include those individuals described in § 438.50(d)(3), children with serious emotional disturbances, individuals with disabling mental disorders, individuals with serious and complex medical conditions, and individuals with physical and or mental disabilities that prevent them from performing one or more activities of daily living. Further, we deleted the reference to § 438.50(d)(1) for individuals entitled to Medicare benefits as these individuals are already exempt individuals who cannot be required to enroll in benchmark or benchmark-equivalent plans because of the requirement in section 1937(a)(2)(iii) of the Act.

We revised paragraph (h) of § 440.315 to clarify that exempt individuals include "an individual with respect to whom child welfare services are made available under part B of title IV to children in foster care and individuals with respect to whom adoption or foster care assistance is made available under part E of title IV, without regard to age."

We have revised paragraph (i) at § 440.315 to state that parents and caretaker relatives whom States are required to cover under section 1931 of the Act, are considered exempt individuals. This provision reverses the prior rule which limited the exemption to individuals who were eligible for Medicaid based on the eligibility for TANF; eligibility for Medicaid is not based, under Federal laws, on eligibility for TANF.

We added a new paragraph (m) in § 440.315 to include medically needy or those eligible as a result of a reduction of countable income based on costs incurred for medical care in the list of populations who are exempt from mandatory enrollment in benchmark or benchmark-equivalent plans.

Section 440.320 State Plan Requirements: Optional Enrollment for Exempt Individuals

We revised paragraphs (a)(1), (a)(2), and (a)(3) at § 440.320 to require that a State that chooses to offer enrollment in a benchmark or benchmark-equivalent plan to exempt individuals must effectively inform such individuals prior to enrollment that the individual is exempt and that enrollment is voluntary. The State must inform the individual of the benefits in the benchmark or benchmark-equivalent plan and provide a comparison of how they differ from traditional Medicaid State plan coverage, and document in the individual's eligibility file that prior to enrollment the beneficiary was provided a comparison of the benchmark or benchmark-equivalent benefit package to the State plan package, was given ample time to make an informed choice as to enrollment and voluntarily choose to enroll in the benchmark or benchmark-equivalent plan.

We added a new paragraph (a)(4) to clarify that States must comply with the requirements of § 440.320(a)(1), (a)(2), and (a)(3) within 30 days after a determination is made that an individual has become part of an exempt group while enrolled in benchmark or benchmark-equivalent coverage.

We added new paragraphs (b)(1) and (b)(2) in § 440.320 to clarify the disenrollment process for exempt individuals and require that States act upon disenrollment requests promptly for those exempt individuals who choose to disenroll from benchmark or benchmark-equivalent coverage and to require that the State have a process in place to ensure continuous access to all standard State plan services while requests to disenroll from benchmark or benchmark-equivalent coverage are being processed. States must also maintain data to track the number of exempt individuals who enroll in, and dissenroll from benchmark or benchmark-equivalent plans.

Benchmark-Equivalent Health Benefits Coverage (§ 440.335)

We revised paragraph (b) in § 440.335, which lists the mandatory services that benchmark-equivalent plans must provide. In the December 3, 2008 final rule, emergency services was included in the description of other appropriate preventive services designated by the Secretary. To clarify that benchmark equivalent coverage must include emergency services we made emergency services a separate and distinct requirement in paragraph (b)(5) and renumbered the paragraph relating to preventive services as (b)(6) in § 440.335. We also added family planning services and supplies to the description of required preventive services.

Actuarial Report for Benchmark-Equivalent Coverage (§ 440.340)

We revised § 440.340(b)(7) to require States to take into account the impact of cost sharing limitations when calculating actuarial equivalency.

EPSDT Services Requirement (§ 440.345)

We revised paragraph (a) in § 440.345 to reflect the new requirements in CHIPRA to cover 19 and 20 year olds for full EPSDT services. This section requires that "The State must assure access to early and periodic screening, diagnostic and treatment (EPSDT) services through benchmark or benchmark-equivalent plan benefits or as additional benefits to those plans for any child under 21 years of age eligible under the State plan in a category under section 1902(a)(10)(A) of the Act."

We removed the term "wrap-around" and replaced it with "additional" in paragraphs (a)(1) and (a)(2) in § 440.345 of this regulation, and the words "through wrap-around," and replaced them with "additional" in § 440.345(b) of this regulation. We have also revised the "sufficiency" provision. Together these modifications are intended to make it clear that EPSDT services must in all circumstances be provided by the State Medicaid program; either through the benchmark or benchmark-equivalent plan or as an "additional" service. We have also added a statutory cite "under section 1937 of the Act" after the word "benefits" in § 440.345(b) of this regulation.

Employer-Sponsored Insurance Health Plans (§ 440.350)

We removed the language "the additional or wrap-around" and replaced it with "additional" in § 440.350(a) of this regulation.

We replaced the term "cost-effectiveness" with "economy and efficiency" in § 440.350(b) of this regulation to be consistent with the new section heading of § 440.370.

State Plan Requirement for Providing Additional Services (§ 440.360)

We removed the term "wrap-around" in the section heading in § 440.360 of this regulation. We also revised § 440.360 by removing the language "or wrap-around".

Economy and Efficiency (§ 440.370)

We removed the section heading "Cost-effectiveness" and replaced it with "Economy and efficiency" in § 440.370 of this regulation.

Comparability (§ 440.375)

We removed the section heading "Comparability and scope of coverage" and replaced it with "Comparability" in § 440.370 of this regulation. We also revised § 440.375 by removing the language "or requirements relating to the scope of coverage other than those contained in this subpart".

Delivery of Benchmark and Benchmark-Equivalent Coverage Through Managed Care Entities (§ 440.385)

We replaced the title "Freedom of choice" with "Delivery of benchmark and benchmark-equivalent coverage through managed care entities." We revised this section by removing the option to provide benchmark or benchmark-equivalent benefit plans without regard to the requirements for freedom of choice in § 431.51 of this chapter. Section 611(a) of CHIPRA clarified that benchmark and benchmark equivalent plans must comply with all requirements of title XIX other than 1902(a)(1) and 1902(a)(10)(B). We therefore revised the title and text of 440.385 to provide that States wishing to deliver benchmark and benchmark-equivalent benefit packages through a managed care entity may do so but must comply with the requirements of section 1932 of the Act and 42 CFR part 438.

Assurance of Transportation (§ 440.390)

We revised § 440.390 to specify that if a benchmark or benchmark-equivalent plan does not include transportation to and from medically necessary covered Medicaid services, the State must nevertheless assure that emergency and non-emergency transportation is covered for beneficiaries enrolled in the benchmark and benchmark-equivalent plan, as required under § 431.53 of this chapter.

V. Collection of Information Requirements

The following requirements are subject to the Paperwork Reduction Act (PRA). While some elements contained in the sections listed below are approved under OMB control number 0938–0993, the current information collection will need to be revised to reflect changes contained in this final rule. CMS is revising this PRA package to make necessary updates and to incorporate any new requirements not currently approved by OMB. The revised package will be published in a

60-day **Federal Register** notice seeking public comment.

Section 440.320 State Plan Requirements: Optional Enrollment for Exempt Individuals

Section 440.320(a) requires a State to: (1) Inform the individuals that the enrollment is voluntary and that the individual may disenroll from the benchmark or benchmark-equivalent coverage at any time and regain immediate access to standard full Medicaid coverage under the State plan; (2) Inform the exempt individual of the benefits available under the benchmark or benchmark-equivalent benefit package and provide a comparison of how they differ from the benefits available under the standard full Medicaid program; and, (3) Document in the exempt individual's eligibility file that the individual was informed in accordance with this section and voluntarily chose to enroll in the benchmark or benchmark-equivalent benefit package.

Section 440.330 Benchmark Health Benefits Coverage

Section 440.330(d) requires States wishing to opt for Secretarial-approved coverage to submit a full description of the proposed coverage and include a benefit-by-benefit comparison of the proposed plan to one or more of the three other benchmark plans specified.

Section 440.340 Actuarial Report for Benchmark-Equivalent Coverage

Section 440.340 requires a State trying to obtain approval for benchmark-equivalent health benefits coverage described in § 440.335 to submit, as part of its State Plan Amendment, an actuarial report. The report must provide sufficient detail to explain the basis of the methodologies used to estimate the actuarial value or, if requested by CMS, to replicate the State's result.

Section 440.345 Requirement To Provide EPSDT Services

Section 440.345(a)(2) requires a State to include a description in their State Plan of how the additional services will be provided to ensure that all individuals under 21 receive full EPSDT services. The description must describe the populations covered and the procedures for assuring those services.

Section 440.350 Employer-Sponsored Insurance Health Plans

Section 440.350(b) requires a State to set forth in the State plan the criteria it will use to identify individuals who would be required to enroll in an available group health plan to receive benchmark or benchmark-equivalent coverage.

Section 440.360 State Plan Requirement for Providing Additional Services

This section requires States opting to provide additional services to the benchmark-equivalent plans, to describe the populations covered and the payment methodology for these services in their State plan.

Section 440.390 Assurance of Transportation

A State must assure medically necessary transportation for beneficiaries enrolled in a benchmark or benchmark-equivalent plan even if transportation is not a service provided in the benchmark or benchmark-equivalent plan.

VI. Regulatory Impact Analysis

A. Overall Impact

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

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects of $100 million or more in any 1 year. As a result, since there is an economic impact of more than $100 million in any 1 year, this final rule is categorized as economically significant and thus is consequentially a major rule under the Congressional Review Act.

The regulatory impact analysis in this final rule incorporates provisions of the Children's Health Insurance Program Authorization Act (CHIPRA) of 2009, enacted on February 4, 2009, which corrected language in the DRA and subsequently amended section 1937 "State Flexibility for Medicaid Benefit Packages." In addition, this final rule incorporates provisions of the American Recovery and Reinvestment Act (ARRA) of 2009 related to the temporary increase in the Federal matching percentage (FMAP) for Medicaid, enacted on February 17, 2009. The estimated aggregate Federal savings for fiscal years 2006 through 2014, as shown in Table 1, is estimated to be $4.97 billion. Also, the estimated aggregate State savings for fiscal years 2006 through 2014, as shown in Table 2, is $3.36 billion.

In the December 3, 2008 "final rule," we estimated aggregate impacts for fiscal years 2006 through 2010 of $2.28 billion in Federal savings and $1.72 billion in State savings. In this final rule, the updated aggregate impacts, for the same time period of fiscal years 2006 through 2010, are $1.84 billion in Federal savings and $1.05 in State savings. As a result, relative to the December 3, 2008 final rule, this yields a reduction in the aggregate impacts of $440 million in Federal savings and $670 million in State savings, for fiscal years 2006 through 2010. We estimated the impact of this rule by analyzing the potential Federal savings related to lower per capita spending that may be achieved if States choose to enroll beneficiaries in eligible populations in plans that are less costly than projected Medicaid costs. To do this, we developed estimates based on the following assumptions:

- The number of eligible beneficiaries and the Federal Medicaid costs of these beneficiaries are based on 2003 Medicaid Statistical Information System (MSIS) data;
- Projections of the number of eligible beneficiaries and their associated Federal Medicaid costs were made using assumptions from the President's Budget 2007, including enrollment growth rates and per capita spending growth rates;
- The relative costs of the new plans allowed under this rule to current Medicaid spending were estimated based on reviews of Medicaid spending data and the plans described in this rule. Additionally, we have assumed that not all States would immediately use the options made available through this rule; therefore, we assume that State use of these plans will continue to increase through 2011. We assumed that use in 2006 will be about 10 percent of 2011-level of use; 40 percent in 2007; 60 percent in 2008; 80 percent in 2009; and 90 percent in 2010. We do not assume any further expansion beyond 2011.

These estimates assume that there will be a negligible impact on State administration costs. As States already have experience in dealing with alternative plan designs, including through waivers or managed care plans, we assumed States are equipped to

implement these plans and will be part of their normal administrative spending.

Also, these estimates are subject to a substantial amount of uncertainty and actual experience may be significantly different. The range of possible experience is greater than under most other rules for the following two reasons. First, this rule provides the option for States to use alternative plans; to the extent that States participate more or less than assumed here (both the number of States that participate and the extensiveness of States' use of these plans), Federal savings may be greater than or less than estimated. Second, this rule also provides a wide range of options for States in designing these plans; to the extent that States use plans that are relatively more or less costly than assumed here, Federal savings may be less than or greater than estimated.

TABLE 1—ESTIMATED ANNUAL FEDERAL SAVINGS DISCOUNTED AT 0 PERCENT, 3 PERCENT AND 7 PERCENT—FROM FY 2006 TO FY 2014

[In $millions]

Discount rate	2006	2007	2008	2009	2010	2011	2012	2013	2014	Total savings 2006–2014
0%	$50	$210	$340	$570	$670	$710	$740	$810	$870	$4,970
3%	49	198	311	506	578	595	602	639	667	4,145
7%	47	183	278	435	478	473	461	471	473	3,299

We anticipate that States will phase in alternative benefit programs, and changes will not be fully realized until 2010. The majority of savings will be achieved through cost avoidance of future anticipated costs by providing appropriate benefits based on a population's health care needs, appropriate utilization of services, and through gains in efficiencies through contracting. States will be able to take greater advantage of marketplace dynamics within their State. We also anticipate that a number of States will use this flexibility to create programs that are more similar to their CHIP programs. Because States are no longer tied to statewideness and comparability rules for individuals who are not disabled, not aged, or not blind, they will be able to offer individuals and families different types of plans consistent with their needs and available delivery systems.

TABLE 2—ESTIMATED ANNUAL STATE SAVINGS DISCOUNTED AT 0 PERCENT, 3 PERCENT AND 7 PERCENT—FROM FY 2006 TO FY 2014

[In $millions]

Discount rate	2006	2007	2008	2009	2010	2011	2012	2013	2014	Total savings 2006–2014
0%	$40	$160	$250	$280	$320	$480	$560	$610	$660	$3,360
3%	39	151	229	249	276	402	455	482	506	2,788
7%	37	140	204	214	228	320	349	355	359	2,206

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities as that term is used in the RFA (include small businesses, nonprofit organizations, and small governmental jurisdictions). The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7 million to $34.5 million in any 1 year). (For details, see the Small Business Administration's final rule that set forth size standards for health care industries, at 65 FR 69432, November 17, 2000.) Individuals and States are not included in the definition of a small entity. The Secretary has determined that this provision applies to States only and will not affect small entities.

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

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2010, that threshold is approximately $135 million. Because this rule does not mandate State participation in using these benchmark plans, there is no obligation for the State to make any change to their Medicaid program. As a result, there is no mandate for the State. Therefore, we estimate this final will not mandate expenditures in the threshold amount of $135 million in any 1 year.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This final rule will not impose direct cost on States or local governments or preempt State law. The rule will provide States the option to implement alternative Medicaid benefits through a Medicaid State plan amendment.

Comment: One commenter questioned the validity of CMS's Regulatory Impact Analysis, believing that the proposed rule will cause additional administrative effort in order for American Indians/Alaska Natives beneficiaries to participate.

Response: CMS is required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)) to conduct a regulatory analysis of the impact of any regulatory revision to the Medicare, Medicaid, and/or Children's Health Insurance Program before adoption of any rule. A Regulatory Impact Analysis was completed for this rule. We believe there is negligible impact on State administrative costs since States already have experience in dealing with alternative plan designs, including through waivers or managed care plans. Thus, we have assumed States are equipped to implement these plans and that costs will be part of their normal administrative spending. We believe this would be true for any State that chooses to offer benchmark or benchmark-equivalent plans to the Medicaid beneficiaries including American Indians/Alaska Natives Medicaid beneficiaries.

B. Anticipated Effects

Before section 6044 of the DRA became effective on March 31, 2006, State Medicaid programs generally were required to offer at minimum the same standard benefit package to each individual, regardless of income, eligibility category, or geographic location. Some States offered alternative benefit packages to certain individuals under section 1115 demonstration waivers approved by the Centers for Medicare & Medicaid Services. This provision allows for similar program alternatives under the State plan. Without a waiver, States may form larger pools by combining Medicaid individuals with their public employees.

C. Alternatives Considered

This rule finalizes requirements for States to elect alternative Medicaid benefit programs through the adoption of a Medicaid State plan amendment. The final requirements in this rule were designed to permit State flexibility while assuring that beneficiaries will get quality care that meets their needs. Under this rule, we will allow States to define the alternative benefit packages by reference to the benchmark or benchmark-equivalent standard, while making it clear that children under 21 are eligible for the full range of Medicaid benefits under EPSDT. We will also permit States to combine an alternative benefit package with alternative benefit delivery methods, such as through managed care or employer-based coverage, although compliance with all Medicaid rules other than comparability or statewideness is required unless directly contrary to this statute. An alternative might have been to require the State to document any deviation from otherwise applicable State plan requirements, much as is required under section 1115 demonstration waivers, 1915(b) waivers, 1915(c) waivers, or any combination thereof. We have not elected this alternative because it would be cumbersome for States, it will not be consistent with the statutory use of benchmark and benchmark-equivalent coverage as reference points for permissible benefit packages, and it will not improve the clarity of the State plan. Another alternative might have been to limit State flexibility under this provision to variation in the amount, duration and scope of benefits without providing authority for an integrated approach combining alternative benefits with alternative benefit delivery methods. We have not elected this alternative because an integrated approach allows greater State flexibility to tailor both benefits and delivery methods to the eligible groups of individuals being served.

D. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table 3 below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this rule. This table provides our best estimate of the decrease in Medicaid payments as a result of the changes presented in this rule. All savings are classified as transfers to the Federal Government, as well as to States.

TABLE 3—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM FY 2006 TO FY 2014

[In $millions]

Category	Transfers				
	Year dollar	Units discount rate			Period covered
		7%	3%	0%	
Annualized Monetized Transfers	2006	−$506.3	−$532.3	−$552.22	FYs 2006–2014
From Whom To Whom?	Federal Government to beneficiaries, providers				
Annualized Monetized Transfers	2006	−338.5	−358.1	−373.33	FYs 2006–2014
From Whom to Whom?	State Governments to beneficiaries, providers				

Column 1: Category—Contains the description of the different impacts of the rule; it could include monetized, quantitative but not monetized, or qualitative but not quantitative or monetized impacts; it also may contain unit of measurement (such as, dollars). In this case, the Federal and State annualized monetized impacts of the rule are presented.

Column 2: Year Dollar—Contains the year to which dollars are normalized; that is, the first year that dollars are discounted in the estimate.

Column 3: Unit Discount Rate—Contains the discount rate or rates used to estimate the annualized monetized impacts. In this case, three rates are used: 7 percent; 3 percent; 0 percent.

Column 4: Primary Estimate—Contains the quantitative or qualitative impact of the rule for the respective category of impact. Monetized amounts are generally shown in real dollar terms. In this case, the federalized annualized monetized primary estimate represents the equivalent amount that, if paid (saved) each year over the period covered, would result in the same net

present value of the stream of costs (savings) estimated over the period covered.

Column 5: Period Covered—Contains the years for which the estimate was made.

Rows: The rows contain the estimates associated with each specific impact and each discount rate used.

Estimated Savings—The following table shows the discounted costs (savings) for each discount rate over the period covered. The monetized figures represent the net present value of the impact in the year the rule takes effect. These numbers represent the anticipated annual reduction in Federal and State Medicaid spending under this rule.

"From Whom to Whom?"—In the case of a transfer (as opposed to a change in aggregate social welfare as described in the OMB Circular), this section describes the parties involved in the transfer of costs. In this case, the expenditures represent a reduction in Federal and State governments spending on behalf of beneficiaries.

E. Conclusion

We estimate that the use of benchmark plans under this rule will result in total Federal savings of $4.97 billion and State savings of $3.36 billion for fiscal years 2006 through 2014. This translates to an annualized Federal savings of $506.3 million and $532.3 million at the 7 percent and 3 percent discount rates. Also, this yields an annualized State savings of $338.5 million and $358.1 million at the 7 percent and 3 percent discount rates over the same time period of fiscal years 2006 through 2014. These savings would arise as States use the plans described by this rule to manage the costs of their Medicaid program by modifying plan benefits for targeted beneficiaries. The actual savings will heavily depend on the number of States that ultimately implement these plans, the number of beneficiaries States cover with these plans, and the specific design and selection of benchmark plans.

For reasons stated above, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined 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 440

Grant programs—health, Medicaid.

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

PART 440—SERVICES: GENERAL PROVISIONS

■ 1. The authority citation for part 440 continues to read as follows:

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

■ 2. Subpart C, consisting of § 440.300 through § 440.390, is revised to read as follows:

Subpart C—Benchmark Benefit and Benchmark-Equivalent Coverage

Sec.

440.300 Basis.
440.305 Scope.
440.310 Applicability.
440.315 Exempt individuals.
440.320 State plan requirements: Optional enrollment for exempt individuals.
440.325 State plan requirements: Coverage and benefits.
440.330 Benchmark health benefits coverage.
440.335 Benchmark-equivalent health benefits coverage.
440.340 Actuarial report for benchmark-equivalent coverage.
440.345 EPSDT services requirement.
440.350 Employer-sponsored insurance health plans.
440.355 Payment of premiums.
440.360 State plan requirement for providing additional services.
440.365 Coverage of rural health clinic and federally qualified health center (FQHC) services.
440.370 Economy and efficiency.
440.375 Comparability.
440.380 Statewideness.
440.385 Delivery of benchmark and benchmark-equivalent coverage through managed care entities.
440.390 Assurance of transportation.

Subpart C—Benchmark Benefit and Benchmark-Equivalent Coverage

§ 440.300 Basis.

This subpart implements section 1937 of the Act, which authorizes States to provide for medical assistance to one or more groups of Medicaid-eligible individuals, specified by the State under an approved State plan amendment, through enrollment in coverage that provides benchmark or benchmark-equivalent health care benefit coverage.

§ 440.305 Scope.

(a) *General.* This subpart sets out requirements for States that elect to provide medical assistance to certain Medicaid eligible individuals within one or more groups of individuals specified by the State, through enrollment of the individuals in coverage, identified as "benchmark" or "benchmark-equivalent."

(b) *Limitations.* A State may only apply the option in paragraph (a) of this section for an individual whose eligibility is based on an eligibility category under section 1905(a) of the Act that could have been covered under the State's plan on or before February 8, 2006.

(c) A State may not require but may offer enrollment in benchmark or benchmark-equivalent coverage to the Medicaid eligible individuals listed in § 440.315. States allowing individuals to voluntarily enroll must be in compliance with the rules specified at § 440.320.

(d) Prior to submitting to the Centers for Medicare and Medicaid Services for approval a State plan amendment to establish a benchmark or benchmark-equivalent benefit plan or an amendment to substantially modify an existing benchmark or benchmark-equivalent benefit plan, a State must have provided the public with advance notice of the amendment and reasonable opportunity to comment with respect to such amendment, and have included in the notice a description of the method for assuring compliance with § 440.345 of this subpart related to full access to EPSDT services, and the method for complying with the provisions of section 5006(e) of the American Recovery and Reinvestment Act of 2009.

§ 440.310 Applicability.

(a) *Enrollment.* The State may require "full benefit eligible" individuals not excluded in § 440.315 to enroll in benchmark or benchmark-equivalent coverage.

(b) *Full benefit eligible.* An individual is a full benefit eligible if determined by the State to be eligible to receive the standard full Medicaid benefit package under the approved State plan if not for the application of the option available under this subpart.

§ 440.315 Exempt individuals.

Individuals within one (or more) of the following categories are exempt from mandatory enrollment in benchmark or benchmark-equivalent coverage.

(a) The individual is a pregnant woman who is required to be covered under the State plan under section 1902(a)(10)(A)(i) of the Act.

(b) The individual qualifies for medical assistance under the State plan on the basis of being blind or disabled (or being treated as being blind or disabled) without regard to whether the

individual is eligible for Supplemental Security Income benefits under title XVI on the basis of being blind or disabled and including an individual who is eligible for medical assistance on the basis of section 1902(e)(3) of the Act.

(c) The individual is entitled to benefits under any part of Medicare.

(d) The individual is terminally ill and is receiving benefits for hospice care under title XIX.

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

(f) The individual is medically frail or otherwise an individual with special medical needs. For these purposes, the State's definition of individuals who are medically frail or otherwise have special medical needs must at least include those individuals described in § 438.50(d)(3) of this chapter, children with serious emotional disturbances, individuals with disabling mental disorders, individuals with serious and complex medical conditions, and individuals with physical and/or mental disabilities that significantly impair their ability to perform one or more activities of daily living.

(g) The individual qualifies based on medical condition for medical assistance for long-term care services described in section 1917(c)(1)(C) of the Act.

(h) The individual is an individual with respect to whom child welfare services are made available under part B of title IV to children in foster care and individuals with respect to whom adoption or foster care assistance is made available under part E of title IV, without regard to age.

(i) The individual is a parent or caretaker relative whom the State is required to cover under section 1931 of the Act.

(j) The individual is a woman who is receiving medical assistance by virtue of the application of sections 1902(a)(10)(ii)(XVIII) and 1902(aa) of the Act.

(k) The individual qualifies for medical assistance on the basis of section 1902(a)(10)(A)(ii)(XII) of the Act.

(l) The individual is only covered by Medicaid for care and services necessary for the treatment of an emergency medical condition in accordance with section 1903(v) of the Act.

(m) The individual is determined eligible as medically needy or eligible because of a reduction of countable income based on costs incurred for medical or other remedial care under section 1902(f) of the Act or otherwise based on incurred medical costs.

§ 440.320 State plan requirements: Optional enrollment for exempt individuals.

(a) *General rule.* A State plan that offers exempt individuals as defined in § 440.315 the option to enroll in benchmark or benchmark-equivalent coverage must identify in its State plan the exempt groups for which this coverage is available, and must comply with the following provisions:

(1) In any case in which the State offers an exempt individual the option to obtain coverage in a benchmark or benchmark-equivalent benefit package, the State must effectively inform the individual prior to enrollment that the enrollment is voluntary and that the individual may disenroll from the benchmark or benchmark-equivalent coverage at any time and regain immediate access to standard full Medicaid coverage under the State plan.

(2) Prior to any enrollment in benchmark or benchmark-equivalent coverage, the State must inform the exempt individual of the benefits available under the benchmark or benchmark-equivalent benefit package and the costs under such a package and provide a comparison of how they differ from the benefits and costs available under the standard full Medicaid program. The State must also inform exempt individuals that they may disenroll at any time and provide them with information about the process for disenrolling.

(3) The State must document in the exempt individual's eligibility file that the individual was informed in accordance with this section prior to enrollment, was given ample time to arrive at an informed choice, and voluntarily and affirmatively chose to enroll in the benchmark or benchmark-equivalent benefit package.

(4) For individuals who the State determines have become exempt individuals while enrolled in benchmark or benchmark-equivalent coverage, the State must comply with the requirements in paragraphs (a)(1) through (a)(3) of this section above within 30 days after such determination.

(b) *Disenrollment Process.* (1) The State must act upon requests promptly for exempt individuals who choose to disenroll from benchmark or benchmark-equivalent coverage.

(2) The State must have a process in place to ensure that exempt individuals have access to all standard State plan services while disenrollment requests are being processed.

(3) The State must maintain data that tracks the total number of beneficiaries that have voluntarily enrolled in a benchmark plan and the total number of individuals that have disenrolled from the benchmark plan.

§ 440.325 State plan requirements: Coverage and benefits.

Subject to requirements in § 440.345 and § 440.365, States may elect to provide any of the following types of health benefits coverage:

(a) Benchmark coverage in accordance with § 440.330.

(b) Benchmark-equivalent coverage in accordance with § 440.335.

§ 440.330 Benchmark health benefits coverage.

Benchmark coverage is health benefits coverage that is equal to the coverage under one or more of the following benefit plans:

(a) *Federal Employees Health Benefit Plan Equivalent Coverage (FEHBP—Equivalent Health Insurance Coverage).* A benefit plan equivalent to the standard Blue Cross/Blue Shield preferred provider option service benefit plan that is described in and offered to Federal employees under 5 U.S.C. 8903(1).

(b) *State employee coverage.* Health benefits coverage that is offered and generally available to State employees in the State.

(c) *Health maintenance organization (HMO) plan.* A health insurance plan that is offered through an HMO, (as defined in section 2791(b)(3) of the Public Health Service Act) that has the largest insured commercial, non-Medicaid enrollment in the State.

(d) *Secretary-approved coverage.* Any other health benefits coverage that the Secretary determines, upon application by a State, provides appropriate coverage to meet the needs of the population provided that coverage. States wishing to elect Secretarial approved coverage should submit a full description of the proposed coverage, (including a benefit-by-benefit comparison of the proposed plan to one or more of the three other benchmark plans specified above or to the State's standard full Medicaid coverage package under section 1905(a) of the Act), and of the population to which the coverage would be offered. In addition, the State should submit any other information that would be relevant to a determination that the proposed health benefits coverage would be appropriate for the proposed population. The scope

of a Secretary-approved health benefits package will be limited to benefits within the scope of the categories available under a benchmark coverage package or the standard full Medicaid coverage package under section 1905(a) of the Act.

§ 440.335 Benchmark-equivalent health benefits coverage.

(a) *Aggregate actuarial value.* Benchmark-equivalent coverage is health benefits coverage that has an aggregate actuarial value, as determined under § 440.340, that is at least actuarially equivalent to the coverage under one of the benchmark benefit packages described in § 440.330 for the identified Medicaid population to which it will be offered.

(b) *Required coverage.* Benchmark-equivalent health benefits coverage must include coverage for the following categories of services:

(1) Inpatient and outpatient hospital services.

(2) Physicians' surgical and medical services.

(3) Laboratory and x-ray services.

(4) Well-baby and well-child care, including age-appropriate immunizations.

(5) Emergency services.

(6) Family planning services and supplies and other appropriate preventive services, as designated by the Secretary.

(c) *Additional coverage.* (1) In addition to the categories of services of this section, benchmark-equivalent coverage may include coverage for any additional services in a category included in the benchmark plan or described in section 1905(a) of the Act.

(2) If the benchmark coverage package used by the State for purposes of comparison in establishing the aggregate actuarial value of the benchmark-equivalent package includes any of the following four categories of services: Prescription drugs; mental health services; vision services; and hearing services; then the actuarial value of the coverage for each of these categories of service in the benchmark-equivalent coverage package must be at least 75 percent of the actuarial value of the coverage for that category of service in the benchmark plan used for comparison by the State.

(3) If the benchmark coverage package does not cover one of the four categories of services in paragraph (c)(2) of this section, then the benchmark-equivalent coverage package may, but is not required to, include coverage for that category of service.

§ 440.340 Actuarial report for benchmark-equivalent coverage.

(a) A State plan amendment that would provide for benchmark-equivalent health benefits coverage described in § 440.335, must include an actuarial report. The actuarial report must contain an actuarial opinion that the benchmark-equivalent health benefits coverage meets the actuarial requirements set forth in § 440.335. The report must also specify the benchmark coverage used for comparison.

(b) The actuarial report must state that it was prepared according to the following requirements:

(1) By an individual who is a member of the American Academy of Actuaries (AAA).

(2) Using generally accepted actuarial principles and methodologies of the AAA.

(3) Using a standardized set of utilization and price factors.

(4) Using a standardized population that is representative of the population involved.

(5) Applying the same principles and factors in comparing the value of different coverage (or categories of services).

(6) Without taking into account any differences in coverage based on the method of delivery or means of cost control or utilization used.

(7) Taking into account the ability of the State to reduce benefits by considering the increase in actuarial value of health benefits coverage offered under the State plan that results from the limitations on cost sharing (with the exception of premiums) under that coverage.

(c) The actuary preparing the opinion must select and specify the standardized set of factors and the standardized population to be used in paragraphs (b)(3) and (b)(4) of this section.

(d) The State must provide sufficient detail to explain the basis of the methodologies used to estimate the actuarial value or, if requested by CMS, to replicate the State's result.

§ 440.345 EPSDT services requirement.

(a) The State must assure access to early and periodic screening, diagnostic and treatment (EPSDT) services through benchmark or benchmark-equivalent plan benefits or as additional benefits provided by the State for any child under 21 years of age eligible under the State plan in a category under section 1902(a)(10)(A) of the Act.

(1) Sufficiency. Any additional EPSDT benefits not provided by the benchmark or benchmark-equivalent plan must be sufficient so that, in combination with the benchmark or benchmark-equivalent benefits plan, these individuals have access to the full EPSDT benefit.

(2) State Plan requirement. The State must include a description of how the additional benefits will be provided, how access to additional benefits will be coordinated and how beneficiaries and providers will be informed of these processes in order to ensure that these individuals have access to the full EPSDT benefit.

(b) [Reserved]

§ 440.350 Employer-sponsored insurance health plans.

(a) A State may provide benchmark or benchmark-equivalent coverage by obtaining employer sponsored health plans (either alone or with additional services covered separately under Medicaid) for individuals with access to private health insurance.

(b) The State must assure that employer sponsored plans meet the requirements of benchmark or benchmark-equivalent coverage, including the economy and efficiency requirements at § 440.370.

(c) A State may provide benchmark or benchmark-equivalent coverage through a combination of employer sponsored health plans and additional benefit coverage provided by the State that wraps around the employer sponsored health plan which, in the aggregate, results in benchmark or benchmark-equivalent level of coverage for those individuals.

§ 440.355 Payment of premiums.

Payment of premiums by the State, net of beneficiary contributions, to obtain benchmark or benchmark-equivalent benefit coverage on behalf of beneficiaries under this section will be treated as medical assistance under section 1905(a) of the Act.

§ 440.360 State plan requirement for providing additional services.

In addition to the requirements of § 440.345 the State may elect to provide additional coverage to individuals enrolled in benchmark or benchmark-equivalent plans. The State plan must describe the populations covered and the payment methodology for these services. Additional services must be in categories that are within the scope of the benchmark coverage, or are described in section 1905(a) of the Act.

§ 440.365 Coverage of rural health clinic and federally qualified health center (FQHC) services.

If a State provides benchmark or benchmark-equivalent coverage to individuals, it must assure that the individual has access, through that

coverage or otherwise, to rural health clinic services and FQHC services as defined in subparagraphs (B) and (C) of section 1905(a)(2) of the Act. Payment for these services must be made in accordance with the payment provisions of section 1902(bb) of the Act.

§ 440.370 Economy and efficiency.

Benchmark and benchmark-equivalent coverage and any additional benefits must be provided in accordance with Federal upper payment limits, procurement requirements and other economy and efficiency principles that would otherwise be applicable to the services or delivery system through which the coverage and benefits are obtained.

§ 440.375 Comparability.

States have the option to amend their State plan to provide benchmark or benchmark-equivalent coverage to individuals without regard to comparability.

§ 440.380 Statewideness.

States have the option to amend their State plan to provide benchmark or benchmark-equivalent coverage to individuals without regard to statewideness.

§ 440.385 Delivery of benchmark and benchmark-equivalent coverage through managed care entities.

In implementing benchmark or benchmark-equivalent benefit packages, States must comply with the managed care provisions at section 1932 of the Act and part 438 of this chapter, if benchmark and benchmark-equivalent benefits are provided through a managed care entity.

§ 440.390 Assurance of transportation.

If a benchmark or benchmark-equivalent plan does not include transportation to and from medically necessary covered Medicaid services, the State must nevertheless assure that emergency and non-emergency transportation is covered for beneficiaries enrolled in the benchmark or benchmark-equivalent plan, as required under § 431.53 of this chapter.

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

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Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: March 2, 2010.

Kathleen Sebelius,

Secretary.

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