

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 440

[CMS–2232–F]

RIN 0938 A048

Medicaid Program; State Flexibility for Medicaid Benefit Packages

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

ACTION: Final rule.

SUMMARY: This final rule will 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. It also 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 recipients. In addition, this final rule responds to public comments on the February 22, 2008, proposed rule that pertain to the State Medicaid benefit package provisions.

DATES: *Effective Date:* These regulations are effective on February 2, 2009.

FOR FURTHER INFORMATION CONTACT: Donna Schmidt, (410) 786–5532.

SUPPLEMENTARY INFORMATION:

I. Background

Under title XIX of the Social Security Act (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 Deficit Reduction Act (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 services for individuals under age 21, family planning services to individuals of child-bearing age, nurse-midwife services, certified pediatric nurse practitioner services, 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 Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171), enacted on February 8, 2006, 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 included or mandated in the benchmark coverages. 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.

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 recipients. 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 Sections 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 new statutory authority for States to provide medical assistance to recipients, within one or more groups of Medicaid eligible recipients 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 based on 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:

- The recipient 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.
- The recipient 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.

- The recipient who is entitled to benefits under any part of Medicare.
- The recipient who is terminally ill and is receiving benefits for hospice care under title XIX.
- The recipient 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.

- The recipient 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; in foster care or other out of home placement; or 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.

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

- The recipient 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.

- The recipient 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 relates to 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).

- The recipient 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.

- The recipient who qualifies for medical assistance as a TB-infected individual on the basis of section 1902(a)(10)(A)(ii)(XII) of the Act.
- The recipient who is not a qualified alien (as defined in section 431 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996) and receives only 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 plan 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 better integrate disease management programs to provide better coordinated care which 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 recipients specified in § 440.315. When a State offers exempt recipients the option to enroll in a benchmark or benchmark-equivalent benefit package, the State would inform the recipients that enrollment is voluntary and that the individual may opt out of 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 recipient 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. 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 recipient. For example, one recipient may be enrolled in the FEHBP 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 would 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. Individuals mandated into a benchmark or benchmark-equivalent plan and entitled to have access to EPSDT services cannot opt out of the benchmark or benchmark-equivalent plan just to receive these services. While 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 recipients have access to full EPSDT services under 1905(r) of the Act.

In addition, individuals would need to first seek coverage of EPSDT services through the benchmark or benchmark-equivalent plan before seeking coverage of such through wrap-around benefits.

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 recipient 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 recipient 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 need 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 recipients 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 recipients 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 recipients without regard to freedom of choice. States may restrict recipients 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 recipients 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. The majority of the commenters represented transportation providers, medical providers, and Medicaid beneficiaries, particularly Medicaid beneficiaries who rely on dialysis treatments. Other commenters represented State and local advocacy groups, national associations that represent various aspects of

beneficiary 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 proposed rule. 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 rule. Some commenters also requested a more restrictive interpretation of the statutory provisions. However, most commenters oppose the 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 believed 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 thank those commenters who supported the 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 as written. We address suggestions for restrictive interpretations below in the discussion of specific proposed provisions.

Comment: Several commenters believe that the accelerated pace of this short comment period, given the broad implications, will lead to a short-cited, onerous rule that has dangerous health impacts for the poor. This rule was issued in the **Federal Register** on

February 22, 2008. The deadline for submission of comments was March 24, 2008. Other rulemaking has taken a longer period. Given the impact of the discussion, a longer time period is warranted.

Some commenters stated that the 30-day comment period 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 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 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: We disagree with the commenters suggesting that 30 days is too short of a time period to respond to the regulation. Section 553(c) of the Administrative Procedures Act requires that after the publication of a proposed rule, the Agency shall give interested persons an opportunity to participate in the rulemaking. Neither the Administrative Procedures Act nor the Medicaid statute specify a time period for submission of comments. For Medicaid rules we allow 30 days or 60 days based on the complexity and size of the rule, or the need to publish the final rule quickly. We elected a 30-day comment period because of the limited deviation from plain statutory requirements and the interest of getting guidance quickly to States on the DRA flexibilities contained herein. Since this provision of the DRA was effective March 31, 2006 it made sense to provide guidance to States as quickly as possible.

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 recipients 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. In an effort to provide States with maximum flexibility, we have interpreted this statutory term to mean any eligibility category listed under section 1905(a) of the Act. Thus, all recipients within a category covered or potentially covered under the State's Medicaid plan would 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 recipients will deter those individuals, including children, from receiving appropriate care. Commenters indicated that individuals with low incomes are likely to forgo 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: We have developed these policies based on what is provided for in statute. And, since the Medicaid program is administered broadly by the States, they have the flexibility to determine how they will design their programs. We do review and approve all State plan amendments to assure continuity of and access to necessary medical health care.

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, behavioral healthcare advocates report 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 recipients. Those commenters are concerned that many private insurance plans do not provide adequate mental health services. And other commenters noted that benchmark coverage is likely to prove entirely inadequate for individuals who need mental health services. They 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, they 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.

In a similar vein, 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 recipients experiencing mental illness or who have

a developmental disability. They 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 was enacted in response to States' desire for more flexibility in modernizing their Medicaid programs and adopting benefit programs tailored to the needs of the varied populations they serve. This regulation is consistent with Congressional intent and reflects little interpretive policy by CMS. The DRA provides that States can impose alternative benchmark or benchmark-equivalent benefit packages at their option; that is, States are not required to implement these provisions.

As a result, we believe that the concerns expressed by these commenters on the sufficiency of potential alternative benefit packages should be addressed to States for consideration in determining whether to elect alternative benefit packages, and the scope of such packages.

We disagree that benchmark and benchmark-equivalent programs necessarily lead to barriers to access and care. Benchmark and benchmark-equivalent plans are simply tools that States can use to contain costs and inhibit over-utilization of health care through Medicaid, particularly through the emergency room, while at the same time providing States new opportunities to provide benefit plans to meet the appropriate health care needs of Medicaid populations. We believe States may use this flexibility to create innovative Medicaid programs that further strengthen and support the overall health care system.

This new flexibility provides States the tools they need to provide person-centered care to maximize health outcomes for individuals. These tools may be used in conjunction with other Medicaid and State Children's Health Insurance Program (SCHIP) authorities to strategically align the Medicaid program with today's health care environment and expand access to affordable mainstream coverage and

improve quality and coordination of care.

Regarding the coverage of mental health services, children and adults with special medical needs, individuals with HIV/AIDS, and long-term care and community-based service options, benchmark and benchmark-equivalent plans must be appropriate to meet the health care needs of the population being served, which may mean that benchmark coverage may be more generous than a State's Medicaid plan. Benchmark 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 better integrate disease management programs to provide better coordinated care, targeting the specific needs of individuals with special health needs.

We also think it is important to note that children under the age of 19 are required to receive EPSDT services either as a wrap-around service or as part of the benchmark or benchmark-equivalent benefit plan.

Moreover, certain Medicaid eligibility coverage 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. The law provides that States can offer these alternative benefit packages and we do not believe this rule poses a barrier to accessing health care.

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. States requested maximum flexibility in designing their Medicaid programs in order to provide appropriate health care coverage to our Nation's most

vulnerable populations and to maintain growth and provide for the sustainability of the Medicaid program over the long term. Congress, in working with our Nation's leaders, responded and enacted the DRA of 2005.

In providing for benchmark benefit packages, several innovative ways of providing coverage to the Medicaid populations have been provided to States. Benchmark options include Federal Employees Health Benefits Plan Equivalent coverage, State Employee coverage, Health Maintenance Organization coverage, or Secretary approved coverage. States have the option of considering Employer Sponsored Insurance coverage as long as the Employer Sponsored Insurance coverage meets the criteria of benchmark coverage. States can also consider benchmark-equivalent coverage as long as the coverage includes basic services consisting of 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, such as emergency services. Specifically, benchmark plans can be designed to address the specific health care needs of specific populations, and a State may select one or more benchmark coverage options. The flexibility granted to States in considering these options provides that States can tailor benefits to better meet the needs of their low-income populations.

Comment: One commenter stated that the proposed rule, read together with other CMS rules like the citizenship documentation requirement and CMS's SCHIP 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 Native Americans to prove both citizenship and identity in order to obtain Medicaid services. Commenters also raised concerns about the SCHIP review strategy outlined in an August 17, 2007 letter sent to State Health Officials. And commenters 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 disagree that providing States with benefit flexibility creates

barriers to accessing appropriate care and instead contend that this provides flexibilities to States in an effort to create benefit packages that appropriately meet the needs of their Medicaid populations. Citizenship documentation requirements, the August 17 State Health Officials letter, 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, and CMS policy discretion was very limited.

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

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

To address the unique needs of the AI/AN population, we recommend working with States to ensure that alternative benefit packages recognize the unique services offered by IHS and tribal providers, and the unique health needs of the AI/AN population.

Comment: One commenter contended that there are no provisions to require States to ensure that AI/ANs 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 AI/ANs'

health care status and the health care status of the rest of the country. The commenter added that for AI/ANs, 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 AI/ANs. 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. The Medicaid statute does not provide any special protections for benefit packages applicable to AI/AN recipients, but this does not mean that benefit packages will be deficient. As noted above, to address the unique needs of the AI/AN population, we recommend working with States to ensure that alternative benefit packages recognize the unique services offered by IHS and tribal providers, and the unique health needs of the AI/AN population. Furthermore, AI/AN beneficiaries are not prevented from going to IHS or tribal facilities for health care as a result of this rule.

Comment: Another commenter stated on behalf of AI/ANs, the Indian and tribal health care system is woefully under-funded and tribal providers rely on Medicaid revenues to supplement that meager funding. Forcing AI/ANs 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: CMS does not anticipate a dramatic decrease in services furnished under benchmark plans versus traditional Medicaid benefits. In fact, to date CMS has approved nine benchmark benefit programs, and most offer State plan services plus additional services like preventive care, personal assistance services, or disease management services. Indeed, for individuals under the age of 19, section 1937 ensures that all needed services will be available through the requirement that EPSDT services must be provided either as wrap-around to, or as part of, the benchmark or benchmark-equivalent plan.

Moreover, section 1937 does not provide a basis to exclude IHS or tribal health providers from participation in the delivery system for alternative benefits. In terms of the assertion of overall under-funding for IHS and tribal

health programs, CMS does not determine those funding levels.

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 AI/AN 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 AI/ANs 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 and believe that there was no requirement for consultation on this rule, since the effect on AI/AN

recipients results from the statute itself, and not this rule. The rule itself does not have a direct effect on such individuals, or on the relationship between the Federal government and Tribes. Therefore, we have concluded that this rule does not reach the threshold of requiring consultation.

We encourage States which decide to implement alternative benefit packages to consult with Tribes and notify them whenever possible on policies that will directly affect the Tribes. In terms of exempting AI/ANs from benchmark plans, it is important to note that this rulemaking was taken directly from provisions of section 1937 of the Act, as added by section 6044 of the DRA. These provisions give States increased flexibilities in the management of their Medicaid programs. This regulation exempts from mandatory enrollment in an alternative benefit package the groups specifically set forth in section 1937. The statute provides no authority to mandate exemption of other groups. It is possible that some AI/ANs fit into one of the exempt groups.

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.

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 copays 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 health care and basic needs such as food. The commenter indicated that Native Americans and other low-income groups should be exempt from premiums and cost-sharing requirements.

Response: This rule concerns new flexibility for States in providing health care coverage through alternate benefit packages that was authorized under section 1937 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 recipients may not exceed cost-sharing limits applicable under sections 1916 and 1916A of the Act. Under section 1916A

of the Act, there are tiered individual service limits based on family income, and an aggregate cap of 5 percent of family income. These limits protect individuals in benchmark plans.

It is important to note, first, that alternative benefit package programs are at a State's option. Second, numerous Medicaid eligibility categories are exempt from mandatory enrollment in alternative benefit packages and can be enrolled only voluntarily. Such individuals must be provided a comparison of the benchmark option versus the State plan option before they choose to enroll. That comparison would include information on the cost-sharing obligations of beneficiaries. In choosing the benchmark option over the State plan option, these individuals would thus have made an informed choice. And if the benchmark option is not meeting the exempt individual's needs, they may revert back to traditional Medicaid at any time.

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 recipients 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 do not believe that will necessarily be the case. For the nine benchmark State plan amendments approved to date, most offer traditional State plan services as well as additional services like prevention and disease management.

By tying benefit flexibility to benchmark plans, Congress ensured that alternative benefit packages will be

similar to those available in the marketplace. This protects Medicaid recipients from significant reductions in benefits. Benchmark options include Federal Employees Health Benefits Plan coverage, State Employee coverage, coverage offered by a Health Maintenance Organization in the State with the largest commercial non-Medicaid population, or Secretary approved coverage. States have the option of considering Employer Sponsored Insurance coverage so long as the Employer Sponsored Insurance coverage meets the criteria of benchmark coverage. States can also consider benchmark-equivalent coverage as long as the coverage includes basic services such as 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 determined that other appropriate preventive services should include emergency services.

Benchmark equivalent plans may include care management, care coordination, and/or home health services, but it is possible that some plans will not include these services and we do not believe that a requirement that States include these specific services would be consistent with the statutory goal of increasing State flexibility.

Another important protection from benefit reduction is that the alternative benefit package is required to include the EPSDT benefit for children under the age of 19. If the services are not provided as part of the benchmark or benchmark-equivalent plan, these services must be provided by the State as wrap-around benefits. Further, States, at their option, can provide for additional services or wrap-around services to benchmark or benchmark-equivalent programs.

Another protection is that exempt individuals have the opportunity to make an informed choice before enrolling 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. If the benchmark or benchmark-equivalent is not meeting the exempt individual's health care needs, the exempt individual has the option to return to State plan coverage immediately. If the exempt individual is in need of these services and they are not offered in the

benchmark plan, the individual can return to the regular Medicaid benefit package.

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 that differences in covered benefits be excluded as a justifiable cause for beneficiaries to switch health plans after the change period.

Response: We have revised the regulation at § 440.305 to incorporate compliance with managed care requirements at section 1932 of the Act and at 42 CFR part 438 of Federal regulations, except when the State demonstrates that such requirements are impractical in the context of, or inconsistent with, methods of offering coverage that is appropriate to meet the needs of the targeted population. This would mean that, in providing information to beneficiaries who are offered managed care plans to obtain alternate benefit coverage, States would be required to comply with the requirements at § 438.10, so that States 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; and the process and procedures for obtaining emergency services.

In order to maintain State flexibility, State plan amendments will be reviewed on an individual case-by-case basis and could provide for exceptions from managed care requirements when impractical or inconsistent with the methods of delivering appropriate coverage to the targeted population. This would mean that, if States can meet the standard of offering benchmark or benchmark-equivalent coverage that is appropriate to meet the health care needs of the targeted population, CMS would consider State program designs that require flexibility in this regard.

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: If States choose to offer benchmark or benchmark-equivalent plans to Medicaid beneficiaries, States must assure that access to providers and claims payment must be in compliance with current Federal regulations.

Comment: One commenter raised 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 rebill plans in the event that a plan is billed for a Medicaid recipient 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: This rule does not address provider billing issues because this is the kind of administrative issue that is more properly handled on a State level. 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 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 which mandatory enrollment can occur are outlined in § 440.431 and specify that only full benefit eligibles can be mandatorily enrolled in benchmark benefit packages. We have required in § 440.320 that exempt individuals be fully informed regarding the choice for enrollment in benchmark or benchmark-equivalent plans. We have also required that States comply with the 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, 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 and the services provided by the benchmark plan are expected to be appropriate to meet the needs of the population it serves.

It is important to note that for those who voluntarily enroll in benchmark or benchmark-equivalent plans, if medically necessary services are needed that are not provided as part of the benchmark program, such individuals can revert to traditional Medicaid coverage at any time to receive the services. Requests for individuals to opt out must be acted upon promptly. Further, we included a requirement for States to have a process in place to ensure continuous access to services while any opt out request is being processed. See 42 CFR 440.320.

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. These sections provide States with the flexibility to consider individuals who are unable to meet their cost-sharing obligations and establish a course of action that will be taken in such an instance. Exemptions for individuals in the case of undue hardship, however, are a state option and may not be available in all States.

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 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.

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 complained 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 should 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.

We note that there are already a number of Federal requirements for States to provide public notice of, and seek public involvement in, Medicaid program issues. CMS requires in § 447.205 that States must provide public notice of any significant proposed change in its methods and standards for setting payment rates for services. There are public process requirements for setting institutional payment rates at section 1902(a)(13)(A) of the Act. We also require in § 438.50(b)(4) that States offering benefits through a mandatory managed care program must specify the process the State uses to involve the public in both design and initial implementation of the managed care program and the methods it uses to ensure ongoing public involvement once the managed care program has been implemented. Additionally, States submitting a section 1115 demonstration proposal must provide a written description of the process the State will use for receipt of public input into the proposal. (See 59 FR 49249).

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 recipients. The commenter asserts that Medicaid recipients 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 recipients receiving treatment for chronic illnesses.

Response: Rate setting is a process that States undertake with their contracted providers. It is outside the scope of this rule, and was not addressed by the provisions of section 1937 of the Act. Nor did section 1937 address or limit the use of mail order

prescription requirements, or otherwise address or limit the coverage of, or payment for, prescription drugs. These issues are outside of the scope of this rule.

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. Section 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 have 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.

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 alternate benefit package requirements. We have included the medically needy with the

list of exempt populations because the medically needy population is effectively exempted by exclusion from the definition of "full benefit eligible".

We note that we have allowed States flexibility to define the exempt group of "medically frail and special needs" individuals, and States could include in this group, for example, children with serious emotional disturbances and individuals with mental illness.

We encourage States to broadly define medically frail and/or individuals with special medical needs to include these individuals.

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: We released a State Medicaid Director's letter on June 5, 1998 in which CMS provided guidance that Medicaid eligibility is not tied under Federal law to States' TANF eligibility criteria.

The impact of this exemption in the context of alternative benefit packages would be that only individuals receiving medical assistance solely on the basis of the individual's TANF eligibility can be exempt from mandatory enrollment into benchmark or benchmark-equivalent packages. Because we believe linking does not currently occur in State Medicaid programs, we believe there are no individuals affected by this exemption. It is important to note that individuals eligible under section 1931 of the Act can be mandatorily enrolled in benchmark or benchmark-equivalent plans and are also not affected by this exemption.

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, AI/ANs. Several commenters believed that the same compelling policy reasons for excluding AI/ANs from mandatory managed care support excluding them from mandatory enrollment in benchmark plans, and request that we revise the rule to be consistent with current policy described in the Medicaid managed care rule of 2002.

Response: The commenter pointed out that 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. That was a misreading of the statute and we have 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 statutory exempt category at section 1937(a)(2)(vi) 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 the 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 contain a separate definition of adults with special medical needs.

After reviewing public comment, we have determined to allow States flexibility to adopt reasonable definitions of "individuals with special medical needs" as long as that definition includes the children specified in § 438.50(d)(3).

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 we must also recognize that those special protections were not included under section 1937. 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 AI/ANs are not a statutory group that is exempt from enrollment in an alternative benefit package, they remain exempt from mandatory enrollment in managed care. As a result, a State that operates an alternative benefit package through managed care providers must provide AI/ANs 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.

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: CMS does not believe there is extra work involved in determining eligibility that would reduce potential savings. CMS currently has approved nine State plan amendments offering benchmark benefits to Medicaid beneficiaries. Some States have converted some of their section 1115 populations into State plan populations covered through benchmark benefit packages. CMS also has several benchmark State plan amendments pending Federal review. We would like to point out that this Medicaid State plan option was modeled partly based on the success seen in separate SCHIP programs as well as in section 1115 demonstrations with similar flexibility. Additionally, CMS has identified in section VI of the "Regulatory Impact Analysis" of this regulation that savings can accrue if States choose to adopt alternative benefit programs and that savings will be achieved through cost avoidance of future anticipated costs by providing appropriate benefits based on meeting a population's health care needs, achieving appropriate utilization of services, and through gains in efficiencies through contracting. We believe States will be able to take greater advantage of marketplace dynamics within their State, and we anticipate that a number of States will use this flexibility to create programs that are similar to their SCHIP programs. We believe that because States are no longer tied to statewideness and comparability, States will be able to offer individuals and families different types of plans consistent with their health care needs and available delivery systems.

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 by each State in light of the particular eligibility conditions in that State. For example, the phrase could refer to 209(b) States, 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”. And the 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: We have not defined this term in this rule and, after considering public comment on the issue, have determined to allow State flexibility in adopting a reasonable interpretation. CMS will require that States offering alternative benefit packages to 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, CMS intends to interpret the required public input process, to include informing interested parties of the State’s proposed definition of “medically frail.”

Comment: Another commenter suggested CMS use the existing HHS (Maternal and Child Health Bureau) definition of “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 “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 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 TEFR children, children in foster care or receiving other out of home placement, children receiving foster care or adoption assistance or are receiving services through a community based coordinated care system.

We appreciate commenters’ suggestions of additional populations for inclusion in the definition of special medical needs. In this final rule, we are allowing States flexibility to adopt a reasonable definition of the term. CMS encourages States to consider all of these individuals for inclusion in the definition of “individuals with special medical needs.”

To maintain maximum State flexibility, we are thus not imposing a Federal definition other than requiring that the population include at least those children identified in § 438.50(d)(3). CMS will require that States offering alternative benefit packages inform CMS as to their definition of “special medical needs.” States will be required to ensure that exempt populations, including individuals with “special medical needs” are not mandatorily enrolled in alternative benefit packages, but are instead offered an informed choice. Additionally, CMS intends to 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 States should provide information and assistance to exempt individuals who are given the option to enroll in alternative coverage so they can make an informed choice. We proposed in § 440.320 that States must inform the recipients that enrollment is voluntary and that the individual may opt out of the benchmark or benchmark-

equivalent benefit package at any time and regain immediate eligibility for the standard full Medicaid program under the State plan. We also proposed that States must inform the recipient of the benefits available under the benchmark or benchmark-equivalent benefit package and provide a comparison of how the benefits differ from the benefits 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 have revised the proposed rule at § 440.320(a)(1) to require that the State must “effectively” inform the individuals. To the extent that the informed choice process continues to raise concerns, we may issue guidance as to what processes are necessary to insure that the informed choice process is effective.

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 opt out.

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. Further, individuals should also receive information on how to opt out of 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. Exempt individuals must be afforded the opportunity to opt out of benchmark or benchmark-equivalent coverage if it is determined that the coverage is not meeting their health care needs.

In addition, when alternative benefit packages are furnished through managed care contractors, all managed care requirements apply, as indicated at § 440.305(e). For managed care entities, pursuant to § 438.10, all informational materials and instructional materials relating to enrollees and potential enrollees must be provided in a manner and format that may be easily understood.

Comment: Some commenters stated that the rules should provide for

immediate revocation of any voluntary election at the discretion of those excluded individuals who elect an alternative plan. They 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. They 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. And they 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 it necessary to revert to traditional Medicaid and/or for individuals who are later determined eligible for an exempted group, opt out requests must be acted upon promptly and States must have a process in place to ensure continuous access to services while opt out requests are being processed.

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.

At this time, we do not see a need for additional oversight measures when alternative benefit packages are offered outside of the managed care context.

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 opt into 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. And, 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 redetermining eligibility for enrollees.

Additionally, if it becomes apparent that 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), it is incumbent upon the State to provide the individual with information about their benefit options. These individuals must have the

opportunity to receive State plan services that may not be available in the benchmark plan either as wrap-around to the benchmark plan or by reverting to traditional Medicaid.

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 "opt-out" approach to their enrollment. They suggested that the proposed language could allow or even encourage States to adopt an opt-out approach without further clarification, the language could be read to allow States to initially enroll all exempt persons who do not affirmatively opt out. 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 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. Further, 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 is 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.

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 provide benchmark or benchmark-equivalent benefit options, individuals exempt from mandatory enrollment 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. We believe that in order for exempt individuals to make an informed choice, the information must be fully detailed. But we have determined not to include specific standards for these benefit crosswalks in the regulation itself because we believe this issue is better addressed in case-by-case program reviews.

Comment: Another commenter believed CMS should prohibit States from implementing procedures that make it harder 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.

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.

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 transition of individuals if they become eligible for exempt categories and thus 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 opt out requests are acted upon promptly and that States must have a process in place to ensure continuous access to services while any opt out requests are being processed. These State plan requirements would mean that if an individual becomes 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 transition individuals quickly and/or to provide information to individuals quickly to ensure an informed choice. We believe that States should not rely on the individual's ability to revert back to Medicaid. These individuals are entitled to the full range of Medicaid benefits. They must have the choice to receive them either as part of, or as wrap-around to, the benchmark plan or as part of 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 or who have not met the 5-year bar for lawful permanent resident aliens) are exempt individuals that cannot be mandatorily enrolled in benchmark plans.

Unqualified individuals are not entitled to Medicaid unless they are aliens eligible for Medicaid coverage in situations where care and services are necessary for the treatment of the alien's emergency medical condition (see section 1903(v) of the Act). Thus, these individuals can be enrolled in a benchmark or benchmark-equivalent plan on a voluntary basis. The limitations in § 440.320 and section 1903(v) of the Act would apply.

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. They 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. We have approved six Secretary-approved benchmark plans. All of these six plans include not only all regular Medicaid State plan services but provide for additional services like disease management and/or preventive services as well.

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 women's freedom of choice is critical in the delivery of these services. 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, 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: Even if one of the statutorily-specified benchmark packages did not contain family planning services, the statute nonetheless permits States to base an alternative benefit package on that benchmark. CMS has no authority to disapprove the use of a statutorily-specified benchmark plan as the basis for an alternative benefit package. Consequently, we are revising § 440.375 to update the title and revise the text of this section to indicate that States can provide benchmark or benchmark-equivalent coverage to recipients 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 Secretarially-approved coverage, we agree with the commenters that if a benchmark benefit plan is provided to individuals of child bearing age that did not include family planning services, it may not be appropriate to meet the needs of the population it serves. Additionally, if a benchmark or benchmark-equivalent benefit package does not include family planning services, States have the option of providing wrap-around or additional benefits to the benchmark. Because of the flexibility granted by the DRA, States can submit innovative designs for implementing Medicaid programs to their beneficiaries. CMS will review each State plan amendment on a case by case basis and will consider the merit of each design based on the standard that benchmark benefit packages "are appropriate to meet the needs of the targeted population."

Comment: Other commenters believed that one reason States may wish to design a plan under the option for benchmark-equivalent or Secretary approved 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 can be offered as benchmark plans, so long as basic services are provided as part of the benchmark-equivalent benefits or the benefit package is appropriate to meet the needs of the population it serves for Secretary-approved coverage. The rule is consistent with these flexibilities. Additionally, the rule provides that the scope of a Secretary-approved health benefits package or any wrap-around or 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.

In considering the benchmark packages that have been approved by CMS, States have created innovative designs that do offer additional services and do provide for efficiency.

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 less 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 will still be 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: Another commenter pointed out that the benchmark 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: CMS clarifies that any and all services under section 1905(a) of the Act must meet medical necessity. Prescription drugs, mental health services, vision services, or hearing services would meet the test of medical necessity, however, it is important to note that these services are not considered mandatory services under the State plan but rather are considered optional services. Many States have chosen not to provide Medicaid beneficiaries with optional services under their state's Medicaid State plan.

Further, it is the DRA that specifies 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 is also not required to provide the coverage. This would be logical since, in calculating the actuarial value of the benchmark-equivalent, the actuarial value would be calculated based only on the services included in the benchmark plan and not calculated based on services that are not included. This is consistent with the statutory provision, and we have maintained this flexibility in the rule.

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 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 interpreted other appropriate preventive services to include services such as emergency services, but have left States with flexibility to define other appropriate preventive services. We disagree with the commenter that additional services should be added to the list of services that are required services under benchmark-equivalent plans.

It is important to note, however, that States, at their option, can provide additional or wrap-around services to benchmark or benchmark-equivalent plans. Including rehabilitation services may be appropriate for some populations. Additional and wrap-around services are discussed in § 440.360 of this rule.

We did not receive any comments to § 440.340 Actuarial report. Therefore, § 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. 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: We agree that it is important for individuals to receive services from the same provider, whenever possible. We believe that an individual's primary care provider is in the best position to "manage" an individual's care. For individuals enrolled in a benchmark or benchmark-equivalent benefit plan, the primary care provider is going to be serving the individual under that plan. If an individual is entitled to additional services, the primary care provider should be responsible for providing and/or coordinating the individual's care and should be aware of any additional services the individual needs.

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 these 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: It is important for individuals to first seek coverage of EPSDT services through the benchmark plan since we believe the benchmark provider should serve as the "medical home" for the individual. Thus, the benchmark provider becomes the one central source of a child's pediatric record and can guard against duplication and gaps in services. The benchmark provider ensures that care is managed and coordinated, providing

access to specialists and necessary support services. Also, the benchmark provider facilitates access to information regarding the services to which the individual is entitled and information regarding how and when to access such services. We believe that in accessing services first through the benchmark plan the provider can act as a facilitator who coordinates and leverages the attributes and resources of a complex healthcare system and advocate for the beneficiary as they navigate care options and information available to them. As such, we believe the individual will be provided with better health care service and will experience better health care outcomes overall.

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 read "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. 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 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 should clearly explain the benchmark and wrap-around benefits available to EPSDT eligibles under the age of 19.

Additionally, we agree with the commenter that the word "may" was inaccurate in the preamble to the proposed rule. The law specifically requires that States are required to wrap-around 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 eligibles. 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, and not 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 opt out.

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 opt out. 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 19 applies to benchmark and

benchmark-equivalent coverage. We have provided that States can offer employer sponsored insurance if the insurance is considered a benchmark 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 cost-effectiveness coverage requirements at § 440.370. By requiring that employer sponsored plans meet the requirements of benchmark or benchmark-equivalent coverage and since benchmark or benchmark-equivalent coverage must provide EPSDT to children under the age of 19 either as part of, or as wrap-around 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 19. 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: We have promulgated language in this rule consistent with the statutory language enacted in the DRA. Requiring States to extend EPSDT benefits to 19 and 20 year olds enrolled in benchmark plans would require a change in law since section 1937(a)(1)(A)(ii) of the Act provides only that children under 19 years old must receive coverage of EPSDT as defined in section 1905(r) of the Act. States are given the option to extend EPSDT benefits in benchmark plans to 19 and 20 year olds. This option is similar to the choice States currently have in extending Medicaid eligibility to 19 and 20 year olds; thus, extending EPSDT to 19 and 20 year olds under the State plan. We note that in approving nine benchmark State plan amendments, most States with approved benchmark plans have extended EPSDT coverage to 19 and 20 year olds enrolled in these plans.

Comment: One State Medicaid official suggested, instead of the current language in the published proposed rule on (page 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 agree to adopt the language precisely as included in the statute. We have revised the rule to effectuate the clarification.

I. Section 440.350 Employee-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 with the addition of wrap-around services covered separately under Medicaid), a State may elect to provide premium payments on behalf of the recipient 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 19 to receive EPSDT either as wrap-around 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 cost-effective, 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 cost-effectiveness 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 does 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 wrap-around or additional benefits are options that can be added by the State as additional benefits to benchmark or benchmark-equivalent coverage. Any wrap-around services that are added do not need to include all State plan services; however, 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.

The only requirement for wrap-around services is at section 1937(a)(1)(A)(ii) of the Act, which provides that if children under the age of 19 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 wrap-around 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 scope of the categories available under a benchmark coverage package or 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 nine benchmark programs. Of these nine, six have been approved as Secretary-approved programs. At least one of the Secretary-approved plans includes such innovations as high deductible health plans.

We did not receive any comments to § 440.355 Payment of premiums. Therefore, § 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 Wrap-Around 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 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 includes no such requirement for the inclusion of dental coverage as wrap-around or additional services. In fact, section 1937 of the Act provides no examples of wrap-around or additional coverage. The rule provides that additional or wrap-around 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 or considered to be health benefits under 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 19 must receive EPSDT services consistent with section 1905(r) of the Act either as part of, or as wrap-around to, the benchmark plan. Therefore, dental coverage will be provided to children under the age of 19 enrolled in benchmark plans.

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 only

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 recipients 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 Cost-effectiveness. Therefore, we will adopt § 440.370 as written in the proposed rule of February 22, 2008.

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 for 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. We interpreted this “notwithstanding language” to provide that States could offer benchmark or benchmark-equivalent coverage to certain specified Medicaid populations, considering different benefit packages, and to different regions within the State. This provision gives meaning to the statutory language permitting States to offer benchmark or benchmark-equivalent coverage to certain, but not all, Medicaid populations.

For example, States could craft benchmark options that provide individuals with a benefit that integrates acute care and long term care services and a different benefit that provides for traditional State plan services with the addition of disease management services. We believe this provides that States can better meet the needs of their Medicaid populations, and we further believe that this is consistent with Congressional intent in establishing maximum flexibility for implementing benchmark benefit options.

M. Section 440.380 Statewide ness

Comment: One commenter is concerned that States are given the option to amend their State plan to provide benchmark plan coverage to Medicaid recipients without regard to statewide ness. 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 statewide ness 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. We interpreted this “notwithstanding language” to provide that States could offer benchmark or benchmark-equivalent coverage to certain Medicaid populations, considering different benefit packages, and to 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 could craft benchmark options that provide individuals with a benefit in an urban area of the State that is different from the benefit offered to individuals in the rural area of the State. Moreover, States can test new concepts in pilot areas before expanding the benchmark program to the entire State. We believe this provides that States can better meet the needs of their Medicaid populations, and we further believe that this is consistent with Congressional intent in establishing maximum flexibility 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 provider asserted that provider freedom of choice is critical because of the potentially sensitive nature of the service. The commenter argued that, 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: We agree. Accordingly, we have revised the regulation to ensure that selective contracting does not apply to family planning services providers.

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. Selective contracting provides States with the opportunity to contract with certain providers so long as certain other criteria are maintained.

Specifically, the State must ensure that in order to selectively contract with providers, the selective process does not restrict providers in emergency situations; 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. Also, all providers must be paid on a timely basis consistent with Federal regulations at § 447.45. States previously requested section 1915(b)(4) waiver authority for selective contracting, but now because of the flexibilities outlined in the DRA, we will provide that States can selectively contract with providers in offering benchmark benefit coverage without requesting a 1915(b) waiver. By using State plan authority, the burden for requesting waiver renewals every 2 years would be eliminated.

We believe the authority to provide for selectively contracting is as a result of the DRA language that provides that

"notwithstanding any other provision of Title XIX," States can offer medical assistance through the use of alternative benchmark benefits to certain Medicaid beneficiaries. We believe that Congress intended for States to have a great amount of flexibility to tailor benefit packages appropriate to specified groups of Medicaid recipients. We also believe that Congress intended that efficiency and cost-effectiveness should be maintained in implementing State Medicaid programs. Thus, we have required in § 440.370 that benchmark or benchmark-equivalent coverage must be provided in accordance with economy and efficiency principles. Selective contracting of providers affords the greatest amount of flexibility, works to provide beneficiaries with continuity of care, and is cost-effective.

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: We are not requiring States to incorporate an "any willing provider" requirement when selectively contracting for benchmark or benchmark-equivalent benefits. We believe that the protections we have incorporated into the selective contracting provisions at § 440.385 are sufficient to ensure beneficiary access to benchmark or benchmark-equivalent benefits. And, even under the selective contracting provisions, States have the option to provide that "any willing provider" can provide services to individuals who enroll in benchmark plans, so long as the provider is a qualified provider that meets the criteria established in title XIX and in Federal regulations as a qualified provider, and agrees to accept the reimbursement, quality, and utilization standards set forth in the State plan.

This would mean that States can contract with specific providers in offering specific services; for example, States could contract with a dental managed care plan to provide Medicaid beneficiaries with dental services. We recognize that individuals may have concerns with the flexibility granted herein that States can selectively contract with providers if certain conditions are met. However, over the years States have selectively contracted with providers and we believe individuals continue to receive quality care. We believe that to allow States the option to selectively contract with providers gives States the flexibility to provide for benchmark or benchmark-

equivalent packages consistent with the intent of the DRA while still providing that individuals continue to receive quality health care.

O. Section 440.390 Assurance of Transportation

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: We agree that offering benchmark or benchmark-equivalent benefit packages without regard to the assurance of transportation is consistent with 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. These benchmark plans generally do not pay for NEMT to and from medical providers in all instances. Since section 1937 of the Act gives States the flexibility to provide benefits that are similar to commercial packages, it would appear inconsistent with that flexibility to require the States to provide NEMT that the selected benchmark package do not offer.

Comment: A preponderance of commenters, however, 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 their difficulty to access the needed care. For example, one commenter stated that, in the case of patients with ESRD, many patients would be unable to access dialysis services.

Response: We disagree that benchmark and/or benchmark-equivalent plan options undermine the intent of the Medicaid program and create major barriers to access appropriate care. The benchmark and benchmark-equivalent plan options provide unprecedented flexibilities to States in an effort to create benefit packages that appropriately meet the needs of their Medicaid populations. In order to provide States with maximum flexibility, the rule provides that States can offer benchmark or benchmark-equivalent coverage without regard to the assurance of transportation, which will align these plans with today's health care environment.

Generally, private health insurance plans do not offer non-emergency medical transportation as a medical benefit to enrollees. However, many private health plans do cover emergency ambulance transport, and in some cases, non-emergency ambulance transport for circumstances such as transporting beneficiaries between facilities. When a State selects a private health plan that provides coverage of emergency ambulance and/or non-emergency ambulance transport, the State is required to follow the coverage policy for transportation that is contained in the private health plan.

If, however, the private health plan does not provide emergency transportation or NEMT benefits, the State may choose to provide some or all transportation assistance as a wrap-around service to the benchmark plan. To date, nine States have approved benchmark State plans. Of these nine States, only three do not provide NEMT services to beneficiaries enrolled in benchmark programs.

It is, therefore, important to recognize that section 1937 of the Act contains protections for children and exempt individuals. Children will continue to have access to NEMT as an EPSDT benefit. Exempt individuals will have an informed choice to determine whether enrollment in a alternative benefit package is advantageous, and may take into account the availability of NEMT in making that election.

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 recipients 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.

One 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.

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: Generally, the populations that are mandated to enroll in a benchmark program are healthier and require medical services less frequently than most Medicaid eligibles. Moreover, children who are enrolled in benchmark or benchmark-equivalent coverage will continue to receive NEMT services because NEMT is required under EPSDT. The most vulnerable individuals are statutorily exempt individuals, such as those with disabilities or special medical needs, who cannot be mandated to enroll in a benchmark benefit plan but rather must be provided the choice to enroll, including a comparison of the benefits in the benchmark or benchmark-equivalent plan versus those in the traditional State plan package. If exempt individuals choose to enroll in a plan that does not cover NEMT services, these individuals have the right to disenroll at any time if they find that they need transportation assistance. Because the population for which NEMT may not be provided could be very limited, we do not agree that the impact of allowing States to choose not

to provide NEMT will be great enough to increase Medicaid costs.

To the extent that the commenters are correct that noncoverage of NEMT will lead to higher eventual costs, we believe that States will respond by ensuring coverage for NEMT. It is a State's choice whether to include NEMT benefits when offering benchmark or benchmark-equivalent coverage. It is certain States will consider the potential impact on costs and beneficiaries' health care utilization and status when they make these decisions.

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: We do not agree with the commenter that not requiring NEMT will result in fewer providers participating in the Medicaid program. Provider participation in Medicaid is based on a number of reasons, including patient loads and reimbursement rates.

To the extent that the commenters are correct that noncoverage of NEMT will lead to lower provider participation, we believe that States will respond by ensuring coverage for NEMT. It is a State's choice whether to include NEMT benefits when offering benchmark or benchmark-equivalent coverage. It is certain States will consider the potential impact on provider participation when they make these decisions.

Comment: 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 wheel chairs, 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: As we stated in a previous response, beneficiaries with end-stage renal disease who rely on dialysis treatments and beneficiaries with other physical and mental disabilities, individuals with HIV/AIDS, and those who are medically frail and elderly are likely exempt populations for which mandatory enrollment in benchmark or benchmark-equivalent plans may not occur. If exempt individuals who voluntarily enroll in benchmark plans determine that the plan is not meeting all of their health care needs including NEMT, such exempt individuals must be given the opportunity to disenroll from the benchmark program and revert to traditional Medicaid at any time. Additionally, children under the age of 19 must be provided with EPSDT services and thus will receive NEMT. Furthermore, the benchmark or benchmark-equivalent plans available may provide NEMT services. Consequently, we believe that only a very limited number of the cited individuals would not be provided with NEMT services.

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 in tact 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: Because there are significant portions of the Medicaid population that will still be able to receive NEMT services, even if their State has chosen to implement the benchmark plan option, we do not believe that the flexibility in not providing NEMT to beneficiaries enrolled in benchmark plans would greatly reduce the overall availability of ambulance services, nor would it imperil the financial stability of ambulance services across the EMS community. It should also be noted that Medicaid is not responsible for the general operation or deficit financing of public or private transportation providers. The commenter's assumption that the elimination of NEMT would likely cause over-utilization of emergency ambulance services is unfounded. States as well as private insurers have in place policies stipulating when transport by emergency ambulance is appropriate,

and these policies make it less likely that there would be abuse on the part of beneficiaries.

With regard to the comment 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, we do not believe that it is necessary to require in this regulation specific guidelines that are universally used by commercial insurance. Due to the benchmarking requirements, services in universal use will probably be included in benchmark or benchmark-equivalent plans.

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 EMS systems, 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. 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: We continue to believe that the responsibility for Medicaid NEMT will not be shifted to municipal EMS systems, ADA paratransit programs, or beneficiaries. Many beneficiaries are exempt from mandatory enrollment in benchmark benefit plans and therefore will continue to receive NEMT services if they choose to remain in traditional State plan coverage. If they enroll in benchmark or benchmark-equivalent coverage and determine that the coverage is not meeting their needs, they can revert to traditional Medicaid State plan coverage at any time. Also, children under the age of 19 will receive NEMT because of the EPSDT requirements. Consistent with Federal regulations, States are required to assure non-emergency transportation only 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: Benchmark and benchmark-equivalent plans model the private health insurance plans which frequently cover emergency medical transportation. Thus, there is no need to specifically require coverage of emergency ambulance 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. Another commenter indicated that coordinating transportation would reduce the cost of providing transportation.

Response: Coordination and monitoring of the provision of transportation services is not relevant to this rule. We agree that the reduction of fraud and abuse by States should always be considered by States when designing or implementing their State Medicaid 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. It is clear that the proposed rule is contrary to the intent of Congress.

Response: We are unaware of any attempt by CMS during this regulatory process to end the requirement for States to assure Medicaid non-emergency transportation. On the contrary, on August 23, 2007, CMS published a rule on the “State Option to Establish a Non-Emergency Medical Transportation Program.” When implemented, this regulation will enhance the ability of States to provide NEMT by offering the new option to provide more cost effective non-emergency transportation as a medical service through a brokerage program.

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

encourages use of a brokerage program, while at the same time provides guidance on the 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: CMS understands that there are two separate provisions in the DRA, one providing for a brokerage program for non-emergency medical transportation and the other offering benchmark or benchmark-equivalent benefits to certain Medicaid beneficiaries. These benchmark plans can be offered without regard to the assurance of transportation, including non-emergency medical transportation. CMS understands the confusion this may cause; however, it should be noted that in adopting these transportation provisions in the DRA, Congress provided States with additional flexibilities to redesign their Medicaid programs in order to maintain sustainability. These options are intended to be used by States to improve the delivery of health care to Medicaid beneficiaries as well as to reduce overall costs, including improving the delivery of non-emergency medical transportation.

The brokerage program option for delivering non-emergency medical transportation and the benchmark or benchmark-equivalent benefits option that allows States to deliver benchmark health plans without regard to the assurance of transportation do not contravene each other as the commenter suggests. These are merely options that are part of an array of improvements and cost saving measures that can be selected by States. Because there is no requirement for a State to select either the brokerage program option or the benchmark or benchmark-equivalent option we do not believe that these

transportation provisions are contradictory.

Moreover, as noted below, the fact that States have options to operate fiscally sound transportation programs simply indicates that the flexibility with respect to benchmark and benchmark-equivalent coverage will not necessarily result in the elimination of needed transportation benefits.

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 assumes 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 DRA provided that benchmark or benchmark-equivalent plans be available to States at their option and States are not required to implement these provisions. If States choose to offer benchmark or benchmark-equivalent benefit packages to Medicaid beneficiaries, States must comply with the requirements of section 1937 of the Act including EPSDT for children under age 19 and voluntary enrollment and informed choice to exempt individuals. Further, States can offer additional or wrap-around services to beneficiaries. If NEMT and emergency ambulance services are included in the benchmark or benchmark-equivalent plan the State has chosen to offer Medicaid beneficiaries, these transportation services should be provided to the beneficiaries enrolled in the benchmark or benchmark-equivalent plan. States also have the option of providing NEMT and/or emergency transportation services as a wrap-around benefit.

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 or 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 disagree with the commenter. In the "Regulatory Impact Analysis," we made two key assumptions: (1) The per capita cost of benchmark plans relative to per capita costs for Medicaid, and (2) the rate at which these plans will be used. Given the amount of flexibility States have in designing these plans, we do not have information that drills down into service-level estimates. Subsequently, we did not specifically account for the impact that not providing NEMT would have. In our opinion, the proposed rule provides States with so much flexibility it would not be possible to anticipate how many States might have benchmark plans that would have an impact on transportation. Furthermore, since there are significant portions of the Medicaid population that will still be able to receive transportation services, even if their State chooses to implement a benchmark or benchmark-equivalent plan that has limited or no transportation coverage, we do not believe the impact as being significant since beneficiaries have always been personally responsible for seeking alternative transportation before requesting assistance from the Medicaid program.

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 includes 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 recipients 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: States have broad flexibility in designing non-emergency and emergency transportation programs for the Medicaid population. Consistent with this flexibility, we believe that States are best suited to define the differences between emergency and non-emergency transportation and when and under what conditions it is appropriate to transport beneficiaries by ambulance. In determining this difference, we expect States to remain consistent with the definition of transportation found in § 440.170.

Additionally, experience has shown us that many of the States that have submitted benchmark State plan amendments have included transportation as a covered benefit, even when the private plan does not provide a transportation benefit.

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-emergent 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: We acknowledge that many private health plans cover emergency medical transport and some also cover non-emergency ambulance transport. Therefore, it is highly likely that benchmark plans will cover these services. However, we maintain that private health plans do not generally cover transportation to and from outpatient providers for routine services.

In terms of contracting with providers, the contracting process between States and providers is a State process. CMS is not intending to enter into that process as part of this rule.

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 (*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 recipients 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: We disagree with the commenters that believe we do not have authority to allow for States to offer benchmark or benchmark-equivalent plans without regard to the assurance of transportation. Section 1937 permits States to offer benchmark or benchmark-equivalent coverage “notwithstanding any other provision of Title XIX.” We have interpreted this language to provide a basis for flexibility with regard to requirements related to the scope of benefits available through benchmark or benchmark-equivalent coverage to provide that such benefits can be offered without regard to the requirement at § 431.53 to assure transportation to and from covered medical services. This regulation is thus consistent with the statutory language, and the overall purpose to ensure State flexibility in offering benefits. Moreover, the assurance of transportation is not a statutory benefit, but is a regulatory requirement that should not be given precedence over the statutory flexibility expressly provided by Congress. The statute itself provides that States can impose alternative benchmark or benchmark-equivalent benefit packages at their option, and must reasonably be read to include flexibility in the scope of benefits including transportation benefits.

We also note that the availability of this flexibility does not mean that beneficiaries will necessarily lose transportation benefits. States are not required to offer benchmark or benchmark-equivalent coverage and, if they do, they are not required to limit coverage of transportation to and from providers. As noted above, States may determine that such coverage is

essential to ensuring appropriate coverage to meet the needs of the target population.

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” a recipient 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, we have not defined “medically frail” because CMS wishes to maintain the State flexibility; however, we encourage States to consider all of these examples in their definition, when considering that these individuals may be in need of transportation.

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 recipients receive. Also, the commenters asserted that the “notwithstanding any other provision of this title” will not pass a challenge in the court system because it discriminates against disabled individuals.

Response: We disagree with the commenters that the flexibility to not assure transportation is discriminatory because this requirement applies to all individuals enrolled in benchmark or benchmark-equivalent plans (with certain limitations). All individuals are treated equally including all exempt individuals. Disabled individuals can only enroll in a benchmark program that does not include NEMT by choice.

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: We do not believe that this rule contravenes Executive Order 13330, which requires coordination of transportation among Federal agencies, but does not supersede program coverage limitations or purposes. In other words, section 1937 simply does not require NEMT to be included as a benefit or administrative activity of alternative benefit programs, and Executive Order 13330 does not change that circumstance.

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 understand that Alaska has unique transportation needs and that the vast majority of AN villages are accessible only by plane, boat, snow machine, or dog-sled. We are also aware that tribal health services provide the majority of health care to Medicaid eligible tribal populations. Before the passage of the DRA, Alaska provided transportation through a broker under section 1915(b) authority. In 2006, Alaska converted its non-emergency transportation waiver to the State plan non-emergency medical transportation brokerage program option provided by the DRA.

While AN beneficiaries have not been specifically excluded from mandatory enrollment in a benchmark plan, due to the rural nature of the areas in which these beneficiaries live and the unique transportation needs of ANs in Alaska, we do not believe that AN beneficiaries are at risk of losing needed transportation benefits. We do not believe it is in the interest of the State to eliminate such benefits, nor that it would be consistent with appropriate

coverage to meet the needs of the targeted population.

IV. Provisions of the Final Regulations

For the most part, this final rule incorporates the provisions of the February 2008 proposed rule. Those provisions of this final rule that differ from the February 2008 proposed rule are as follows:

Scope (§ 440.305)

We have added a new paragraph (d) at § 440.305 to provide for public input, which states “Any state that opts to offer alternative benchmark or benchmark-equivalent coverage to Medicaid beneficiaries must secure public input prior to the submission of any State plan amendment to CMS.”

We have also added a new paragraph (e) at § 440.305 to indicate that in implementing benchmark or benchmark-equivalent package, States must comply with the managed care rules at section 1932 of the Act and 42 CFR part 438 if benchmark or benchmark-equivalent benefits are provided through managed care plans, except when the State demonstrates that such requirements are impractical in the context of, or inconsistent with, methods of offering coverage that is appropriate to meet the needs of the targeted population.

Exempt Individuals (§ 440.315)

We have revised paragraph (f) to indicate that the definition of individuals who are medically frail and/or the definition of individuals with special medical needs will be left to State discretion but the definition for individuals with special medical needs must at least include those individuals described in § 438.50(d)(3). Further, we deleted the reference to § 438.50(d)(1) for individuals entitled to Medicare benefits as these individuals are already exempt individuals for whom voluntary enrollment because of the requirement in section 1932(a)(2)(iii) of the Act.

We have 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 for which voluntary enrollment in benchmark or benchmark-equivalent plans can occur.

Section 440.320 State Plan Requirements: Optional Enrollment for Exempt Individuals

We have revised paragraphs (a)(1), (a)(2), and (a)(3) to indicate that the State must effectively inform exempt individuals prior to enrollment that the individual has the opportunity to

voluntarily enroll in a benchmark or benchmark-equivalent plan, 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 the individual's eligibility file that prior to enrollment he was provided a comparison of the benefit 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 have added a new paragraph (a)(4) to indicate 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 have added a new paragraph (b)(1) and (b)(2) to discuss the disenrollment/opt out process and require that States act upon opt out requests promptly for those exempt individuals who choose to opt out of benchmark or benchmark-equivalent coverage and must have a process in place to ensure continuous access to services while requests to opt out of benchmark or benchmark-equivalent coverage are being processed.

EPSDT Services Requirement (§ 440.345)

We have revised paragraph (a) in § 440.345 to be completely reflective of the statutory language, which indicates 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 wrap-around benefits to those plans 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.”

Comparability and Scope of Coverage (§ 440.375)

We revised the title and text of this section to indicate that States have the option to amend their State plan to provide benchmark or benchmark-equivalent coverage to recipients without regard to comparability or requirements relating to the scope of coverage other than those contained in this subpart.

Freedom of Choice (§ 440.385)

We have redesignated paragraph (b)(3) as paragraph (b)(4) in § 440.385 of this regulation. In newly revised paragraph (b)(3), we have made clarifying changes to indicate that selective contracting

does not apply to family planning providers.

V. Collection of Information Requirements

While the following requirements are subject to the PRA, they are currently approved under OMB# 0938-0993 with an expiration date of October 31, 2009.

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 opt out of 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 recipient 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 recipient's eligibility file that the recipient 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 wrap-around benefits or additional services will be provided to ensure that recipients 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 Wrap-around 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

At proposed § 440.390, a State may at its option amend its State plan to provide benchmark or benchmark-equivalent coverage to recipients without regard to the assurance of transportation to medically necessary services requirement specified in section 42 CFR 431.53.

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, as further amended), 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), and Executive Order 13132 on Federalism (August 4, 1999), and Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 (as amended) by Executive Order 13258, which merely reassigns responsibility of

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

We issued a State Medicaid Director's letter on March 31, 2006, providing guidance on the new flexibilities available to States as a result of the enactment of the Deficit Reduction Act of 2005. This final rule simply codifies that guidance. States have already begun implementing this provision well in advance of this final rule. As a result, while we anticipate that implementation of this flexibility will be economically significant, the significance is based on the changes authorized by statute and not based on discretionary policies contained in the rule itself. The impact of the rule will be limited to ensuring uniform policies for States that implement the flexibility afforded under section 1937 of the Act, as added by the DRA of 2005. The aggregate amount of Federal savings is estimated to be \$2.3 billion from FY 2006 through FY 2010.

We have 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 assume 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.

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 have assumed States are equipped to implement these plans and will be part of their normal administrative spending.

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.

ESTIMATED ANNUAL FEDERAL SAVINGS DISCOUNTED AT 0 PERCENT, 3 PERCENT AND 7 PERCENT—FROM FY 2006 TO FY 2010
[In millions]

Discount rate	2006	2007	2008	2009	2010	Total 2006–2010
0%	\$70	\$280	\$460	\$660	\$810	2,280
3%	68	264	421	586	699	2,038
7%	65	245	375	504	578	1,767

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 SCHIP

programs. Because States are no longer tied to statewideness and comparability rules for non-disabled, non-aged, and non-blind populations, they will be able

to offer individuals and families different types of plans consistent with their needs and available delivery systems.

ESTIMATED ANNUAL STATE SAVINGS DISCOUNTED AT 0 PERCENT, 3 PERCENT AND 7 PERCENT—FROM FY 2006 TO FY 2010

[In millions]

Discount rate	2006	2007	2008	2009	2010	Total 2006–2010
0%	\$50	\$210	\$350	\$500	\$610	\$1,720
3%	49	198	320	444	526	1,537
7%	47	183	286	381	435	1,332

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 \$6.5 million to \$31.5 million in any 1 year.) Individuals and States are not included in the definition of a small entity. We have determined, and the Secretary certifies, 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. We have determined, and the Secretary certifies, 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 2008, that threshold is approximately \$127 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.

Therefore, there is no mandate for the State. We believe this final rule will not mandate expenditures in that amount.

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 government 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 AI/AN 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 State 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 AI/AN 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 recipient, regardless of income, eligibility category, or geographic location. Some States offered alternative benefit packages to certain recipients 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 the constraints of a waiver. Moreover, Medicaid families will gain continuity in coverage as family members move together from Medicaid and the State Children’s Health Insurance Program (SCHIP) to, eventually, private coverage. Today, because of the lack of flexibility in Medicaid, one child may be receiving Medicaid, another in SCHIP, and the parent has access to private coverage. With benefit flexibility in State Medicaid programs, families could enroll under the same plan, with the same providers and one set of administrative rules. Administrative simplification can help families maintain health insurance coverage and give them experience with private insurance coverage that would become important when their income rises above Medicaid and SCHIP eligibility levels and mitigate the need for dependence. States with strong employer-based coverage may emphasize family coverage premium assistance. States may form larger pools by combining Medicaid recipients 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 maximize State flexibility while assuring that beneficiaries will get quality care that meets their needs. Under this rule, we will permit States to define the alternative benefit packages only by reference to the benchmark or benchmark-equivalent standard (with the exception of the EPSDT wrap-around benefits). We will also permit States to combine an alternative benefit package with alternative benefit delivery methods, such as through managed care, employer-based coverage, or selective contracting. 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 15 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—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED SAVINGS, FROM FY 2006 TO FY 2010
[In \$millions]

Category	Transfers				
	Year dollar	Units discount rate			Period covered
Annualized Monetized Transfers		7%	3%	0%	
	2006	-\$430.8	-\$445.0	-\$456.0	2006–2010
From Whom To Whom?	Federal Government to Beneficiaries, Providers				
Year	2006	2007	2008	2009	2010
Annualized Monetized Transfers	-\$70	-\$280	-\$460	-\$660	-\$810
From Whom to Whom?	Federal Government to Beneficiaries, Providers				
Annualized Monetized Transfers	Year dollar	Units discount rate			Period covered
		7%	3%	0%	
	2006	-\$324.9	-\$335.7	-\$344.0	2006–2010
From Whom to Whom?	State Governments to Beneficiaries, Providers				
Year	2006	2007	2008	2009	2010
Annualized Monetized Transfers	-\$50	-\$210	-\$350	-\$500	-\$610
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 only impact is the Federal annualized monetized impact of the rule.

Column 2: 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 3: Year Dollar—Contains the year to which dollars are normalized; that is, the first year that dollars are discounted in the estimate.

Column 4: 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 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.

“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 costs represent a reduction in Federal Government spending on behalf of beneficiaries. The table may also contain minimum and maximum

estimates and sources cited. In this case, there is only a primary estimate and there are no additional sources for the estimate.

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

E. Conclusion

We project that the use of benchmark plans under this rule will result in \$2.3 billion in Federal savings from 2006–2010. 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. A new subpart C, consisting of § 440.300 through § 440.390, is added to part 440 to read as follows:

Subpart C—Benchmark Benefit and Benchmark-Equivalent Coverage

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440.380 Statewide-ness.
440.385 Freedom of choice.
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 recipients 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 recipients within one or more groups of individuals specified by the State, through enrollment of the recipients 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 would 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 opt in must be in compliance with the rules specified at § 440.320.

(d) Any State that opts to offer alternative benchmark or benchmark-equivalent coverage to Medicaid beneficiaries must secure public input prior to the submission of any State plan amendment to CMS.

(e) In implementing benchmark or benchmark-equivalent package, States

must comply with the managed care rules at section 1932 of the Act and part 438 of this chapter if benchmark or benchmark-equivalent benefits are provided through managed care plans unless the State demonstrates that such requirements are impractical in the context of, or inconsistent with, methods of offering coverage appropriate to meet the health care needs of the targeted population.

§ 440.310 Applicability.

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

(b) *Full benefit eligible.* A recipient 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.

For recipients within one (or more) of the following categories, the State plan may offer, but may not require under § 440.310, the opportunity to obtain benefits through enrollment in benchmark or benchmark-equivalent coverage:

(a) The recipient 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 recipient 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 recipient is entitled to benefits under any part of Medicare.

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

(e) The recipient 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 recipient is medically frail or otherwise an individual with special medical needs. For these purposes, the State’s definition of individuals with special needs must at least include

those individuals described in § 438.50(d)(3) of this chapter.

(g) The recipient 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 recipient is an individual with respect to whom aid or assistance is 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 recipient 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 welfare reform effective date defined in section 1931(i) of the Act). This provision relates to those individuals who qualify for Medicaid solely on the basis of qualification under the State's TANF rules.

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

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

(l) The recipient is not a qualified alien (as defined in section 431 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996) and receives care and services necessary for the treatment of an emergency medical condition in accordance with section 1903(v) of the Act.

(m) The recipient 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 opt out of 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 recipient 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.

(3) The State must document in the exempt recipient's eligibility file that the recipient was informed in accordance with this section prior to enrollment, was given ample time to arrive at an informed choice, and voluntarily 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 within 30 days after such determination.

(b) *Disenrollment or Opt/Out Process.*

(1) The State must act upon requests promptly for exempt individuals who choose to opt out of benchmark or benchmark-equivalent coverage.

(2) The State must have a process in place to ensure that exempt individuals have continuous access to services while opt out requests are being processed.

§ 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 of 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 opt for 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 in § 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) Other appropriate preventive services, such as emergency 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 taking into account 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 wrap-around benefits to those plans 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.

(1) *Sufficiency:* Any wrap-around EPSDT benefits 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 wrap-around benefits will be provided to ensure that these recipients have access to the full EPSDT benefit.

(b) Individuals must first seek coverage of EPSDT services through the benchmark or benchmark-equivalent plan before seeking coverage of such through wrap-around benefits.

§ 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 the addition of wrap-around 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 cost-effectiveness 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 recipients.

§ 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 wrap-around services.

If the State opts to provide additional or wrap-around 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 or wrap-around 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 Cost-effectiveness.

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 and scope of coverage.

States have the option to amend their State plan to provide benchmark or benchmark-equivalent coverage to recipients without regard to comparability or requirements relating to the scope of coverage other than those contained in this subpart.

§ 440.380 Statewideness.

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

§ 440.385 Freedom of choice.

(a) States have the option to amend their State plan to provide benchmark or benchmark-equivalent coverage to recipients without regard to the

requirements for free choice of provider in § 431.51 of this chapter.

(b) States may restrict recipients 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:

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

(2) Do not apply in emergency circumstances.

(3) Does not apply to family planning providers.

(4) 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 this chapter.

§ 440.390 Assurance of transportation

A State may at its option amend its State plan to provide benchmark or benchmark-equivalent coverage to recipients without regard to the assurance of transportation to medically necessary services requirement specified in § 431.53 of this chapter.

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

Dated: August 8, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: September 29, 2008.

Michael O. Leavitt,
Secretary.

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