comment on the final rule that supersedes the rule we are withdrawing.

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

Dated: April 17, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Approved: May 14, 2002.

Tommy G. Thompson,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 400, 430, 431, 434, 435, 438, 440, and 447

[CMS–2104–F]

RIN 0938–AK96

Medicaid Program; Medicaid Managed Care: New Provisions

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

ACTION: Final rule.

SUMMARY: This final rule amends the Medicaid regulations to implement provisions of the Balanced Budget Act of 1997 (BBA) that allow the States greater flexibility by permitting them to amend their State plan to require certain categories of Medicaid beneficiaries to enroll in managed care entities without obtaining waivers if beneficiary choice is provided; establish new beneficiary protections in areas such as quality assurance, grievance rights, and coverage of emergency services; and eliminate certain requirements viewed by State agencies as impediments to the growth of managed care programs, such as, the enrollment composition requirement, the right to disenroll without cause at any time, and the prohibition against enrollee cost-sharing.

EFFECTIVE DATE: These regulations are effective on August 13, 2002. States will have until June 16, 2003, to bring all aspects of their State managed care program (that is, contracts, waivers, State plan amendments and State operations) into compliance with the final rule provisions.

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I. Background

A. General

In 1965, amendments to the Social Security Act (the Act) established the Medicaid program as a joint Federal and State program for providing financial assistance to individuals with low incomes to enable them to receive medical care. Under the Medicaid program, each State establishes its own eligibility standards, benefits packages, payment rates and program administration in accordance with certain Federal statutory and regulatory requirements. The provisions of each State's Medicaid program are described in the State's Medicaid ''State plan'' that we must approve. In addition to approving State plans and monitoring States for compliance with Federal Medicaid laws, the Federal role also includes providing matching funds to State agencies to pay for a portion of the costs of providing health care to Medicaid beneficiaries. Medicaid beneficiaries typically include low-income children and their families, pregnant women, individuals age 65 and older, and individuals with disabilities. (Throughout this preamble, we use the term ''beneficiaries'' to mean ''individuals eligible for and receiving Medicaid benefits.'' The term ''recipients'' in the regulations text has the same meaning as the term ''beneficiary.'')

When the Medicaid program was created, coverage typically was provided through reimbursements by the State agency to health care providers who submitted claims for payment after they provided health care services to Medicaid beneficiaries. This reimbursement arrangement is referred to as ''fee-for-service'' (FFS) payment. Before 1982, 99 percent of Medicaid beneficiaries received Medicaid coverage through fee-for-service arrangements. Since 1982, State agencies increasingly have provided Medicaid coverage through contracts with managed care organizations (MCOs), such as health maintenance organizations (HMOs). Through these contracts an MCO is paid a fixed, prospective, monthly payment for each beneficiary enrolled with the entity for health coverage. This payment approach is referred to as ''capitation.'' Beneficiaries enrolled in capitated MCOs are required to receive health care services provided under the MCO's contract, through the MCO that receives the capitation payment. The Omnibus Budget Reconciliation Act (OBRA) of 1981 (Pub. L. 97–35 enacted on August 13, 1981) allowed State agencies to mandate that Medicaid beneficiaries enroll in MCOs, which increased the use of MCOs. In most States, mandatory enrollment takes place for at least certain categories of beneficiaries. To achieve this mandatory enrollment, before the enactment of the Balanced Budget Act (BBA) of 1997 (Pub. L. 105–33, enacted on August 5, 1997), States were required to obtain a waiver of a Medicaid statutory requirement for beneficiary ''freedom of choice'' of providers. (State programs that offered beneficiaries voluntary enrollment in MCOs do not require these waivers.) As a result, in 1997, just before the passage of the BBA, almost 8.5 million Medicaid beneficiaries, or 43 percent of all Medicaid beneficiaries, were enrolled in MCOs for a comprehensive array of Medicaid services. Some of these beneficiaries and additional Medicaid beneficiaries were enrolled in other organizations that received capitated payment for a limited array of services, such as behavioral health or dental services. These organizations that receive capitation payment for a limited array of services are referred to as ''prepaid health plans (PHPs).''

While the Act was further amended in the 1980s and in 1990 to address certain

aspects of Medicaid managed care, the BBA represents the first comprehensive revision to Federal statutes governing Medicaid managed care in over a decade. In general, Chapter One (subtitle H) of the BBA significantly renovated the Medicaid managed care program by modifying Federal statute to: (1) Allow States to mandate the enrollment of certain Medicaid beneficiaries into MCOs without having to first seek a waiver of Federal statutory requirements; (2) eliminate requirements on the composition of enrollment in MCOs that had not been proven to be effective; (3) apply consumer protections that were receiving widespread acceptance in the commercial and Medicare marketplaces to Medicaid beneficiaries; for example, consumer information standards and standards for access to services; and (4) apply the advances and developments in health care quality improvement that are in widespread use in the private sector to Medicaid managed care programs. Specifically, sections 4701 through 4710 of the BBA provisions: (1) Reduce requirements for State agencies to obtain waivers to implement certain managed care programs; (2) eliminate enrollment composition requirements for managed care contracts; (3) increase beneficiary protections for enrollees in Medicaid managed care entities; (4) improve quality assurance; (5) establish solvency standards; (6) protect against fraud and abuse; (7) permit a period of guaranteed eligibility for Medicaid beneficiaries; and (8) improve certain administrative features of State managed care programs.

We have already implemented provisions of the BBA that did not require regulations. CMS provided guidance on these provisions through the issuance of State Medicaid Director letters, which are listed below. These letters can be found on the CMS website at *www.hcfa.gov/medicaid/letters/*.

STATE MEDICAID DIRECTOR LETTERS ON MANAGED CARE PROVISIONS OF THE BBA

Section of the Act issued	Subject	Date
1932(a)(1)	State Plan Option for Managed Care	December 17, 1997.
1932(b)(1)	Specification of Benefits	December 17, 1997.
1932(d)(2)	Marketing Restrictions	December 30, 1997.
1932(b)(6), 1128B(d)(1), 1124(a)(2)(A), 1932(d)(3), 1903(i), 1916(a)(2)(D), 1916(b)(2)(D), and 1903(m)(1)(C).	Miscellaneous Managed Care Provisions	December 30, 1997.
1932(a)(1)(B), 1932(a)(3), and 1903(m)(2)(A)	Definition of a managed care entity, Choice, Repeal of 75/25, and Approval Threshold.	January 14, 1998.
1932(c)(2) and 1903(a)(3)(C)	External Quality Review	January 20, 1998.
1932(a)(4)	Enrollment, Termination, and Default Assignment	January 21, 1998.
1905(t) and 1905(a)(25)	PCCM Services Without Waiver	January 21, 1998.
1932(e)	Sanctions for Noncompliance	February 20, 1998.
1932(a)(5) BBA Section 4710(a)	Provision of Information & Effective Dates	February 20, 1998.
1932(b)(2)	Emergency Services	February 20, 1998.
1932(b)(4)	Grievance Procedures	February 20, 1998.
1932(d)(1)	Debarred Individuals	February 20, 1998.
1932(b)(3), 1932(b)(7), and 1932(b)(5)	Enrollee-Provider Communications, Antidiscrimination of Providers, and Adequate Capacity.	February 20, 1998.
1932(d)(2)	Effective Date of Marketing Restrictions	February 20, 1998.
1902(e)(2)	Guaranteed Eligibility	March 23, 1998.
BBA Section 4710(c)	Application to Waivers	March 25, 1998.
1932(b)(2)	Prudent Layperson Standard	May 6, 1998.
1932(b)(2)	Post-Stabilization Services	August 5, 1998.
1932(b)	Emergency Services	April 18, 2000.

B. Statutory Basis

Section 4701 of the BBA enacted section 1932 of the Act, changes terminology in title XIX of the Act (most significantly, the BBA uses the term ''managed care organization'' to refer to entities previously labeled ''health maintenance organizations'', and amends section 1903(m) to require that MCOs and MCO contracts comply with applicable requirements in newly added section 1932 of the Act. Among other things, section 1932 of the Act permits States to require most groups of Medicaid beneficiaries to enroll in managed care arrangements without waiver authority granted under section 1915(b) or 1115(a) of the Act. Under the statute before the BBA, a State agency was required to obtain Federal authority to waive beneficiary free choice of providers in order to restrict their coverage to managed care arrangements. Section 1932 also defines the term ''managed care entity'' (MCE) to include MCOs and primary care case managers (PCCMs); establishes new requirements for managed care enrollment and choice of coverage; and requires MCEs and State agencies to provide specified information to enrollees and potential enrollees.

Section 4702 of the BBA amended section 1905 of the Act to provide for States to contract with primary care case managers without waiver authority. Instead, primary care case management services may be made available under a State's Medicaid plan as an optional service.

Section 4703 of the BBA eliminated a former statutory requirement that no more than 75 percent of the enrollees in an MCO be Medicaid or Medicare beneficiaries.

Section 4704 of the BBA created section 1932(b) of the Act to add increased protections for those enrolled in managed care arrangements. These protections include, the application of a ''prudent layperson's'' standard to determine whether emergency room use by a beneficiary was appropriate; criteria for showing adequate capacity and services; grievance procedures; and protections for enrollees against liability for payment of an organization's or provider's debts in the case of insolvency.

Section 4705 of the BBA created section 1932(c) of the Act, which requires States to develop and implement quality assessment and improvement strategies for their managed care arrangements and to provide for external, independent review of managed care activities.

Section 4706 of the BBA provided that, with limited exceptions, an MCO must meet the same solvency standards set by States for private HMOs, or otherwise be licensed or certified by the State as a risk-bearing entity.

Section 4707 of the BBA enacted section 1932(d) of the Act to add protections against fraud and abuse, such as restrictions on marketing and sanctions for noncompliance.

Section 4708 of the BBA added a number of provisions to the Act to improve the administration of managed care arrangements. These include, provisions raising the threshold value of managed care contracts that require the Secretary's prior approval, and permitting the same copayments in MCOs as apply to fee-for-service arrangements.

Section 4709 of the BBA allows States the option to provide 6 months of guaranteed eligibility for all individuals enrolled in an MCE. Section 4710 of the BBA specifies the effective dates for all the provisions identified in sections 4701 through 4709 of the BBA, and specifies that these provisions do not apply to the extent they are inconsistent with the terms and conditions of waivers under section 1915(b) or section 1115 of the Act.

C. Federal Register Publications

On September 29, 1998, we published in the **Federal Register** (63 FR 52022) a proposed rule to implement the above provisions of the BBA. In that 1998 proposed rule, we also proposed to strengthen regulatory requirements of PHPs by incorporating regulatory requirements that would otherwise apply only to MCOs. We received over 300 comments on the 1998 proposed rule. The comments were extensive and generally addressed all sections of that proposed rule. On January 19, 2001, we published in the **Federal Register** (66 FR 6228) a final rule with comment period that summarized, and responded to the public comments we received on the proposed rule. It also contained additional provisions not included in the 1998 proposed rule. Among these were revisions eliminating the existing ''upper payment limit'' (UPL) on risk capitation payments in § 447.361, and replacing this limit with provisions in § 438.6(c) setting forth requirements designed to ensure that rates were actuarially sound. We invited comments only on these last two changes.

In a **Federal Register** notice (66 FR 11546) published on February 26, 2001, we announced a 60-day delay in the effective date of the January 19, 2001 final rule with comment period. This 60-day delay postponed the effective date of the rule until June 18, 2001. This delay in effective date was necessary to give Department officials the opportunity for further review and consideration of the new regulations. During that review, we heard from key stakeholders in the Medicaid managed care program, including States, advocates for beneficiaries, and provider organizations. These parties expressed strong (sometimes opposing) views about the regulation. In particular, concerns were expressed about the revisions based on public comments we received on the proposed rule. Other commenters raised concerns about how we chose to implement those provisions in the final rule without further opportunity for public comment.

As a result of these comments, on June 18, 2001, we published a final rule in the **Federal Register** that further delayed the effective date of the January 19, 2001 final rule with comment period an additional 60 days, from June 18, 2001 until August 17, 2001, (66 FR 32776) for further review and consideration on the most appropriate way to address the concerns expressed by key stakeholders. In response to these concerns, on August 20, 2001 we published a new proposed rule in the **Federal Register**. In addition, in order to give us the time to consider the public comments and take final action on the new proposed rule, we also published in the August 17, 2001 **Federal Register** an interim final rule with comment period that further delayed until August 16, 2002, the effective date of the January 2001 final rule with comment period.

The new proposed rule was published to address the concerns that were expressed to the Department during our review. After careful consideration, we decided the best approach was to make some modifications to the January 19, 2001 final rule and republish it as a proposed rule. This would enable the public the opportunity to comment on all of the provisions and revisions.

In developing the proposed rule, we were guided by several considerations. First, we gave serious attention to all the concerns that were communicated to us. Second, we tried to discern when a difference of opinion represented different goals or different methods of achieving the same goals. Finally, we believed that all commenters expressed the same goal, namely: Strong, viable, Medicaid managed care programs that deliver high quality health care to Medicaid beneficiaries. We note that we have published elsewhere in this **Federal Register** a final rule withdrawing the January 19, 2001 final rule with comment period.

We have drafted the provisions of this final rule in full recognition of the statutorily designed structure of the Medicaid program as a Federal-State partnership. States are assigned the responsibility of designing their State programs, and typically do so addressing local, as well as State needs. We have drafted this final rule to recognize the responsibilities of the States and the need to employ different approaches to achieving the same goal within their varying State marketplaces and health care delivery systems.

Finally, we appreciate that new advances and findings in health care, health care quality assessment and improvement, and health services research unfold on an almost daily basis. In many instances, States have been at the forefront of implementing these new developments and innovations. We have sought to standardize, through regulation, those practices that have been found to be necessary to the delivery of high quality health care. We simultaneously have sought to continue to allow States, in consultation with their State and local partners and customers (beneficiaries), to determine the best approach to implementing their managed care program when there is an absence of clear evidence about the superiority of a given approach.

Overall, we recognize the great diversity and sometimes ''special needs'' of Medicaid beneficiaries. While the greatest numbers (54 percent) of Medicaid beneficiaries are children, 11 percent are age 65 or older. Medicaid also serves as a significant source of health care for individuals with disabilities and conditions that place them at risk of developing disabilities. In 1997, more than 6 million children and adults were eligible for Medicaid on the basis of a physical, mental, or cognitive disability. The Medicaid program insures more than half of all people with Acquired Immune Deficiency Syndrome (AIDS) in this country and up to 90 percent of children with AIDS. Medicaid also is a significant source of health care coverage for individuals with serious and persistent mental illness, and children in foster care. Our report to the Congress, ''*Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care*'' (November 6, 2000), summarized existing evidence on effective practices in caring for individuals with special health care needs.

The regulations in this final rule are mostly set forth as new provisions in part 438. All new managed care regulations created under the authority

of the BBA, other sections of existing Medicaid regulations pertaining to managed care, and appropriate cross references will appear in this new part. By creating this new part, we aim to help users of the regulations to better understand the overall regulatory framework for managed care.

D. Overview of Medicaid Managed Care

Medicaid managed care programs have been in existence almost since the inception of the Medicaid program in 1965. In New York State, Medicaid beneficiaries were enrolled in the Health Insurance Plan of Greater New York beginning in 1967. The State of Washington began contracting with Group Health of Puget Sound in 1970, and, by 1972, various regional operations of Kaiser-Permanente served Medicaid beneficiaries in three different States. Initially, there were no statutory or regulatory provisions specifically addressing the use of managed care by State agencies.

As a result of the increasing use of managed care in Medicaid, Medicare and the private sector, statutory provisions and regulations have since been adopted to specifically address Medicaid managed care. In 1976, the Health Maintenance Organization Act put forth the first specific Federal requirements for Medicaid contracts with HMOs or comparable organizations, by essentially requiring, with some exceptions, that contracts with entities to provide ''comprehensive'' specified services, be entered into only with Federally qualified HMOs. By 1981, little more than 1 percent of Medicaid beneficiaries were enrolled in managed care. Further legislative and regulatory changes made in 1981 and 1982 made possible more widespread use of managed care by State agencies but were also accompanied by increased requirements in some areas (For example, OBRA 1981 required that Medicaid enrollees be allowed to voluntarily disenroll without cause from HMOs. This was subsequently amended to permit a 6-month lock-in for individuals enrolled in federally qualified HMOs.) Until the enactment of the BBA, modification of the statutes and regulations governing Medicaid managed care after OBRA 1981 and the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248, enacted on September 3, 1982) has occurred in a piecemeal manner. The BBA represents the first major revision of the statutes governing Medicaid managed care in over a decade.

The period from 1981 to the present has seen significant changes in Medicaid managed care programs. While only approximately 250,000 Medicaid beneficiaries were enrolled in managed care in 1981, by 1997 this number had increased to over 15 million. As of June 2000, approximately 56 percent of the entire Medicaid population received at least some services through an MCO, PHP, or a primary care case management arrangement. In the last decade, a number of studies and reports have documented that State agencies need both flexibility and assistance to implement new approaches and tools to effectively administer their contracts with MCOs. A 1997 General Accounting Office Report entitled, ''*Medicaid Managed Care—Challenge of Holding Plans Accountable Requires Greater State Effort,*'' indicated the need for priority attention to beneficiary information and education, and access to care and quality monitoring.

As noted above, Medicaid managed care contracts were originally entered into by some State agencies without any specific statutory provision for these arrangements. When the Congress acted to regulate managed care arrangements, it limited the applicability of these statutory requirements to contracts that were comprehensive in the services they covered.

Specifically, the statutory requirements enacted by the Congress in section 1903(m) of the Act have always applied to contracts for inpatient services plus any one of the other services specified in section 1903(m)(2)(A) of the Act, or for any three of the non-inpatient services specified in section 1903(m)(2)(A) of the Act. Managed care contracts that were less than comprehensive remained exempt from all statutory managed care requirements. In recognition of this fact, we have in the past exercised our authority under section 1902(a)(4) of the Act to specify ''methods of administration'' that were ''necessary for proper and efficient administration'' to impose regulatory requirements on entities that were exempt from the statutory requirements in section 1903(m), either because they provided less than comprehensive services or because they were specifically exempted by the Congress from complying with section 1903(m) requirements. These entities were called ''prepaid health plans,'' or ''PHPs.''

The regulatory requirements we applied to PHPs were not as stringent in many areas as those under section 1903(m). For example, while PHPs were subject to an enrollment composition requirement like comprehensive HMO contractors, the PHP enrollment composition requirement could be waived by the State for ''good cause.'' PHPs also were not subject to the section 1903(m) requirement that beneficiaries have the right to disenroll without cause at any time, and beneficiaries enrolled in PHPs thus could have their ability to disenroll restricted under section 1915(b) waiver authority, (where the right to disenroll required under section 1903(m) could not be waived).

In part, because of the less stringent requirements that applied to PHPs, there has been a substantial growth in PHP enrollment. Some of these PHPs are single service managed care plans (for example, behavioral health plans) and their enrollees are also enrolled in other managed care plans for their routine primary and acute care. Other PHPs, such as the Health Insurance Plan (HIP) of New York, provide a full range of services, but were exempted by the Congress from the requirements in section 1903(m) of the Act. As discussed more fully below, certain PHPs are required to meet most of the provisions that apply to MCOs.

Concurrent with the increasing size of, and need for, stronger Medicaid managed care programs, over the last decade we have been developing improved tools, techniques, and strategies that State agencies can use to strengthen their managed care programs. In 1991, we began the Quality Assurance Reform Initiative (QARI) to provide technical assistance tools and assistance to State agencies. In 1993, we produced a QARI guide entitled, ''*A Health Care Quality Improvement System for Medicaid Managed Care—A Guide for States,*'' which contained four areas of guidance for States: (1) A framework for quality improvement systems for Medicaid managed care programs; (2) guidelines for internal quality assurance programs of Medicaid HMOs and PHPs; (3) guidelines for clinical and health services focus areas and use of quality indicators and clinical practice guidelines; and (4) guidelines for the conduct of external quality reviews conducted under section 1902(a)(30)(C) of the Act. In 1995, we worked collaboratively with the National Committee for Quality Assurance (NCQA) and the American Public Human Services Association to produce a Medicaid version of the Health Plan Employer Data and Information Set (HEDIS). HEDIS is a standardized quality performance measurement system used by private sector purchasers of managed care services, which we modified for use by State agencies. We contracted with NCQA to develop ''*Health Care Quality*

Improvement Studies in Managed Care Settings: Design and Assessment—A Guide for State Medicaid Agencies''.

In 1996, we undertook the Quality Improvement System for Managed Care (QISMC) initiative to accomplish several goals: (1) To update the 1993 QARI guidelines; (2) to develop coordinated Medicare and Medicaid quality standards that would reduce duplicative or conflicting efforts; (3) to make the most efficient and effective use of recent developments in the art and science of quality measurement, while allowing sufficient flexibility to incorporate developments in this rapidly evolving discipline; and (4) to assist the Federal government and State agencies in becoming more effective ''value-based'' purchasers of health care for vulnerable populations. In developing QISMC, we worked with representatives from, and with tools developed by, health plans, State agencies, advocacy organizations, and experts in quality measurement and improvement such as the NCQA, the Foundation for Accountability (FACCT) and the Joint Commission on the Accreditation of Healthcare Organizations. With the assistance of the experts and their products, we identified the approaches, tools, and techniques that we believed would most effectively measure and improve health care quality in managed care. The quality assurance provisions of this final rule espouse the same philosophy and goals for performance improvement as are reflected in QISMC, but have been modified based on recent developments in Medicaid, managed care, and quality assessment and improvement. For example, QISMC was written before our report to the Congress addressing individuals with special health care needs.

In 1997, the Agency for Health Care Policy and Research (AHCPR) (now, the Agency for Healthcare Research and Quality) produced a set of consumer survey instruments and measurement tools under the auspices of the Consumer Assessment of Health Plan Study (CAHPS). The CAHPS instruments include measures and tools specifically designed for use by State agencies. Also in 1997, the George Washington University Center for Health Policy Research published a compendium of provisions of State contracts with Medicaid managed care organizations. This nationwide study of Medicaid managed care contracts has provided valuable information that can be used by all State agencies in the design and management of their managed care contracts.

More recently, in 1999, we produced a technical assistance manual for State agencies entitled, ''*Writing and Designing Print Materials for Beneficiaries: A Guide for State Medicaid Agencies.*'' This technical assistance tool for States was in direct response to the BBA statutory provisions calling for dissemination of information to Medicaid beneficiaries. A contract with FACCT produced a manual describing valid and reliable tools that State agencies can use to identify children and adults with special health care needs. In addition, a contract with the Center for Health Program Development and Management at the University of Maryland Baltimore County will develop a guidance manual for States that will describe various approaches to using health status-based risk adjustment in making payments to MCOs.

These and other tools we have in planning stages can be applied to the efforts of State agencies to become even more effective in purchasing managed care services for Medicaid beneficiaries. This final rule provides an opportunity to clarify for MCOs, beneficiaries, and State agencies, how these advances in the management and oversight of health care can be applied to Medicaid managed care programs.

Through these regulations, we promote uniform national application of knowledge and best practices learned from these initiatives. While we promote uniform best practice, the Medicaid statute has always given State agencies latitude to design their Medicaid programs, as long as they meet certain minimum Federal standards. Current Federal requirements in the Medicaid managed care area are imposed either as conditions for Federal matching funds to support contracts with MCOs, as conditions for receiving a waiver of freedom of choice under section 1915(b) of the Act, or as conditions for falling within the section 1932 exception to the freedom of choice requirement in section 1902(a)(23) of the Act. In the first case, failure to comply with section 1932 requirements could result in a disallowance of Federal financial participation (FFP) in contract payments. In the latter two cases, if the State fails to meet conditions for the section 1932 exception to the freedom-of-choice requirement in section 1902(a)(23), or has its section 1915(b) waiver nonrenewed or terminated for a failure to meet waiver conditions, the State agency would be out of compliance with the freedom of choice requirement in section 1902(a)(23), and the State agency would be subject to a compliance enforcement action under section 1904 of the Act.

Because the Medicaid program is a State-administered program subject to Federal guidance and rules, Medicaid regulations do not generally adopt the same approach to regulating managed care organizations as Federal Medicare regulations. Instead, Medicaid rules generally regulate State agencies and place requirements on their contracts with managed care organizations or managed care programs. This final rule adopts this direction in implementing the new requirements in the BBA.

Section 4710(c) of the BBA provided for a time-limited exemption from the requirements in sections 4701 through 4710 for approved waiver programs or demonstration projects under the authority of sections 1115 or 1915(b) of the Act. Specifically, the BBA in section 4710(c) provided that none of the provisions contained in sections 4701 through 4710 would affect the terms and conditions of any approved section 1915(b) waiver or demonstration project under section 1115, as the waiver or demonstration project was in effect on the date of the enactment of the BBA (that is, August 5, 1997.) We interpreted this ''grandfather provision'' to apply only for the period for which the waiver or demonstration project was approved as of August 5, 1997. Thus, at the expiration of any 2-year waiver period under section 1915(b), or at the end of the period for which a demonstration project was approved under section 1115, the grandfather provision in section 4710(c) would no longer apply.

In general, during the period approved as of August 5, 1997, any provision of a State's approved section 1115 or section 1915(b) waiver program that was specifically addressed in the State's waiver proposal, statutory waivers, special terms and conditions, operational protocol, or other official State policy or procedures approved by us, was not affected by the BBA provisions, even if it differed from the BBA managed care requirements. As long as the BBA provisions were addressed in the State's approved waiver materials, no determination needed to be made as to whether the State's policy or procedures meet or exceeded the BBA requirements. If the BBA provisions were not addressed, the State was required to meet the BBA requirements, except as specified below for newly submitted or amended waivers.

As noted above, under our interpretation, the exemption from the BBA requirements applied to section 1915(b) waiver programs only until the date that the waiver authority approved or in effect as of August 5, 1997 expired, which in all cases occurred no later than

1999. As of the date of the two year section 1915(b) waiver period approved on August 5, 1997 expired, the State was required to comply with all BBA requirements that in effect.

In the case of section 1115 demonstrations, while the ''grandfather'' provision in section 4710(c) only applies until the end of the period for which the demonstration project was approved as of August 5, 1997, if the demonstration project has been extended under the provisions in section 1115(e) of the Act, existing terms and conditions inconsistent with BBA requirements are extended for three years, nullifying the effect of the ''expiration'' of the grandfather provision in section 4710(c). Therefore, any exemptions from the BBA requirements to which these programs were entitled under the ''grandfather provision'' may continue during the period of the extended waiver authority.

The Medicare, Medicaid, and State Child Health Insurance Program Benefits Improvement and Protection Act of 2000 (BIPA), enacted on December 21, 2000 (Pub. L. 106–554) provided for additional extensions of section 1115 health care reform demonstrations, but did not include language extending the same terms and conditions through this period. Thus, we conclude that provisions of the BBA would apply to the demonstrations in these extension periods under BIPA as well as all other demonstrations in extensions under any authority other than section 1115(e)(2), unless the Secretary uses his discretionary authority to waive the requirements.

For newly submitted or amended section 1915(b) or section 1115 waivers, the Secretary retains the discretionary authority to waive the BBA managed care provisions. Generally, waivers are granted that allow States some flexibility in operating their Medicaid programs, while promoting the proper and efficient administration of a State's plan. In particular, for the BBA provisions related to increased beneficiary protections and quality assurance standards, we anticipate that the BBA provisions would apply unless a State can demonstrate that a waiver program beneficiary protection or quality standard would equal or exceed the BBA requirement.

II. Provisions of the Proposed Rule and Analysis of and Response to Public Comments

We received comments from 387 States, national and State organizations, health plans, advocacy groups and other individuals on the August 20, 2001 proposed rule. The comments were extensive and generally pertained to the new rate-setting provisions, the quality requirements and the grievance system requirements contained in the proposed rule. We carefully reviewed all of the comments and revisited the policies contained in the proposed rule that related to the comments. This final rule responds to these comments. In the following discussion, we present a summary of the proposed provisions and our responses to the public comments.

In the proposed rule, we set forth the new organizational format for part 438 as follows:

Subpart A—General Provisions
Subpart B—State Responsibilities
Subpart C—Enrollee Rights and Protections
Subpart D—Quality Assessment and Performance Improvement
Subpart E—[Reserved]
Subpart F—Grievance System
Subpart G [Reserved]
Subpart H—Certifications and Program Integrity
Subpart I—Sanctions
Subpart J—Conditions for Federal Financial Participation

A. General Provisions (Subpart A)

1. Basis and Scope (Proposed § 438.1)

Section 438.1 of the proposed regulation set forth the basis and scope of part 438 including the fact that regulations in this part implement authority in sections 1902(a)(4), 1903(m), 1905(t), and 1932 of the Act. Proposed § 438.1 also briefly described these statutory provisions.

2. Definitions (Proposed §§ 400.203, 438.2, 430.5)

Sections 400.203, 438.2 and 430.5 of the proposed rule included definitions of terms that would apply for purposes of proposed part 438. In reviewing the definitions in this section of the proposed rule, we recognized that the current definition of health insuring organization (HIO) is confusing, and not useful to the reader. The current definition encompasses entities that also meet the definition of managed care organization (MCO), and are subject to MCO requirements. This is because the language in section 1903(m)(2)(A) contemplates that there would be HIOs that are subject to the requirements in that section, including the requirement that the HIO meet the definition of MCO. (The introductory clause to the requirements in section 1903(m)(2)(A) includes the parenthetical ''including a health insuring organization.'')

This language dates to a time when HIOs that arranged for care were exempt from the MCO requirements in section 1903(m)(2)(A). Specifically, the language was added in 1985 legislation (the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA)) that ''grandfathered'' this exemption for HIOs operating before January 1, 1986. The parenthetical language was designed to make clear that other ''HIOs'' would be subject to 1903(m)(2)(A) requirements. Because one of the requirements of section 1903(m)(2)(A) is meeting the definition of MCO, any entity in this latter category would be covered by references in the regulations to MCOs. Thus, the term HIO has no legal significance for these entities. The term HIO is only relevant insofar as an exemption from section 1903(m)(2)(A) uses this term to refer to the exempt entity.

In the Omnibus Budget Reconciliation Act of 1990 (OBRA 90), the Congress again used the term HIO, in exempting certain county-operated entities in California from section 1903(m)(2)(A) requirements. After these amendments, the term HIO is only legally relevant for purposes of identifying this new group of exempt entities, and the entities grandfathered in COBRA. For this reason, and to avoid confusion, in this final rule, we are changing the definition of HIO to refer only to these section 1903(m)(2)(A)-exempt entities for which the term has continuing legal relevance. This change has no effect on any entities' rights or obligations.

Also among these definitions are new definitions of a ''Prepaid Inpatient Health Plan'' (PIHP) and a ''Prepaid Ambulatory Health Plan'' (PAHP). These new definitions divide the definition of ''Prepaid Health Plan'' (PHP) in the January 19, 2001 final rule into two subcategories of PHPs, to which different regulatory requirements would apply in this final rule. PIHPs are entities that provide some inpatient services, and would be subject to more requirements than PAHPs, which do not provide inpatient services. We received the following comments on the proposed definitions in the proposed rule, including the new proposed definitions of PIHP and PAHP.

Comment: One commenter expressed concern that the proposed definition of ''provider'' included in § 400.203 encompasses all entities and individuals engaged in, or arranging for, the delivery of a medical service in a managed care delivery system. The commenter believed that this broad definition creates a problem when applied in proposed § 438.214(b), which requires the credentialing of providers who participate with an MCO or PIHP. The commenter contended that including all

ancillary and non-licensed providers under this credentialing requirement goes far beyond current industry standards that apply only to licensed health professionals such as physicians, psychologists, podiatrists, and mid-level practitioners. The commenter suggested limiting the scope of the requirements in § 438.214(b) to those health professionals that are engaged in the delivery of direct patient care and are licensed within their State.

Response: The definition of ''provider'' as published in our proposed rule, mirrors the definition of provider used in the Medicare+Choice regulations. However, to further clarify the definition in the proposed rule, and to be consistent with the definition of ''physician'' used in section 1861(r)(1) of the Act, we revised the definition of ''provider'' to be ''any individual or entity that is engaged in the delivery of health care services and is legally authorized to do so by the State in which it delivers the services.'' We believe that the proposed definition is correct, and the requirements that States have a process for credentialing and recredentialing all individuals involved in the delivery of health care services is an appropriate beneficiary protection. There is no requirement that the process be the same for each provider type within a network, only that there be a process in place. Further, this definition provides States the flexibility to determine what State requirements any provider must meet (for example, licensure and certification requirements) in order to provide services under managed care arrangement, and allows States, at their option, to include licensure or certification requirements imposed by tribal governments.

Comment: One commenter suggested that we add the definition of health care professional in § 438.102 to this section.

Response: Proposed § 438.102(a) contains the statutory definition of health care professional found in section 1932(b)(3)(C) of the Act, which specifically applies to the provisions governing enrollee-provider communications. However, in light of the fact that this term is also used for other purposes throughout part 438, we agree with the commenter that the definition of health care professional in proposed § 438.102 should be moved to § 438.2, and have done so.

Comment: A large number of commenters opposed the separation of PHPs into PIHPs and PAHPs. Some felt that we had not provided sufficient reasons for making this distinction, that the primary purpose of the change was to exempt a broad catch-all category of PAHPs from regulatory standards, and argued that defining the entity and the level of regulation based on the scope of the services provided was not logical, and could deny beneficiaries needed protections. These commenters felt that this distinction could jeopardize the quality and consistency of health care, particularly for women, due to the PAHPs' exemption from anti-discrimination provisions, State quality strategies, adequate service and capacity requirements and grievance and appeal rights. The commenters further noted that the January 19, 2001 final rule would apply to all PHPs. Several commenters felt that the new definitions could lead to gaming by contractors and create an incentive for MCOs or PIHPs to carve out various services (for example, inpatient hospital services) in order to limit the degree to which they are regulated. One commenter suggested that the term PAHP be more clearly defined, or limited to a specific set of non-medical or non-health care services, in order to prevent such carve-outs.

Some commenters wanted to return to the original PHP definition and subject all PHPs to all MCO requirements, while others suggested keeping the current PHP definition but allowing for individual rules to be relaxed where they are inapplicable.

Other commenters supported making the distinction between types of PHPs and believed that basing this distinction on the scope of services is a useful way to distinguish between requirements that are relevant to each contracting arrangement, and to provide the flexibility needed to appropriately regulate each type of contractor.

Response: We believe that the distinction between types of PHPs established in the proposed rule is appropriate and we will maintain the separate definition of PIHP and PAHP in this final rule. There are clear differences in terms of the degree of financial risk, contractual obligation, scope of services, and capitation rates paid to these different types of entities. The distinction between PIHPs and PAHPs based upon the scope of services in their contract is modeled after the requirement in section 1903(m)(2)(A) of the Act, which defines the scope of contracted services that requires an MCO. This scope of services is set forth in § 438.2, which defines comprehensive risk contract as a risk contract that covers inpatient hospital services and any of the following services, or any three or more of the following services: (1) Outpatient hospital services; (2) Rural health clinic services; (3) FQHC services; (4) Other laboratory and X-ray services; (5) Nursing facility (NF) services; (6) Early and periodic screening diagnostic, and treatment (EPSDT) services; (7) Family planning services; (8) Physician services; or (9) Home health services.

PHPs were originally designated by regulation as entities that incurred risk for a lesser scope of services. Since that time, the PHP definition has been expanded to include a scope of services that would have required an MCO, except that their contracts covered only a portion of inpatient hospital services (for example, inpatient mental health services) rather than all inpatient hospital care. These entities incurred far greater risk, were obligated to provide a greater range of services, and have greater responsibility for the beneficiary care than the early PHPs, which were predominantly capitated primary care physicians and physician groups at risk for the cost of physician and one other outpatient Medicaid service.

Recognizing that the scope of contractual responsibility for these larger PHPs, now designated PIHPs, was far more like the responsibilities in MCO contracts, we have imposed most MCO requirements on these entities. The PAHP designation allows us to impose requirements on this smaller group that are more appropriate to the scope of services they are obligated to provide. Not only do we believe it is unnecessary to subject prepaid dental plans, transportation providers, and capitated primary care case managers to the same standards as MCOs and PIHPs, it is not logical to impose the same administrative burdens on contractors who receive a fraction of the amount in capitation rates that MCOs and PIHPs are paid. Further, for these types of entities, access to care could be negatively impacted by the imposition of inappropriate levels of administrative burdens.

Further, we do not believe it likely that MCOs and PIHPs that contract with States will arbitrarily reduce the benefit package they provide in order to limit the degree to which they are regulated. First, much of the savings to be achieved from managed care come from reductions in the cost of inpatient care for beneficiaries, and a contractor would not likely choose to carve-out the source of most of their potential savings. Neither is it to the State's advantage to permit such carve-outs, since the State would then be obligated to assume all responsibilities for coordination of care required under Subpart D that would otherwise be the contractor's responsibility.

Finally, we believe that the distinction is clear between PIHPs and PAHPs and MCOs. If an entity has less-

than a comprehensive risk contract, but has any responsibility for an enrollee's inpatient hospital or institutional care, it is a PIHP and subject to all PIHP requirements. However, as discussed below, in § 438.8 we have expanded the requirements that apply to PAHPs, as described in that section.

Comment: Several commenters felt that many PHPs that provide a comprehensive range of services; (for example, outpatient services, including primary care, mental health care, reproductive health care, and/or HIV services), but do not provide inpatient care should not be exempt from the managed care requirements in the proposed rule. One commenter asked whether an entity responsible only for behavioral health services (inpatient and outpatient) is considered a PIHP.

Response: In making the distinction between PIHPs and PAHPs, we have not changed current policy under which entities that contract for a subset of inpatient and outpatient care, as with behavioral health carve-outs, do not have comprehensive risk contracts subject to the statutory requirements that apply to MCOs. Thus, in answer to the commenters' question, such a behavioral health contractor is a PIHP (due to its provision of some inpatient services), not an MCO. Similarly, the definition of comprehensive risk contract in section 1903(m)(2)(A) of the Act has not changed, so that an entity that is at risk for inpatient hospital services generally, and any one of the other specified services, or three or more of the services identified in the definition of comprehensive risk contract, falls under the MCO requirements in section 1903(m)(2)(A).

Comment: Several commenters argued that ambulatory and community-based plans should not be exempt from essential protections, while others felt that these programs did not need to be included as PIHPs.

Response: We are not expanding the PIHP definition to include these programs. If these programs are responsible for institutional care, they will be subject to PIHP requirements. Otherwise, we believe their scope of risk and operations for these programs are more like PAHPs.

Comment: One commenter believed that the use of the terms PIHP and PAHP would permit States to mandate enrollment in PIHPs and PAHPs of populations who were exempted from mandatory enrollment in MCOs and PCCMs under the authority in section 1932(a).

Response: The authority in section 1932(a)(1) of the Act and proposed § 438.50 permitting States to mandate managed care enrollment through a State plan amendment does not extend to certain specified groups of beneficiaries who are exempted from having managed care enrollment mandated under that provision. In addition, the authority in section 1932(a)(1) is limited to mandating enrollment in MCOs and PCCMs, and does not give States authority to mandate enrollment in either PIHPs or PAHPs, unless the PAHP qualifies as both a PCCM and a PAHP. But, this would still not permit the mandatory enrollment of the exempted groups under section 1932(a). However, the exemption of certain populations from mandatory enrollment under section 1932(a)(1) applies only to enrollment under the new authority in that section, and did not preclude the mandatory enrollment of these groups of beneficiaries in MCOs, PCCMs, PIHPs, or PAHPs under existing authority in sections 1115 or 1915(b) of the Act.

Comment: One commenter believes that the definition of ''primary care'' should include services provided by a Master of Social Work, psychologist, psychiatrist, physician assistant, advanced registered nurse practitioner, or other health care professional.

Response: The definition of primary care in this section is taken from section 1905(t)(4) of the Act, which specifically identifies the services that the Congress intended to be included as primary care. We do not believe adding the services suggested by the commenter would be an appropriate extension of this section of the Act. We note, however, that States have the option of using physician assistants, certified nurse midwives, and nurse practitioners as primary care case managers, although the primary care services they provide would still be as defined in this section.

3. Contract Requirements (Proposed § 438.6)

Proposed § 438.6 set forth rules governing contracts with MCOs, PIHPs, PAHPs and PCCMs. Paragraph (a) of proposed § 438.6 required the CMS Regional Office to review and approve all MCO, PIHP and PAHP contracts, including those that are not subject to the statutory prior approval requirement implemented in § 438.806. Paragraph (b) set forth the entities with which a State may enter into a comprehensive risk contract. Paragraph (c) proposed new rules governing payments under risk contracts, to replace the upper payment limit in § 447.361. Paragraph (d) contained requirements regarding enrollment; that enrollments be accepted in the order of application up to capacity limits, that enrollment be voluntary unless specified exceptions apply, and that beneficiaries not be discriminated against based on health status. Paragraph (e) provided that MCOs, PIHPs, and PAHPs can cover services for enrollees in addition to those covered under the State plan. Paragraph (f) required that contracts must meet the requirements in § 438.6. Paragraph (g) required that risk contracts provide that the State and HHS have access to financial records of contractors and subcontractors. Paragraph (h) required compliance with physician incentive plan requirements in §§ 422.208 and 422.210. Paragraph (i) required compliance with advance directive requirements. Paragraph (j) provided that with certain exceptions, HIOs are subject to MCO requirements. Paragraph (k) proposed new rules from section 1905(t)(3) of the Act that apply to contracts with primary care case managers. Paragraph (l) and (m) set forth existing requirements for subcontracts and enrollees' right to choice of health professional to the extent possible and appropriate, respectively. Because of the volume of comments we received on this section, we have grouped our comments and responses according to the paragraph designation. We note that we did not receive comments on paragraphs (a), (b), (d), (h) and (j) of this section and are therefore implementing those provisions as proposed.

• Payment Under Risk Contracts (Proposed § 438.6(c))

General Comments

This section proposed new rules to replace the upper payment limit (UPL) for risk contracts in § 447.361, which is being repealed as part of this final rule. The new rules require actuarial certification of capitation rates; specify data elements that must be included in the methodology used to set capitation rates; require States to consider the costs for individuals with special health care needs or catastrophic claims in developing rates; require States to provide explanations of risk sharing or incentive methodologies; and impose special rules, including a limitation on the amount that can be paid in FFP under some of these arrangements.

Comment: Nearly all commenters expressed strong support for replacing the UPL with an actuarial process and methodology requirement.

Response: We appreciate the commenters' support. We have been working for several years to move away from the UPL requirement for risk-based managed care contracts and appreciates the input it has received from a number of sources including States, managed

care entities, actuaries, and various organizations in this process. There was a broad consensus among these parties to eliminate the UPL requirement.

Comment: Commenters wanted us to allocate additional resources to ensure that the agency has the necessary expertise to review rates and to provide technical assistance to States in order to implement the new rate setting process.

Response: We have been providing training and tools to review payment rates under these rules to our regional office personnel who are responsible for the review all of the MCO, PIHP, and PAHP risk contracts using this new methodology. The rate review checklists to be used by our regional offices are available from CMS regional offices. Section 1903(k) of the Act specifically authorizes us to provide this assistance to States at no cost, although most States have currently elected to contract with their own actuaries. If States request this assistance as these new requirements are implemented, we will provide it.

Comment: One commenter asked what appeals process is available for rate disputes. Another commenter recommended that we establish a mechanism to mediate disputes between MCOs and States over rates similar to the mediation process currently used in one State, involving: (1) Meetings between State and MCO actuaries where there is a dispute, during which the parties identify areas of continued disagreement; and (2) selection of a mutually acceptable independent actuary to mediate the dispute and make his/her (non-binding) findings available to the State and MCO.

Response: Some States have formal processes for appeals or dispute resolution on payment rates, while in others there may be a more informal process for this purpose. While we support these mechanisms to emphasize the partnership between States and MCOs in Medicaid managed care, and believe they may help to sustain the viability of these programs, we do not believe it would be appropriate for the Federal government to impose specific requirements on States. Rather, we believe that a State should have the flexibility to provide for the processes that works best for that State.

Comment: A number of commenters believed that State rate setting processes should be more open, and that States should be required to disclose core data assumptions regarding the State's rate setting methodology, utilization data for each rate category, and trend factors used. Several other commenters suggested that we require States (other than those using a competitive bidding process) to disclose sufficient information to permit MCOs to replicate the calculation of proposed rates, including the unit cost and utilization assumptions used and assumptions used in calculating administrative cost and retention factors. These commenters believe that this sharing of information will permit informed discussions between States and MCOs in the process and increase the continued viability of Medicaid managed care programs.

Response: We agree that sharing information in a negotiated rate setting process to the extent possible is a good way to enhance the partnership between States and MCOs and to maintain the viability of a State's Medicaid managed care program. However, we recognize that this will not always be possible and may not be a preferred contracting approach in some markets, even where competitive bidding is not the rate setting mechanism used by a State. Consequently, we are not willing to impose a Federal requirement that certain information be shared, and continue to believe that MCOs, PIHPs, and PAHPs contracting with States on a risk basis must make their own independent judgments of proposed rates based on their own costs of doing business and their understanding of the population to be covered.

Comment: One commenter asked how States would be required under the new rules to make payment adjustments to account for changes in trends or new administrative requirements that occur between legislative sessions or contract renewals.

Response: Contracts may be of varying lengths, but any changes to the terms of a contract during that period require a contract amendment that must be reviewed and approved by us. FFP is available for such amended contracts only after both parties have agreed to the changes and CMS has approved the contract amendment. We will not require States to amend contracts due to changes in such things as trends in inflation rates, unless payment rates are changed as a result. However, we believe that changes in the services to be provided or the administrative requirements in a contract would warrant changes in payment rates to reflect the expected impact of the required change in services or administration.

Comment: A commenter asked what would occur if a State refuses to pay rates that have been approved by CMS as actuarially sound. The commenter wanted to know how we would enforce these rates.

Response: We only review the rates that are submitted by States as part of the contract review process. We believe it would be unlikely that States would submit capitation rates for contract approval, and then not pay the approved rates. In the event that this were to occur, and be documented, the State would be subject to a disallowance of FFP for failing to comply with the requirement in section 1903(m)(2)(A)(iii) that rates be actuarially sound.

Comment: One commenter was concerned that eliminating the UPL and requiring actuarially sound capitation rates may increase the burden if States need to continue to calculate a UPL to determine cost effectiveness. Another commenter noted that we had indicated in the proposed rule that we would issue a revised methodology for determining the cost effectiveness of section 1915(b) waivers, and wanted to know (1) when waiver applications would be modified to contain the new methodology and (2) how States are to document cost effectiveness in the interim.

Response: We do not wish to impose additional burden on States in moving from the UPL test to a rule that requires an actuarially sound methodology as set forth in this final rule. As the commenter noted, we are issuing new cost effectiveness requirements for section 1915(b) waiver applications for both new and existing waivers, which will more closely correspond to the principles in the new rate setting guidelines. We expect to issue new guidelines for cost effectiveness before the effective date of this regulation, and will attempt in these guidelines to reduce the burden on States in documenting the cost effectiveness of these waiver programs. Recognizing the difficulty in changing long-standing methodologies in both setting rates and documenting cost effectiveness, we will permit States to use either the current methodology with its FFS comparison, or the rate setting process in this regulation in the period between the effective date of these rules and the final implementation date.

Comment: One commenter asked if we have any guidelines or regulations on the length of time FFS data must be retained, since these data still have some use in setting capitation rates.

Response: We agree that FFS data are one of the possible sources for establishing base year costs and utilization under this rule. However, one of the reasons for moving to the new rate setting rules, and away from the UPL requirement, is that FFS data loses its validity for this purpose as it becomes older. We are not establishing any rule as to the age of data used for rate setting purposes, since we would

rely on an actuarial certification that the data used had sufficient validity for this purpose. For the retention of FFS data in general, § 433.32(b) and (c) require States to retain records, such as FFS data, for 3 years from the date of submission of a final expenditure report (or longer of audit findings have not been resolved). We believe that these data have value for rate setting purposes beyond the time period they are required to be retained under that regulation.

Comment: One commenter suggested that requirements for actuarial soundness extend to payment rates between MCOs and subcontracting providers.

Response: Except in the case of payments to FQHCs that subcontract with MCOs, which are governed by section 1903(m)(2)(A)(ix), we do not regulate the payment rates between MCOs and subcontracting providers. While section 1903(m)(2)(A)(iii) requires that payments to MCOs be actuarially sound, other than in the case of FQHCs, the Congress has not established any standards for payments to subcontractors. We believe that this is because one of the efficiencies of managed care is premised on an MCO's ability to negotiate favorable payment rates with network providers. MCOs must pay sufficient rates to guarantee that their networks meet the access requirements in subpart C of this final rule. We believe that payment rates are adequate to the extent the MCO has documented the adequacy of its network.

Definition of Actuarially Sound Capitation Rates

Comment: Many commenters believed that CMS should go beyond simply defining an actuarially sound process, and instead should establish prescriptive standards for actuarial soundness. Some commenters believed that the definition of ''actuarially sound capitation rates'' should include the concept that rates be sufficient to cover the reasonable costs of the MCO. Other commenters suggested that we adopt the definition of actuarial soundness adopted by the Health Committee of the Actuarial Standards Board in the context of the small group market, which requires that payments ''are adequate to provide for all expected costs, including health benefits, health benefit settlement expenses, marketing and administrative expenses, and the cost of capital. Another commenter believed the definition of actuarially sound rate setting should be replaced with language similar to the following: rates are determined using generally accepted actuarial methods based on analyses of historical State contractual rates and an MCO's experience in providing heath care for the eligible populations, and are paid based on legislative allocations for the Medicaid program. Several other commenters supported our proposed approach requiring that rates be developed using accepted actuarial principles and practices.

Response: As discussed in detail below, we considered various approaches in defining actuarial soundness, but decided that basing the definition on a methodology that uses accepted actuarial principles and practices, and that is certified by a member of the American Academy of Actuaries, is the best approach in that it gives States and actuaries maximum flexibility while still ensuring that rates be certified as actuarially sound.

Comment: A number of commenters wanted the actuarial soundness test at § 438.6(c)(1)(i) to be revised to require that payment rates be adequate to cover the actual cost of services to be provided, and wanted us to take a more active role in assuring the adequacy of rates, including; (1) Reviewing key components and underlying assumptions of the rates, rather than accepting an actuary's certification; (2) ensuring proper adjustment and enforcement of the payment rules; (3) disapproving rates determined to be inadequate; (4) requiring disclosure of rate calculation inputs; and (5) resolving rate calculation disputes between MCOs and States. In contrast, several other commenters believed that we had gone too far in establishing a standard for rate adequacy that would be difficult to administer and justify.

Response: While, as indicated above, there was a consensus among commenters on the need to replace the UPL requirement, there were a wide variety of opinions among commenters on requirements to replace it. In the proposed rule, we sought to strike a balance between merely accepting State assurances on capitation rates in risk contracts on one hand, and requiring that the amounts of the capitation rates paid in each contract meet specific requirements for reasonableness and adequacy on the other. Under the former concept, we did not believe that we would meet our statutory responsibility to ensure that rates are actuarially sound as required under section 1903(m)(2)(A)(iii). Under the latter format, we would be establishing standards for reasonableness and adequacy of rates, which: (1) Would require that a determination be made on every rate cell in each risk contract submitted to us for review; (2) would require that we obtain sufficient actuarial expertise to review every risk contract in Medicaid managed care; and (3) would establish a new ''reasonable and adequate'' payment standard for Medicaid managed care when, in the BBA, the Congress amended title XIX to eliminate a similar requirement for Medicaid payments to institutional providers.

As a result of these considerations, we have established a requirement that payment rates in risk contracts be actuarially sound, that is, that they have been developed in accordance with generally accepted actuarial principles and practices, are appropriate for the populations and services under the contract, and have been certified by an actuary as meeting the requirements in this rule and the standards of the Actuarial Standards Board. This rule then sets forth the basic requirements that States must apply in setting capitation rates, and the documentation that States must provide to us to support their rate setting process. We believe that by reviewing the process used in setting the rates under a risk contract, we will fulfill our regulatory responsibilities to the fiscal integrity of the Medicaid program and will assure that States have considered all relevant factors in this process. We believe that MCOs, PIHPs, and PAHPs, that contract with States on a risk basis, are better able to determine whether rates are reasonable and adequate, and will do so in deciding whether or not to agree to contract or continue to contract with a State to provide services as part of a Medicaid managed care program.

Comment: A commenter believed that we should acknowledge that actuarially sound rates may vary between MCOs in the same service area.

Response: We acknowledge that rates may differ between MCOs in the same area for a variety of reasons, but most often when States utilize risk adjustment based upon health status or diagnosis.

Comment: One commenter asked whether the actuarial soundness requirement applies only to capitation rates under an entire contract, or to each rate cell under the contract.

Response: The requirement in proposed § 438.6(c)(2)(i) that *all* capitation rates paid under risk contracts and all risk sharing mechanisms in the contracts must be actuarially sound applies this requirement to all rate cells, as well as the entire contract, and all payments made under the contract. This is a change from the UPL requirement where individual rate cells within the contract

could exceed the UPL as long as the entire contract did not exceed the UPL. In order to clarify that the requirement for actuarial soundness applies to *all* payments, we are replacing the phrase ''capitation rates paid'' in proposed § 438.6(c)(2)(i) with the word ''payments.''

Comment: One commenter believed that the requirement that rates be ''appropriate'' for the population and services to be covered under the contract to be too vague, and subject to being interpreted by some to mean covering the full cost of care at billed charges.

Response: The term ''appropriate'' as used in this paragraph is merely intended to illustrate the requirements that follow in the remainder of § 438.6. ''Appropriate for populations covered'' means that the rates are based upon specific populations, by eligibility category, age, gender, locality, and other distinctions decided by the State. ''Appropriate to the services to be covered'' means that the rates must be based upon the State plan services to be provided under the contract. There is no stated or implied requirement that MCOs be reimbursed the full cost of care at billed charges.

Basic Requirements

Comment: One commenter wanted us to define the term ''actuarial basis,'' as used in § 438.06(c)(2)(ii), and provide sample contract language to implement this provision.

Response: ''Actuarial basis'' as used in § 438.06(c)(2)(ii) merely refers to the principles and assumptions used by the actuary in computing the rates in the contract. We do not believe it is necessary to define this term in the text of the regulation.

Comment: One commenter was concerned about meeting the requirements of § 438.6(c)(2)(ii), which provides that the contract must specify the capitation rates that are paid. Specifically, the commenter asked if States would be able to submit final rates in an addendum to the contract when the rates are developed after the rest of the contract is implemented.

Response: In answer to the commenter's question, rates must be part of the contract that is approved by us as part of the contract approval process that is a pre-condition for FFP § 438.806 in the case of comprehensive risk contracts with MCOs. If rates are not yet agreed upon between the State and the contractor at the time the remainder of the contract is approved, the State could operate under the payment rates that were previously approved by us, although FFP would not be available in new payment rates until they are approved as well. If the contract is a renewal or extension of a previously approved contract, FFP could be claimed and payments made based the rates in the previously approved contract, until an addendum to that contract with new rates and the supporting documentation required by this section of the regulations is approved.

Requirements for Actuarially Sound Rates

Comment: Some commenters believe that we should clarify that this provision does not preclude States from using additional elements, such as case-rate type payments (for pregnant women or others) and family-based rate cells as long as they are consistent with other requirements.

Response: The requirements in this section are not meant to be all inclusive. States are required either to apply the elements in § 438.6(c)(3), or to explain why they are not applicable. Examples of reasons that these elements would not be applicable would include the State's use of case-rate type methodologies or other rate setting methods, that still meet the test for actuarial soundness, or where the rate cells broken down to this level are not large enough to be statistically valid.

Comment: Several commenters wanted us to require States to explain how they have taken into account: Potential data inaccuracy due to lack of historical Medicaid managed care data for a new population or service; potential data inaccuracy due to reasonably anticipated under-reporting; and other similar data shortcomings that may be reasonably foreseeable.

Response: We agree with the commenters that these are important factors in determining payment rates. The adjustments required to smooth data should include adjustments for incomplete data, whether due to incurred-but-not-reported expenditures, delays in claims submission, or other factors. In response to this comment, we are adding data completion factors to § 438.6(c)(3)(ii) as one of the required data smoothing adjustments. However, we believe that this is not the only mechanism that could be used to account for unexpected costs of new populations or services, and that these issues are better addressed through risk adjustment or risk sharing provisions in the contract.

Comment: Several commenters wanted us to require States to identify their method for compensating MCOs for changes in obligations imposed on the MCOs during a contract year, so that new requirements cannot be imposed while payment rates remain unchanged.

Response: The terms of a contract must be agreed upon by both parties in order for the contract to be in effect, as required by § 438.802(a)(2). One option is for the contract to include a term providing for an increase in payment in the event there are changes in the MCO's obligation (for example, if the contract binds the MCO to cover all State plan services, and services are added to a State plan mid-year). Absent such a provision, the contract would have to be amended in order for payment to be increased to cover new obligations. Any such amendment would have to be approved by us. We will not review and approve those amendments unless both parties, that is, the State and the MCO, PIHP, or PAHP have agreed to the new terms. Thus, we believe that the issue of how changes in contractual obligations are addressed should be the subject of negotiation between the parties, who are in the best position to agree upon an approach that works in their situation.

Comment: One commenter asked whether States will have the flexibility to take into account their FFS budgets, and managed care budget authority, when developing actuarially sound rates.

Response: We understand the fact that all Medicaid programs are subject to budgets set by the governor and/or the State legislature, and that this obviously must be taken into account in negotiating rates with MCOs, as well as in deciding whether the State can afford to do so. In some cases, there may be insufficient funding to begin or to continue a Medicaid managed care program. We are not in a position to determine if and when a State may have insufficient funding. The Medicaid agency may determine this in advance, or as the result of being unable to attract contractors who are willing to operate a managed care program for the payment rates that the State is able to pay. When contracts are submitted to us for review and approval, the determination of whether adequate funding is available has already been made, in that the State has an agreement with one or more managed care entities and has determined that these entities can meet the contractual obligations to be imposed on them. The managed care entities have determined that the rates they are to be paid are adequate to meet their obligations under the contract. We do not have the authority to change the way States budget for their Medicaid programs in this final rule. We will use our authority to review and approve rates in risk contracts based on the

actuarial certification and the documentation provided showing that the requirements in this section are met.

Comment: Several commenters asked what sources we will accept as base utilization and cost data in determining actuarially sound rates (for example, FFS data, encounter data, MCO financial data) and most of these commenters believed that the rule should specify that these other sources are permissible. Another commenter asked who makes the determination as to whether ''costs'' are to be determined by FFS history, MCO experience, or other factors.

Response: A State's FFS data would be the best source of baseline data, since they represent the most complete claims history available on the population to be covered under managed care, but only to the extent that the data are recent enough to be valid for this purpose. The fact that there is an increasing number of States that lack recent FFS data to use for rate setting is one of the main reasons that it has become necessary to repeal the UPL requirement. We agree that other sources, such as encounter data, need to be used for this purpose. However, we also recognize that not all States have even begun to collect encounter data, and that not all of those States that are collecting the data have yet developed mechanisms to ensure their validity. States without recent FFS history and no validated encounter data will need to develop other data sources for this purpose. States and their actuaries will have to decide which source of the data to use for this purpose, based on which source is determined to have the highest degree of reliability.

Comment: One commenter believed that experience data used to develop the base period medical cost should only be from the population being rated and categorized by the rate cells used.

Response: In general, we agree with the commenter that the best source of base period data would be the population to be covered under the managed care contract, but as indicated above, this is not always possible. If the data are not available or usable, States must use other data for this purpose.

Comment: One commenter wanted us to clarify that the phrase ''derived from the Medicaid population'' at § 438.6(c)(3)(i) means those Medicaid beneficiaries enrolled in MCOs. As set forth, this provision would permit the use of State FFS cost data, which may have understated cost assumptions, and inflation data, especially in the area of prescription drugs where MCOs are unable to negotiate prices comparable to those available to the States.

Response: We disagree with the commenter. The phrase ''derived from the Medicaid population'' means that the source of the base utilization and cost data is the historical utilization and cost data of the Medicaid eligibles to be covered under the managed care contract. These data may be derived from the FFS history, managed care history, or a combination of both. Regardless of the source, adjustments should be made to achieve a degree of predictability for the rates that are developed. The commenter's example of prescription drug costs represents one specific area where the new rate setting rules allow greater flexibility in rate setting than permitted previously. Under the UPL requirement, capitation rates in a contract could not exceed what would have been paid under FFS for the same services provided to a comparable population. For the prescription drug component of a capitation rate, this amount would have been net of the amount of drug rebates received by the State through its FFS system. Under the new rules, the component of the capitation rate for prescription drugs will not be limited by the UPL.

Comment: Several commenters wanted CMS to require States to provide information on base year costs by primary service category included in the contract, such as, pharmaceuticals, hospital, and physician services, and to clarify that these data will specifically include unit cost and utilization data as separate assumptions, in order to evaluate the adequacy of the rates.

Response: States must report information on base year costs by the primary service category, at a minimum, for the primary services included in the contract. Further, we agree with the commenter that States should use separate assumptions with respect to unit cost and utilization data.

Comment: One commenter believed that the proposed regulation was unclear as to the adjustment factors to be used to make base period data comparable to the Medicaid population in cases in which data specific to the Medicaid population do not exist.

Response: As discussed above, the best source of data for determining base period cost and utilization will have to be determined by the State and its actuaries, subject to CMS approval. States will also need to determine what adjustments are necessary to make data comparable to the Medicaid population if there are no usable Medicaid data available. We would expect these adjustments to be based upon a comparison of the population whose data are used to the State's Medicaid population in terms such as income, demographics, and historical medical costs. In instances where non-Medicaid data are used, the required actuarial certification will need to include an explanation of the adjustments used to make the data comparable.

Comment: Several commenters suggested that base year costs be trended forward by ''medical'' inflation, not just ''inflation'' as stated in the proposed rule, and that we should clarify this in the regulation text.

Response: We agree with the commenters, and in response to this comment have changed the regulation text at § 438.6(c)(3)(ii) accordingly. In making this change, we want to emphasize that the rate of medical inflation may be determined from such sources as the medical market basket or the State's historical Medicaid costs.

Comment: Some commenters wanted the administrative adjustment to be expanded to require it to reflect an MCO's cost of complying with Medicaid managed care requirements in such areas as service delivery, reporting, and operational and accountability standards. These commenters argued that administrative costs would have to be significantly increased to comply with the quality provisions and other reporting requirements in this regulation, and that payment rates should reflect these costs.

Response: We agree that the capitation rate should include an administrative adjustment that recognizes administrative costs incurred by the contractor in providing the services to be delivered under the contract. However, we recognize that this adjustment may not necessarily fully compensate the contractor for its administrative costs under the contract, and potential contractors need to consider proposed payment rates in the aggregate, as to whether or not they will be sufficient to cover both the cost of services and the administrative costs it will incur under the terms of the contract.

Comment: Several commenters asked that we clarify how the limits in proposed § 438.6(c)(4)(ii) (regarding an assurance that all payment rates are based only upon services covered under the State plan) apply to the adjustments for inflation and administration in paragraph (c)(3)(ii), and whether we plan to issue guidelines on acceptable adjustment factors and any limits that will be in place.

Response: The intent of this limitation in § 438.6(c)(4)(ii) is to prevent States from obtaining FFP for things such as State-funded services for which FFP would not ordinarily be available, by

including them in an MCO, PIHP, or PAHP contract. This limitation is extended to the adjustments in paragraph (c)(3)(ii), so that the only administrative costs recognized are those associated with the MCO's, PIHP's, or PAHP's provision of State plan services to Medicaid enrollees. We do not intend to issue specific guidelines on these limits, as we believe that decisions will have to be made on a case-by-case basis.

Comment: Several commenters urged us to specify that risk or profit levels, along with an administrative component, should be included in actuarially sound rates, and that the adjustment requirement in § 438.6(c)(3)(ii) is not sufficient to achieve this purpose.

Response: This is another area where we believe all MCOs, PIHPs, and PAHPs which intend to contract with States must consider proposed payment rates in the aggregate, as to whether or not the payments will be sufficient to cover the cost of all of their contractual obligations and their desired risk and profit levels as well. We do not believe it would be appropriate to establish standards for risk and profit levels.

Comment: One commenter believed that there are many other adjustments that should be applied beyond those listed in the proposed rule, such as adjustments for new procedures or technologies or the addition of new Medicaid benefits.

Response: We agree that there are other appropriate adjustments currently used by States in setting their capitation rates, and will approve those supported by the accompanying certification and documentation as contracts are reviewed and approved. However, we are not mandating any additional adjustments at this time.

For the addition of new Medicaid benefits, however, we believe that the inclusion of any additional Medicaid services during the term of a contract could either be handled through a contract amendment or a contract term that provides for the contingency, subject to CMS approval, subject to CMS approval.

Comment: A number of commenters expressed concerns over the requirements in § 438.6(c)(3)(iii) that rate cells be specific to the enrolled population by eligibility category, age, gender, and locality or region. Some commenters asked whether this provision mandates the use of these specific breakouts in developing rate cells, and were concerned that requiring rate cells to be broken down to this level could result in rates in some small cells that are not actuarially sound in States with small populations. Other commenters wanted us to clarify that other types of rate cells, such as case rate or family-based cells are permissible.

Response: It is our intent that, to the extent possible and practical, rate cells be broken down by these categories. The vast majority of capitation rates in Medicaid managed care contracts currently use these breakouts. However, we recognize that there are valid reasons why this breakout may not be appropriate or possible in a particular State—because of such factors as the size of the population, or because a decision has been made to use another methodology, which still complies with the overall requirement for actuarial soundness. For this reason, the introductory language in § 438.6(c)(3) requires States to apply the elements in setting their capitation rates, ''or explain why they are not applicable.''

Comment: Several commenters wanted us to specify the type of explanation it would accept for a State that does not use these adjustments, and quantify the burden on States to comply with this provision. One commenter asked whether the explanation could cover an entire managed care program, or whether the State had to separately justify every region or county where the program operates. One commenter wanted us to allow States to use an actuarially appropriate method that may include these cells as appropriate, without requiring the State to justify its approach during each rate-setting process.

Response: We believe that the most obvious reason a State would not use rate cells broken out to this degree would be insufficient numbers of enrollees in any one category for the category to have statistical validity. Another example that would be accepted is the use of a different methodology such as case rates or family-based cells, provided the methodology still meets the other requirements of this section and has the required actuarial certification. These decisions will be made on a case-by-case basis, and we do not want to limit the flexibility States can have in developing new methodologies by specifying all allowable exceptions in this rule. On the other hand, these rate cells are the most commonly used breakouts in current Medicaid managed care contracts, and we believe that it is not unreasonable to require States to justify other methodologies if that is the approach they decide to use.

We disagree with the commenter that this requirement places any significant burden on States. Most States are already in compliance with the requirement. The remaining States should either be able to provide a simple justification for their alternative methodologies, or need to consider a different approach in setting their capitation rates.

Comment: One commenter wanted us to add a requirement for rate cells by major category of service (that is, inpatient, outpatient, primary care specialist, pharmacy, medical supplies, ambulance and other).

Response: We do not believe that such a requirement would serve a useful purpose. It is important for contracting MCOs, PIHPs and PAHPs to know a payment amount per enrollee, but it is up to the contractor to determine how to allocate that amount at the provider (or service category) level.

Comment: Several commenters felt that the requirements in § 438.6(c)(3)(iv) were not clear. This provision required that there be payment mechanisms and assumptions recognizing higher than average medical costs for certain enrollees, for example, through risk adjustment, risk sharing, or other cost neutral methods. One commenter urged that we clarify that a rate setting method that uses utilization and cost data for populations that include individuals with chronic illness, disability, ongoing health care needs, or catastrophic claims already meets this requirement without additional adjustments, since the higher costs would be reflected in the enrollees' utilization. Another commenter questioned whether this rule requires health status or diagnosis-based risk adjustment, or other risk sharing methods.

Response: The intent of this requirement is that contracts will have some mechanism selected to recognize the financial burden a contractor may incur as a result of enrollees who have much higher than normal health care costs, as a result of either a chronic or acute condition. The fact that the costs of these individuals are included in the aggregate data used for setting rates will not account for the costs to be incurred by a contractor that, due to adverse selection or other reasons, enrolls a disproportionately high number of these persons. Thus, we are requiring some mechanism for risk-sharing or risk adjustment to address this issue. Most MCO contracts currently use either stop-loss, risk corridors, reinsurance, health status-based risk adjusters, or some combination of these approaches. We have not mandated that any particular approach be adopted.

Comment: One commenter asked how we define the terms ''chronic illness'', ''disability,'' ''ongoing health care

needs,'' and ''catastrophic claims,'' as used in § 438.6(c)(3)(iv), and whether these are the same individuals categorized as enrollees at risk of having special health care needs, as may be defined by States in § 438.208(b)(3).

Response: The individuals intended to be covered by this requirement would likely include those described as having special health care needs, but would not necessarily be limited to that group. This provision is also intended to address individuals for whom a contractor may incur short-term catastrophic claims, but who may not be defined by the State as having special health care needs. Further, the individuals referred to in this paragraph are identified by their medical costs, while the individuals referred to in § 438.208(b) are identified by their medical needs.

Comment: One commenter asked whether we intend to make risk adjustment by health status mandatory in the future, since we have indicated that risk adjustment is an appropriate smoothing factor for individuals with special health care needs, and has contracted to produce a guidance manual for States to use health-status risk adjustment.

Response: The commenter is correct that we support the use of health status risk adjusters as one way of making capitation rates more predictable and accurate, and have contracted for technical assistance for States in developing and using payment systems that are risk adjusted based on health status or diagnosis, and will be providing a guidance manual for States to use for this purpose. However, each State will still need to determine whether it wishes to invest the extensive resources necessary to develop and utilize this type of risk adjustment system. We do not intend to mandate this requirement.

Comment: One commenter wanted us to define the term ''appropriate'' as used in § 438.6(c)(3)(iv), which refers to appropriate payment mechanisms and utilization and cost assumptions.

Response: As used both here and in the definition of actuarially sound rates, the term ''appropriate'' means specific to the population for which the payment rate, or in this instance risk sharing mechanism, is intended. This requirement applies to individuals who have health care costs that are much higher than the average. Appropriate for the populations covered means that the rates are based upon specific populations, by eligibility category, age, gender, locality, and other distinctions decided by the State. Appropriate to the services to be covered means that the rates must be based upon the State plan services to be provided under the contract.

Comment: Several commenters wanted us to define the term ''cost neutral'' as used at § 438.6(c)(1)(ii), and specify how this requirement will be measured. One commenter asked whether a risk sharing model, where the State shares a percentage of excess profits and losses with its MCO, would be considered cost neutral. Several commenters asked whether all of the mechanisms mentioned in § 438.6(c)(3)(iv) need to be cost neutral, and whether these mechanisms must be cost neutral over the entire Medicaid program, or just as applied to specific populations.

Response: In using the term ''cost neutral,'' we are requiring that risk sharing mechanisms recognize the fact that while some enrollees will have much higher than average health care costs, other will have much lower than average costs. Actuarially sound risk sharing methodologies will be cost neutral in that they will not merely add additional payments to the contractors' rates, but will have a negative impact on other rates, through offsets or reductions in capitation rates, so that there is no net aggregate impact across all payments. A risk corridor model, as described by the commenter, where the State and contractor share equal percentages of profits and losses beyond a threshold amount, would be cost neutral. In response to these commenters we have added a definition of ''cost neutral'' at § 438.6(c)(1)(iii).

In response to the other commenters, the cost neutrality requirement must apply to all mechanisms described in § 438.6(c)(3)(iv). The mechanism, as set forth in the rate setting methodology, should be cost neutral in the aggregate. How that is determined, however, will differ based on the type of mechanism that is used. A stop-loss mechanism will require an offset to all capitation rates under the contract, based on the amount of the stop-loss. Health status-based risk adjustment may require an adjustment to the capitation rate for all individuals categorized through the risk adjustment system, but the aggregate impact will still be neutral. We recognize that any of these mechanisms may result in actual payments that are not cost neutral, in that there could be changes in the case mix or relative health status of the enrolled population. As long as the risk sharing or risk adjustment system is designed to be cost neutral, it would meet this requirement regardless of unforeseen outcomes such as these resulting in higher actual payments.

Comment: A number of commenters believed that an actuarial certification alone would not be sufficient to justify the payment rates. Some believed that the impact of the adequacy and timeliness of data and the State's budget process must be addressed as well. Other commenters wanted the certification to include enough information for another actuary to independently evaluate the results, including: Underlying data, its source and adjustments made; description of rate methodology; documentation of assumptions used; presentation of rates; and expected impact on each MCO's revenues.

Response: We will be looking beyond the actuarial certification of the capitation rates in reviewing and approving rates in risk contracts. The certification is one part of the documentation that will be required, and as described elsewhere in § 438.6, there are a number of assurances and explanations that must accompany this certification in order for rates to be approved. We do not believe it is necessary, or in some cases appropriate, for other actuaries to be able to independently evaluate the results and assumptions in setting the rates (other than for our actuaries in cases where their assistance is required). As we stated above, we believe that MCOs, PIHPs, and PAHPs contracting with States on a risk basis must make their own independent judgments of proposed rates based on their own costs of doing business and their understanding of the population to be covered, not necessarily their actuaries' review of the State's actuaries' assumptions and process in setting the rates.

Comment: One commenter was concerned that States or their contracted actuaries may be required to provide proprietary information to document the assumptions and methodology used to establish the capitation rates.

Response: We do not believe that States will be required to provide any information that is proprietary in nature in order to justify their capitation rates in risk contracts. However, if there are instances where actuaries believe that information their State is required to submit would represent trade secrets or proprietary information, as described in the Freedom of Information Act (FOIA) (5 U.S.C. 552(a)), the information should be identified as such and may be withheld from public disclosure under the provisions of the FOIA.

Comment: One commenter believed that additional documentation should be required, including: eligibility and enrollment trends; provider

reimbursement at the Medicaid market level; utilization trends; pharmacy and ancillary costs; benefits in the contract period; and administration.

Response: We believe that the documentation requirements in § 438.6(c)(4), along with the other provisions of this rule, will provide sufficient information on which to base decisions to approve or disapprove capitation rates in risk contracts. Thus, we do not believe that the additional documentation suggested by the commenter is necessary.

Comment: A large number of commenters expressed concern over the requirement in § 438.6(c)(4)(ii) that payment rates may only be based upon services covered under the State plan. Some of these commenters felt that MCOs need to maintain the flexibility to arrange for, and provide services in the most efficient manner that meets the needs of the individual, and these alternative services may not be in the State plan. The commenters asked whether this paragraph prohibits States and MCOs from offering additional services or providing services in alternative settings determined to be more appropriate, when these services are not in the State plan. Others asked whether MCOs can still receive payment for these services when they provide them. Some commenters wanted us to allow these costs to be incorporated into the rate calculations.

Response: When a State agency decides to contract with an MCO or other type of managed care entity, it is arranging to have some or all of its State plan services provided to its Medicaid population through that entity. The State has not modified the services that are covered under its State plan, nor is it continuing to pay, on a FFS basis, for each and every service to be provided by the entity. Further, MCOs and other managed care contractors have the ability to do as suggested by the commenters—to provide services that are in the place of, or in addition to, the services covered under the State plan, in the most efficient manner that meets the needs of the individual enrollee.

These additional or alternative services do not affect the capitation rate paid to the MCO by the State. Neither do we believe that the capitation rate should be developed on the basis on these services. This requirement sets forth that principle—that the State determines the scope of State plan benefits to be covered under the managed care contract, and sets payment rates based on those services. This does not affect the MCOs right, however, to use these payments to provide alternative services to enrollees that would not be available under the State plan to beneficiaries not enrolled in the MCO.

Comment: Several commenters asked how the cost of non-State plan services, provided as cost-effective alternatives to State plan covered services, can be factored into the development of the capitation rates when a State uses MCO utilization and cost data in setting rates, if under § 438.6(c)(4)(ii) rates can only be based upon services covered under the State plan. These commenters believed that States need to be able to incorporate the cost of alternative services in rate calculations. Some commenters suggested that trade-offs should be incorporated into the rate calculation so that the cost of these services can be recognized.

Response: We agree that there must be a mechanism whereby States using MCO encounter data can base utilization costs of actuarially correct rates on non-FFS data. However, actuaries must adjust the data to reflect FFS State plan services only. States cannot use unilaterally contractually required or ''suggested'' services not part of the State plan (also known as ''1915(b)(3) services'') to calculate actuarially sound rates. We are open to suggestions from States and their actuaries, but we will not modify the basic principle that rates be based only on services covered under the State plan.

Comment: One commenter asked whether capitation rates can be adjusted to reflect additional requirements for services like EPSDT and other preventive care that may not have been provided under the State plan in FFS.

Response: Another reason that we decided to replace the UPL requirement with the requirement for actuarially sound rate setting is to permit States to pay for the amount, duration and scope of State plan services that States expect to be delivered under a managed care contract. Thus, States may adjust the capitation rate to cover services such as EPSDT or prenatal care at the rate the State wants the service to be delivered to the enrolled population. States may use other mechanisms such as financial penalties if service delivery targets are not met, or incentives for when targets are met.

Comment: Another commenter asked if the requirement in § 438.6(c)(4)(ii) that payment rates based upon the cost of State plan covered services would prohibit payment for administration, profit, and contingencies, and what effect this would have on the FFP match.

Response: As noted previously, we have clarified the language in § 438.6(c)(4)(ii) to indicate that payment may also be made for a contractor's administrative costs directly related to providing Medicaid services covered under the contract. In accordance with § 438.812, all costs under a risk contract are considered a medical assistance cost, so there is no impact on FFP.

Comment: A number of commenters raised questions regarding the requirement at § 438.6(c)(4)(iii) for a comparison of projected expenditures for a past year to actual expenditures for that year. Several commenters wanted to know what our purpose was in requiring the reporting of year-to-year expenditure differences when evaluating actuarial soundness.

Response: The purpose of this requirement is to provide us with an indicator of the accuracy of prior year projections and the rate of growth in a State's expenditures under its managed care program, and to provide some direction to reviewers as to whether it may be necessary to look behind the assumptions used by the State in setting the rates. An increase in expenditures that far exceeds the inflation rate in the medical market basket for a given period may warrant further review, as may rates that have been unchanged through several contracting cycles. However, these are not factors that would, in and of themselves, result in the disapproval of proposed rates.

Comment: One commenter requested that we clarify whether the requirement for documentation is an annual requirement or if the information is to be submitted on some other basis.

Response: This information, along with the rest of the documentation required by this rule, would have to be submitted with any new contract, or contract renewal or amendment that included new rates, as part of that required documentation. Thus, the information is not necessarily required to be submitted on an annual basis. States will need to submit the documentation of past and projected future expenditures in time for us to review the expenditure comparison as part of its review of new, renewed, or amended contracts (with revised rates).

Comment: One commenter asked whether the comparison of expenditure data is intended to cover the State's entire Medicaid population, or only that portion which is to be enrolled in managed care during the contract year.

Response: These data should cover expenditures for all Medicaid eligible beneficiaries in areas where they are or could be enrolled in managed care. Thus, if all TANF eligibles in a part of the State are mandatorily enrolled in managed care, in either a PCCM or an

MCO, they would be included in all of past expenditures data and future projections. Also, if SSI eligibles could voluntarily enroll in managed care, data on all SSI beneficiaries (whether the individuals are enrolled in managed care or not) should be included.

Comment: Several commenters believed that we should clarify what is meant by the provision at § 438.6(c)(4)(iii), which requires ''documenting'' the prior year's expenditures as compared to the projected expenditures in the contract year, and asked what type of documentation would be required, and when it would be due. These commenters wanted to know whether we will issue guidelines on the process to be used to project the prior year's expenditures.

Response: We do not believe the provision of these data is either a complex or burdensome process. We require that the State identify that portion of its expenditures in the most recent complete year that are attributable to populations who are or could be enrolled in managed care.

Comment: One commenter asked what flexibility States will have in determining the methodology for making expenditure projections under this provision, and believed States should be able to provide these projections on the basis of either aggregate or per capita expenditures.

Response: While we are not prescribing the methodology for providing this information, we believe that per capita expenditures are the only valid means to provide the type of information that can be compared from year to year.

Comment: One commenter asked what information States must submit to comply with the requirement at § 438.6(c)(4)(iv) to explain incentive arrangements, or stop-loss, reinsurance, or other risk sharing methodologies in MCO contracts.

Response: These risk sharing methodologies can sometimes be very complex. In order for the mechanism to be approved in the contract, the State or its actuary will need to provide enough information for our reviewer to understand both the operation and the financing of the risk sharing mechanism.

Comment: Several commenters raised questions regarding stop/loss and reinsurance coverage, and asked whether we will require MCOs to obtain stop-loss/reinsurance coverage.

Response: Although a number of States require MCOs to obtain stop-loss or reinsurance coverage, there is no Federal requirement that they do so.

Comment: One commenter asked whether, in cases where the State requires stop-loss insurance, we would require the State to provide a copy of a contract between the MCO and the re-insurer or stop-loss provider to us. Another commenter asked if we would require States to verify the actuarial soundness of MCO stop-loss/reinsurance contracts purchased commercially.

Response: We will not review the actuarial soundness of commercially purchased stop-loss/reinsurance coverage. As mentioned above, there is no Federal requirement that MCOs obtain this coverage, and we will not generally require a copy of the stop-loss/reinsurance coverage contract. However, there are situations where this may be required, due to unusual circumstances, such as an MCO that is financially unstable.

Special Provisions

A number of commenters expressed concerns about the limitation in § 438.814 on FFP in contracts with incentive arrangements or risk corridors. These comments are addressed in the portion of the preamble on that section. For purposes of clarity and in order to include these limitations on payment in the same subpart as the other rules governing payments in risk contracts we have moved these provisions from § 438.814 to § 438.6(c)(5)(ii) and (c)(5)(iii). We have also removed the phrase in § 438.6(c)(5)(i), which excepted risk corridors from the requirement for actuarial soundness, since it contradicted other provisions of the regulation.

Comment: Several commenters wanted us to define the terms ''risk corridors'' and ''incentive arrangements'' as used in § 438.6(c)(5)(ii) and § 438.814.

Response: The term ''incentive arrangements,'' as used in this part, means any payment mechanism under which a contractor may receive additional funds over and above the capitation rates it was paid, for meeting targets specified in the contract. These targets may be for such things as delivery of services such as EPSDT at a specified rate (beyond the level envisioned in the capitation rate), or meeting certain quality improvement standards. Risk corridors are defined as a risk sharing mechanism in which States and MCOs share in both profits and losses under the contract outside of predetermined threshold amount. The amount of risk shared under this arrangement is usually graduated so that after an initial corridor in which the MCO is responsible for all losses or retains all profits, the State contributes a portion toward any additional losses, and receives a portion of any additional profits. In response to these commenters we have added definitions for ''incentive arrangement'' and ''risk corridor'' at § 438.6 in paragraphs (c)(1)(iv) and (c)(1)(v) respectively.

Comment: Several commenters questioned the provision in proposed § 438.6(c)(5)(iii)(C) that would have required the withholding of payments or other financial penalties in any contract with incentive arrangements, where the incentives are not met. These commenters stated that the requirement did not make sense, since these are two different types of provisions that act independently and serve different purposes.

Response: We agree with the commenter that this proposed provision was confusing and have deleted it from this final rule. Proposed § 438.6(c)(5)(iii)(D) has been recodified as § 438.6(c)(5)(iv)(C), with subsequent paragraphs similarly renamed.

Comment: One commenter wanted us to clarify what is intended by the requirement in proposed § 438.6(c)(5)(iii)(E) (now § 436.6(c)(5)(iv)(D) in this final rule), that incentive payments cannot be conditioned on intergovernmental transfer agreements.

Response: The purpose of this prohibition is to prevent incentive arrangements in managed care contracts from being used as funding mechanisms between State agencies or State and county agencies.

Comment: One commenter believes that the requirement in proposed § 438.6(c)(5)(iii)(F), (now § 436.6(c)(5)(iv)(E) in this final rule) that incentive arrangements be necessary for the specified activities and targets is unclear and a highly subjective determination. The commenter felt that the provision should either be deleted, or alternatively that responsibility for the determination of necessity be placed on the State.

Response: We do not believe that this provision is unclear or highly subjective. A State that decides to use incentive arrangements will have made a determination that they are needed in the contract, and we agree that this should be the State's determination.

Comment: Many commenters objected to the provision in proposed § 438.60 prohibiting direct payments to teaching hospitals for graduate medical education (GME) when the hospital's services are provided through managed care. Commenters indicated that this prohibition would disturb longstanding arrangements in many States.

Response: In response to the concerns raised by these commenters, we have modified that section to permit such payments to the extent the capitation rate has been adjusted to reflect the amount of the GME payment made directly to the hospital. We have added new § 438.6(c)(5)(v), which requires States making payments to providers for GME costs under an approved State plan, to adjust the actuarially sound capitation rates to account for the aggregate amount of GME payments to be made directly to hospitals on behalf of enrollees covered under the contract. This amount cannot exceed the aggregate amount that would have been paid under the approved state plan for FFS. We believe this approach addresses State concerns of preventing harm to teaching hospitals and Federal concerns of ensuring the fiscal accountability of these payments. As part of our larger strategy of improving the fiscal integrity of Medicaid payments, we also plan to study existing Medicaid GME payment arrangements and may issue additional policies in the future.

• Services That May Be Covered (Proposed § 438.6(e))

The proposed rule at § 438.6(e) provided that an MCO, PIHP, or PAHP, contract may cover, for enrollees, services that are in addition to those covered under the State plan.

Comment: One commenter was pleased that the proposed rule expressly provides for MCO contracts to cover services that are in addition to those covered under the State plan, because it will allow them to find new, innovative ways to more effectively treat health problems. A few commenters believed these non-State plan services will allow for cost-effective substitutions for State plan services. However, these commenters question why these non-State plan services cannot be used by the State in the development of payment rates under § 438.6(c). One commenter noted that if they are not paid for such non-State plan services it would stifle MCOs in the use of innovative treatment methodologies and technologies. Another commenter questioned how FFP is impacted for these additional services, since they are not allowed to be included in the rate setting methodology under § 438.6(c)(4)(ii). This commenter also asked whether we were requiring payments for these additional services to be actuarially sound and certified as required by § 438.6(c).

Response: Those commenters who appear to believe that § 438.6(e) allows for payment for additional services that can be provided in lieu of State plan services are not correct. The additional services allowed under § 438.6(e) are not included in the calculation of capitation payments. These services may only be offered by an MCO, PIHP, or PAHP paid on a risk basis. This is because these entities would typically use ''savings'' (a portion of the risk payment not needed to cover State plan services) to cover the additional services in question. Additional services may also be provided for under section 1915(b)(3) waiver authority which allows a State to share savings resulting from the use of more cost-effective medical care with beneficiaries by providing them with additional services. In either case these services are additions to State plan services and are paid for by plans or through shared savings under the waiver program. Since payment is made by the plans or through shared savings, such payments do not have to be actuarially sound and certified. In order to clarify the confusion over this provision, we have added the phrase, ''although the cost of the services cannot be included when determining the payment rates under § 438.6(c).'' Further, for a discussion of the prohibition against including non-State plan services in setting capitation rates, see the preamble discussion of § 438.6(c)(4).

• Compliance With Contracting Rules (Proposed § 438.6(f))

This section requires all contracts under this subpart to comply with all Federal and State laws and regulations and meet all requirements of this section.

Comment: We received one comment supporting the provisions regarding compliance with applicable Federal and State laws and regulations found in § 438.6(f).

Response: We are retaining the provisions supported by the commenter in this final rule, and appreciate the commenter's supportive comments.

• Inspection and Audit of Financial Records (Proposed § 438.6(g))

This section of the proposed rule required that the financial records of contractors and subcontractors be available for audit and inspection.

Comment: One commenter supported the explicit requirements of § 438.6(g). The commenter noted that without access to financial arrangements with subcontractors, it is difficult to track whether rates are sufficient to ensure that children have access. The commenter urged us to make this information publicly available.

Response: We are not imposing a requirement on States to make these financial data public, nor will we establish a mechanism to do so at the Federal level. However, under § 438.10(g) (3) enrollees are entitled to obtain information on the structure and operations of their MCO or PIHP, and for States with mandatory managed care under section 1932(a)(1), § 438.10(i)(3)(iv) provides that beneficiaries are entitled to receive quality and performance indicators on the MCOs and PIHPs available to them. We believe that this type of information has more value to Medicaid beneficiaries than the financial data required by this section.

• Advance Directives (Proposed § 438.6(i))

Proposed § 438.6(i) requires that all MCO and PIHP contracts comply with the requirements of § 422.128 (M+C rules) for maintaining written policies and procedures for advance directives, and reflect changes in State law within 90 days.

Comment: One commenter asked for the definition of the term ''advance directive'' as used in § 438.6(i).

Response: The provisions on advance directives are cross referenced to the more detailed M+C rules in § 422.128, which are further linked to the definition of the term in § 489.100. As defined in § 489.100, ''advance directive'' means a written instruction, such as a living will or durable power of attorney for health care, recognized under State law (whether statutory or as recognized by the courts of the State), relating to the provision of health care when the individual is incapacitated.

Comment: One commenter was concerned that providing all adult enrollees with written information on advance directive policies, and including a description of applicable State law changes, will cause MCOs to duplicate information and develop documentation systems that will add unnecessary cost and an administrative burden, thereby reducing efficiency of providing health care.

Response: Because section 1903(m)(1)(A) of the Act requires MCOs to provide information on advance directives to enrollees, we do not have the authority to eliminate or modify the advance directives provision for MCOs under § 438.6(i).

Comment: Another commenter believes the advance directive requirements should be expanded to all managed care enrollees and not just for those enrollees in MCOs and PIHPs. The commenter believes that beneficiaries have the same right to make informed

choices about outpatient treatments as those beneficiaries do about inpatient treatments.

Response: Section 489.102(a) identifies those providers required to comply with advance directive requirements. That section includes providers that could be participating in a PAHP network, including hospital outpatient providers and home health agencies. Therefore, we agree with the commenter that advance directives should apply to PAHPs if their network includes any of the providers that are listed in § 489.102(a). We have added a new § 438.6(i)(2) to include this requirement.

• Additional Rules for Contracts With PCCMs (Proposed § 438.6(k)

This section proposed new rules found in section 1905(t)(3) of the Act which specify the requirements that must be included in contracts with primary care case managers.

Comment: One commenter felt that the contract requirements for PCCMs were too minimal, and that patients in PCCM programs should have rights of access, coverage, information, and disclosure that are as strong as those that apply to MCOs, PIHPs, and PAHPs.

Response: The contract requirements for primary care case managers in proposed § 438.6(k) largely mirror the language set forth in section 1905(t)(3) of the Act, which was added by section 4702 of the BBA. The BBA is clear in setting forth which contracting requirements should be placed on primary care case managers, which should be placed on MCOs, and which apply to all MCOs, PHPs, or PCCMs. PCCM contracts must include those requirements set forth in section 1905(t)(3) as well as any additional requirements in section 1932 of the Act that apply to them. For example, a PCCM must meet the information requirements set forth in § 438.10 that apply to it. We also have applied access, coverage, and information requirements to primary care case managers where applicable. Where the BBA specifies that requirements apply to MCOs, such requirements are not applicable to PCCM contracts. However, where a PCCM is paid on a capitated basis, the PCCM would meet the definition of a PAHP and would also be subject, by regulation, to all PAHP requirements.

Comment: One commenter is concerned that the requirement in § 438.6(k)(2) that ''restricts enrollment to recipients who reside sufficiently near one of the manager's delivery sites to reach that site within a reasonable time using available and affordable modes of transportation'' does not take into consideration the special circumstances and characteristics of frontier states. The commenter wanted us to clarify what is a ''reasonable'' time in frontier states where the nearest provider may be more than 100 miles from the beneficiary, and very few locations have any public or commercial transportation available. The commenter asked whether this prohibits a recipient from choosing a provider who is further away, which could result in decreased beneficiary satisfaction and choice. The commenter suggests a standard based on ''normal and customary'' practices that would allow for a frontier state to better serve its population.

Response: We do not believe that this requirement imposes any unreasonable burden on frontier states as suggested by the commenter. The requirement in proposed § 438.6(k)(2), that beneficiaries be able to access care within reasonable time using affordable modes of transportation, is derived from statutory language in section 1905(t)(3)(B) and cannot be changed. However, states have the flexibility to determine their own standards for reasonableness based on normal distance and travel times in the area, the needs of the beneficiaries, provider availability, and the geographic uniqueness of the State. One example, as noted in the preamble of the proposed rule, is the 30-minute travel time standard that many States have adopted for urban areas. Other States have established 10 to 30 mile distance standard, depending on specific circumstances within the area of the State to be served. We have consistently permitted States to develop their own standards, based upon customary treatment patterns in their unrestricted FFS programs, in the approval of section 1915(b) waiver programs.

While we require States to develop their PCCM programs so that enrollees should not have to travel an unreasonable distance beyond what is customary in the State's unrestricted FFS program, we encourage States, to the extent practical, to make exceptions for beneficiaries who request to travel further than the time and distance standards set by the State, for such reasons as a desire to maintain an ongoing relationship with a particular participating provider. Section 438.6(k)(2) would not prohibit such exceptions, provided the beneficiary was aware of his or her options and could make an informed choice of PCCM.

• Subcontracts (Proposed § 438.6(l))

This proposed rule requires all subcontractors to fulfill the requirements of § 438.6 that are appropriate to the services or activity delegated under the subcontract.

Comment: One commenter asked for clarification about whether the CMS Regional Office must also review and approve all subcontracts since § 438.6(l) requires that all subcontracts must fulfill the requirements of § 438.6, and § 438.6(a) requires the CMS Regional Office to review and approve all MCO, PIHP, and PAHP contracts.

Response: The requirement for Regional Office review of contracts in § 438.6(a) only pertains to contracts between States and MCOs, PIHPs, and PAHPs, but not to subcontracts between any of these entities and their subcontractors. As noted above, § 438.6(l) only requires compliance with provisions in § 438.6 that are ''appropriate'' to the service or activity covered under the subcontract, and we do not believe that such review would be appropriate to the services or activities delegated under the subcontracts, or a worthwhile expenditure of our resources. Our focus is on the contractual relationship between the State and the MCO, PIHP, or PAHP as the primary contractor, as required by section 1903(m) of the Act, with respect to MCOs. The primary contractor is the entity that is obligated to comply with all provisions of the contract, whether it uses subcontractors in order to do this or not. The use of subcontracts does not in any way alter the primary contractor's responsibilities, obligations, or authority under the contract.

• Choice of Health Professional (Proposed § 438.6(m))

This section sets forth the right of an MCO enrollee to choose his or her health professional to the extent possible and appropriate.

Comment: One commenter suggested that the regulations should specify that MCOs must let enrollees choose their primary care provider from among all qualified participating providers, including specialists. The commenter also suggested that when an enrollee is unable to be linked to their first choice of primary care provider, the MCO should have a mechanism for linking the enrollee to that provider when the provider becomes available.

Response: Section 438.6(m) permits an enrollee to choose his or her health professional to the extent possible and appropriate. This would include the selection of primary care providers participating in the MCO, PIHP or PAHP network, unless they were already at capacity. We do not believe it is necessarily appropriate for specialist to act as primary care providers in every

instance. Primary care is defined in § 438.2, and does not describe the range of services provided by many specialists. We believe that the decision on whether a specialist is the appropriate PCP for any enrollee should be left to the MCO, PIHP, PAHP, and/or the State to be determined on an individual basis. If an enrollee is unable to be placed with their first choice of primary care provider, they may continue to check on that provider's availability and change PCP when it becomes possible to do so. We do not believe this change is necessary in the regulation text. However, we are removing reference to MCOs, since this requirement applies to PIHPs and PAHPs as well under § 438.8.

4. Provisions That Apply to PIHPs and PAHPs (Proposed § 438.8)

This section specifies which provisions of this rule apply to PIHPs and which apply to PAHPs.

Comment: Many commenters believed that the same requirements should apply to both PIHPs and PAHPs, and several suggested that both types of PHPs should be subject to the same requirements as MCOs. These commenters argued that both types of entities cover an increasingly large portion of the Medicaid population, that requirements for an adequate and appropriate network are just as relevant and necessary for dental and transportation providers as for MCOs, that children with special health care needs require specialized care regardless of the scope of services their managed care contractor provides, and that any plans that provide any type of medical care should be required to comply with the protections in the BBA, such as network adequacy, credentialing, and grievance rights.

Several other commenters suggested that even plans providing non-medical services, such as transportation should be required to have an adequate network, provide services timely, and have a mechanism to resolve complaints.

Another commenter suggested returning to a single set of requirements for PHPs, but accommodating PHPs covering a more limited array of services by permitting them to deviate from standards that are not applicable to the entity or services it provides or allow additional time to come into compliance.

Other commenters expressed support for the distinction in requirements between PIHPs and PAHPs and the flexibility in the rule to determine how to most appropriately regulate PAHPs.

Response: As stated above in the discussion regarding definitions at § 438.2, we believe that there are clear differences in terms of the degree of financial risk, contractual obligations, scope of services, and capitation rates paid to these different types of entities, and that the scope of rules that apply to these entities under this regulation should reflect these distinct differences. However, in considering the provisions of the proposed rule and the issues raised by commenters, we agree that there are additional provisions of this regulation that should apply to PAHPs and have modified the requirements of the final rule to implement these changes. In § 438.8(b), we have added the following requirements to PAHPs: Advance directives where a PAHP has a network of providers that includes either hospital outpatient departments or home health agencies (see the response to comments on § 438.6(i) advance directives), all of subpart C on Enrollee Rights, and designated portions of subpart D on Quality Assessment and Performance Improvement. We have added new information requirements specific to PAHPs in a new paragraph (h) in § 438.10 (with the existing paragraph (h) renamed paragraph (i)). Finally, at § 438.6(b)(7), we have reaffirmed a PAHP enrollee's right to a fair hearing under § 431.220. We believe that with these changes, we have maintained an appropriate level of regulatory requirements for these entities and provided the necessary degree of flexibility for States to implement these programs and impose any additional requirements States determine to be necessary. In addition, we believe we have provided the necessary level of beneficiary protections for these programs, including network adequacy (where applicable), provider credentialing, and appeal rights. We do not believe that applying additional provisions to PAHPs would be appropriate based on the scope of services they provide and the capitation rates they are paid in comparison to PIHPs and MCOs.

Comment: Several commenters raised specific concerns about PAHP rules governing prepaid dental plans. Some commenters indicated that Medicaid dental patients need patient protections like MCO enrollees, since oral and systemic health are both integral to overall health, and should have the same patient protections. Another commenter asked whether MCO or PAHP rules apply to MCOs that subcontract for dental care. Several commenters were concerned that dental services are provided as part of MCO contracts and FFS as well as by prepaid dental plans, and PAHP dental enrollees should have the same protections as MCO enrollees receiving dental care.

Response: We agree with the commenters regarding the importance of dental health and that beneficiary protections are an important requirement for dental PAHPs, particularly the requirement for network adequacy. One reason that States use prepaid dental plans is because of the lack of dental providers who provide care under FFS. Guaranteeing an adequate network in a dental PAHP will provide Medicaid beneficiaries access to dental care that is often otherwise unavailable.

The determination as to which rules apply to any service or delivery system is the identity of the entity that contracts with the State. Thus, in situations where an MCO has a contract with a State, MCO rules apply to services furnished by the MCO or its sub-contractors, including a subcontracting pre-paid dental plan. Where a PIHP or PAHP contracts with the State, PIHP or PAHP rules apply respectively.

Comment: Several commenters objected to the requirements imposed on PIHPs. They believed that the proposed requirements were unclear, ambiguous, and burdensome, and would require the State to spend money on administrative expenses rather than patient care. These commenters felt that the proposed requirements were targeted to a medical model and did not take into account behavioral health services, such as mental health and substance abuse or rehabilitation models. They pointed out that PIHPs only authorize and pay for community psychiatric hospital beds and not all inpatient hospital care, and thus should not be subject to MCO requirements.

Response: We acknowledge that this rule will impose many new requirements on PIHPs, just as it imposes new requirements on MCOs and PAHPs. Most of the new rules imposed on MCOs were derived from the BBA. Prior to the BBA, PHPs were subject, under Part 434, to most of the rules governing Medicaid-contracting HMOs. We believe that the Congress determined that additional costs and administrative burden were justified in order to provide sufficient protections for beneficiaries enrolled in MCOs. We believe that these same considerations apply to PHPs that provide inpatient services. In addition, we believe that beneficiaries in need of mental health and substance abuse services may be particularly vulnerable, and need these

protections more than some other healthier Medicaid beneficiaries.

Comment: One commenter apparently believed that while PCCMs covering some or all of the following services were subject to PCCM requirements (case management, durable medical equipment, EPSDT, family planning, hearing, home health care, immunizations, laboratory, outpatient hospital, pharmacy, physician, transportation, vision, and x-ray) a managed care plans covering a subset of theses services would be exempt from all enrollee safeguards and quality and integrity requirements.

Response: It is true that the referenced services can be furnished through a PCCM arrangement, under which the primary care case manager provides physician services and case management, and has the responsibility to refer or prior authorize these other services for their enrollees. It is also true, that in such a case, the PCCM requirements, and any requirement that applies to a ''managed care entity'' (both MCOs and PCCMs) would apply in this case. However, it is also true that a managed care plan that provides a subset of these services would be subject to enrollee safeguards and quality and integrity requirements, as an MCO or a PAHP. An entity that was at risk for the full scope of services described by the commenter (or any subset of three or more of the services described in § 438.2 in the definition of comprehensive risk contract) would be considered an MCO, even though inpatient services were not being provided. If the ''subset of services'' did not trigger the definition of comprehensive risk contract, the entity would still be regulated as a PAHP, and PAHPs are not exempt from *all* enrollee safeguards and quality provisions.

Comment: Several commenters wanted us to impose PIHP requirements on prepaid providers of home and community-based services (under a section 1915(c) waiver) in order to assure that beneficiaries in programs that maximize community-based care and minimize the need for institutionalization will have sufficient protections. One commenter contended that the Supreme Court's decision in *Olmstead* v. *L.C.,* and the President's New Freedom Initiative, dictate that all provisions in the proposed rule that would improve or ensure access to care must be provided to those who need community-based care in order to reside outside of institutions. Other commenters believed that PIHP rules should not apply to home and community-based services, since the rules could discourage participation of these needed providers, and take away State and local discretion to impose, waive, or adjust requirements as best determined at that level.

Response: Home and community based service providers by definition do not provide ''inpatient'' care, and accordingly would not meet the definition of PIHP. In light of our decision, discussed above, to impose additional requirements on PAHPs, we believe that we have provided sufficient beneficiary protections for PAHPs that provide home and community based services, while at the same time accommodating the latter commenter's concern about requirements discouraging participation. In so doing, we believe that we are helping to implement the *Olmstead* v. *L.C.* decision and the President's New Freedom Initiative, and to ensure access to community-based care with appropriate enrollee protections and quality assurance.

Comment: One commenter felt that all PIHPs and PAHPs should be subject to sanctions if they do not comply with the regulations.

Response: The sanction authority enacted by the Congress in the BBA is limited to MCOs. We do not believe we have authority, by regulation, to authorize States to impose civil money penalties on PAHPs or PIHPs. However, States may cover PIHPs and PAHPs under their own State sanction laws, and we encourage States to do so whenever they believe it is necessary.

Comment: One commenter wanted us to add a provision to exempt MCOs with less than 500 members from the same requirements from which PAHPs are exempt.

Response: Because PIHP and PAHP requirements are based on broad on the authority in section 1902(a)(4) of the Act, we have the discretion to impose those requirements on PIHPs and PAHPs that we determine to be appropriate through regulations. However, requirements for MCOs are specified in sections 1903(m) and 1932 of the Act, and are not subject to modification by regulation on the basis of the number of an MCO's enrollees.

5. Information Requirements (Proposed § 438.10)

Proposed § 438.10 set forth the requirements that apply to States, MCOs, PIHPs, PAHPs, PCCMs, and enrollment brokers concerning the provision of information to enrollees and potential enrollees. Paragraph (a) defined the terms used in this section. Paragraph (b) set forth the basic rule that all information provided must be in a manner and format that may be easily understood. Paragraph (c) established rules regarding language. Paragraph (d) specified the format for information and that alternative formats must be available. Paragraph (e) described information requirements for potential enrollees. Paragraph (f) set forth the general information requirements for enrollees of all MCOs, PIHPs, PAHPs, and PCCMs. Paragraph (g) contained specific information requirements for MCO and PIHP enrollees. And paragraph (h) set forth the special rules required of States with mandatory enrollment under the State plan authority in § 438.50.

General Comments on § 438.10

Comment: Some commenters appreciated the clarity and content of this section, and stated that they did not believe the provisions were too prescriptive. By contrast, another commenter contended that the requirements were too prescriptive, and would be difficult to meet even for a non-Medicaid population. This commenter believed this section as a whole did not take into consideration the nature of frontier States. The commenter recommended reducing the Federal role in the provision of information to beneficiaries, and letting States have the discretion to determine what is most appropriate.

Finally, one commenter believed that the proposed rule did not ensure that enrollees would receive adequate information to understand their rights and responsibilities, and that it failed to provide potential enrollees with enough information to make an appropriate decision. The commenter believed this is especially true for individuals with chronic health conditions, who often see numerous medical professionals. The commenter asserted that these beneficiaries must have adequate information to make the best decision to ensure that their health needs can be met within a plan's network.

Response: We believe the proposed rule achieves an appropriate balance between ensuring potential enrollees and enrollees have sufficient information, and giving the State flexibility in implementing the regulation. We appreciate the comments in support of the clarity of the proposed rule, and the comment that it contains an appropriate level of prescriptiveness. For frontier areas, enrollees there also need a minimum set of information to navigate a managed care program. We believe the regulations are flexible enough to accommodate the unique circumstances of rural and frontier areas, and have identified specific instances in our responses to

subsequent comments. Finally, we believe the minimum information required in the proposed rule is sufficient for all potential enrollees and enrollees, even those with disabilities or chronic illnesses. There are areas where information that might be especially useful for this population is available upon request instead of provided automatically (for example § 438.10(d) on alternative formats, § 438.10(e)(2)(ii)(D) on summary provider information, and § 438.10(g) on information on plan structure and operations), but the final rule makes clear that these enrollees and potential enrollees must be informed of how and where to get this information.

Definitions (Proposed § 438.10(a))

Proposed paragraph (a) set forth definitions of ''potential enrollee'' and ''enrollee.''

Comment: One commenter supported the definitions of ''potential enrollee'' and ''enrollee.'' Another commenter, however, felt that the regulation needs to clarify who an enrollee is in the case of a specialty plan. For example, in the commenter's State, all Medicaid recipients are required to receive mental health services from certain plans, but the State does not give information about mental health services until an individual actually receives services. This commenter recommended the State or plan should provide minimum general information about the plan and what services are provided at the time of initial enrollment in the plan, and provide more detailed information when the beneficiary first contacts the plan to inquire about services available.

Response: We believe that the definition of enrollee is appropriate for any managed care program, including mental health managed care. We believe that the regulation's flexibility on providing certain information in summary format meets the commenter's first suggestion. We disagree with the suggestion to delay providing the full set of required enrollee information to the point in time when an enrollee requests services. This fails to provide adequate information to enrollees, and could be a barrier to care for enrollees who are unsure of what services the plan provides and how to access those services. We acknowledge that this will result in increased burden for States such as those in which the commenter resides where there is a single PIHP per service area in which every beneficiary is automatically enrolled upon determination of Medicaid eligibility. Some of the anticipated burden could be reduced by providing the required potential enrollee and enrollee information at the same time.

Mechanism To Assist Understanding (Proposed § 438.10(b))

As noted above, proposed paragraph (b) set forth the basic rule that all information provided must be in a manner and format that may be easily understood.

Comment: Numerous commenters believed that the proposed basic rule at § 438.10(b) failed to require States to have a mechanism to help enrollees and potential enrollees understand the managed care program, and failed to require MCOs, PIHPs, and PAHPs to have a mechanism for enrollees and potential enrollees to understand the requirements and benefits of the plan. Several argued that beneficiaries need to have the ability to get information from a variety of resources, not just written material. They felt that a mechanism was needed to ensure that enrollees and potential enrollees have information necessary for informed decisions. Some commenters believed that the lack of such a source of assistance would have a harmful impact on persons with disabilities, especially mental retardation and other cognitive impairments. One commenter urged that such a mechanism be family-friendly. Several commenters noted that such a mechanism was included in the Bipartisan Patient Protection Act (HR 2653), CMS' Report to the Congress entitled ''Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care,'' and the President's Advisory Commission on Consumer Protection and Quality in the Healthcare Industry.

The commenters recommended requiring States to have a mechanism for potential enrollees and enrollees to understand the State's managed care program. Examples included a toll-free hotline, ombudsman, and other types of consumer assistance. Many of the commenters further recommended requiring that MCOs, PIHPs, and PAHPs have a mechanism to help potential enrollees and enrollees understand the requirements and benefits of the specific plan. Two commenters recommended the plan's mechanism need only be provided for enrollees, not potential enrollees.

Response: We agree with commenters that written information may not be sufficient for potential enrollees and enrollees to understand a managed care program. In response to these comments, we have amended § 438.10(b), by adding paragraphs (b)(1) and (b)(2) to require that States, MCOs and PIHPs have mechanisms in place to help beneficiaries that need such help to understand the managed care program, and plan requirements and plan benefits. We believe that it is not necessary to separately require PAHPs and PCCMs to have such mechanisms, as information on such plans could be addressed by the State's mechanism. We will require the mechanism to be available to both potential enrollees and enrollees, especially given that much of the required potential enrollee information need only be provided in summary format. We believe, however, that the State and plans should be given the discretion and flexibility to provide the mechanism most appropriate to their situation, so we are not specifying the type of mechanism that must be in place.

Comment: One commenter requested that health plans be made aware of their responsibility to respond to a beneficiary's questions in a timely manner.

Response: We agree that plans should respond in a timely manner, and expect them to do so. However, we do not believe that it is necessary to specifically provide for this in regulation text.

Comment: Numerous commenters noted that the basic rule requires that only certain information be presented in a manner and format that is easily understood. They objected that this did not appropriately safeguard the rights of beneficiaries. The commenters believed that limiting the requirement to only certain material fails to give beneficiaries with limited English proficiency sufficient information. Some expressed concern that this could also violate section 1932(a)(5)(A) of the Act, which the preamble to the proposed rule characterized as requiring ''all written information be provided in an easily understood language and format.'' Commenters recommended expanding the requirement to include ''all'' materials. On the other hand, there was one commenter who agreed with the limitations on which materials must meet the criteria.

Response: While we share the commenters concern that all material should be in a manner and format that is easily understood, this section of the regulations is derived from section 1932(a)(5)(A) of the Act which specifically requires that responsible parties ''provide all enrollment notices and information and instructional materials * * * in a manner and format which may be easily understood.'' Thus, notwithstanding the unqualified language in the preamble, section 1932(a)(5)(A) of the Act limits the type of information covered by its provisions.

However, in addition to the specific requirements that apply to enrollment notices and information and instructional materials contained in this section, provisions of the regulation governing information on enrollee rights, provider enrollee communications, marketing, grievances and appeals, and termination of MCOs and PCCMs all reference the requirements of this section. We believe that this extends the requirements for an easily understood language and format to virtually all written material provided to potential enrollees and enrollees. Thus, we do not agree that it is necessary to revise the regulation in response to this comment.

Clarifying Responsible Entity (Proposed Rules § 438.10(b) and § 438.10(f))

As noted above, paragraph (b) sets forth the basic principle that information must be provided in a form that is easily understood. However, it does not set forth which entities are obligated to provide what specific information. This also is the case with respect to one paragraph in paragraph (f), which sets forth the general information requirements for enrollees of all MCOs, PIHPs, PAHPs, and PCCMs. The introductory paragraph to paragraph (f) refers to information being made ''available.''

Comment: Numerous commenters objected to the fact that the text of the ''basic rule'' in § 438.10(b) does not identify who is responsible for providing information to potential enrollees and enrollees. One commenter asserted it is not enough for § 438.10(f) to require only that information be made ''available'' to enrollees, because this creates what the commenter believed to be a needless barrier to ensuring beneficiaries have the information they need. Finally, many commenters expressed concern that § 438.10(f)(6) (regarding required information for enrollees) did not specify who was responsible for providing required information to enrollees. Some of these commenters recommended clarifying that the State is responsible for providing required information to enrollees, and that the State can delegate this responsibility to the health plan. Other commenters suggested clarifying that the plan is responsible for providing required information, and that the State is responsible for ensuring compliance.

Response: While the text in § 438.10(b) setting forth the ''basic rule'' does not itself identify who is responsible for providing what information to potential enrollees and enrollees, we believe that other provisions of the regulations text make this clear. Specifically, § 438.10(e)(1) specifies that the State or its contracted entity is responsible for providing required information to potential enrollees; § 438.10(f), with one exception discussed below, specifies which entity or entities is responsible for providing specified information; § 438.10(g) specifies that MCOs and PIHPs are responsible for providing information specific to those types of programs; § 438.10(h) specifies that the State or a PAHP must provide information on PAHPs; and § 438.10(i); specifies the State is responsible for providing certain information required under a State plan amendment.

Within § 438.10(f), each of the paragraphs specifies a responsible party, except, as commenters note, paragraph (f)(6). While § 438.10(f)(3) specifies who is responsible for providing the information in § 438.10(f)(6), we agree that § 438.10(f)(6)—read alone—is unclear. We are revising § 438.10(f)(6) to specify the State or at its discretion, its contracted entity, the MCO, PIHP, PAHP, or PCCM, is responsible for providing required information to enrollees. We will also conform the language identifying responsible parties in § 438.10(f)(4) and § 438.10(g) with the language used in other paragraphs. Finally, while each paragraph in § 438.10(f) requires the *provision* of certain information, in response to this comment, and for consistency, we are revising the introductory paragraph to replace ''made available'' with ''provide.''

Prevalent Languages (Proposed § 438.10(c))

Proposed paragraph (c) required that information be made available in prevalent languages.

Comment: One commenter supported basing the determination of whether a language is prevalent in the potential enrollee and enrollee population, rather than the State's population as a whole. The commenter stated this more appropriately targets those who would use information being translated.

By contrast, a few commenters noted that proposed rule only requires States to identify prevalent languages, not all languages spoken by potential enrollees and enrollees. They asserted this is a weak standard, and disproportionately harms community health centers, which serve a disproportionate share of people with limited English proficiency. The commenters recommended the State be required to identify all languages spoken in State, not just prevalent languages.

Response: We agree with the first commenter that the proposed rule's focus on the enrollee and potential enrollee population in the state is most effective. We disagree with the latter commenters that the proposed ''prevalent languages'' standard is weak. The proposed rule conforms with the Office for Civil Rights' ''Policy Guidance title VI Prohibition Against National Origin Discrimination As It Affects Persons With Limited English Proficiency.'' Specifically, that Guidance suggested that written material should be translated into regularly encountered languages other than English spoken by a significant number or percentage of the population eligible to be served.

Comment: One commenter noted that there is generic (versus plan-specific) information in § 438.10(f)(6) that must be translated into prevalent languages. The commenter believed it would be wasteful and inefficient to require each plan to translate it, and any variation in this generic language across plans would be confusing to beneficiaries. The commenter recommended requiring States to make translations of generic information available to plans.

Response: Nothing in the proposed rule would prohibit the State from translating material that is not plan specific. However, we believe States should have flexibility on whether to adopt this approach.

Comment: One commenter noted that the proposed regulatory provisions placed sole responsibility for identifying prevalent languages on the State. In the commenter's State, there is a model in which plans are required to identify the prevalent languages spoken by their enrollees, and forward that data to the State. The commenter stated this allows the plan to concentrate on the language needs of their membership; the State then combines its data with plans' data for a more accurate picture of non-English languages spoken. The commenter recommended flexibility in this area so that the maximum amount of prevalent language data can be collected at all levels of contact with the enrollee.

Response: We believe the proposed rule provides the flexibility this commenter seeks. Specifically, § 438.10(c)(1) requires the State to ''establish a methodology,'' but gives States the discretion on what the actual methodology is. It would not preclude the methodology described by the commenter.

Comment: Numerous commenters expressed concern that the definition of ''prevalent'' at § 438.10(c)(1) was based on prevalence among the enrollee and

prospective enrollee population at a Statewide level, not a service area level. They observed that if beneficiaries with limited English proficiency are concentrated in a few areas, there may not be enough to meet statewide prevalence threshold. One commenter stated this was especially an issue in more populated States.

The commenters recommended basing prevalence on service area, not a statewide threshold. One recommended it be based on geographic area, as stated in the preamble to the proposed rule. Another commenter recommended the rule define service area. Still others urged the rule go further, and specify a threshold of 5 percent within localized area. A few proposed the rule set a threshold of 10 percent or 3,000 in a service area, with additional specifications if there are 5 percent or less, as well as under 100 potential enrollees or enrollees. Finally, a commenter suggested that if the State does not identify prevalent languages by service area, that plans be required to do so.

Response: We appreciate the commenters' point regarding languages that may be prevalent at a service area level but not meet a statewide threshold. However, we believe the proposed rule takes this into account. Specifically, § 438.10(c)(2) requires the State to ''Provide written information in each prevalent non-English language.'' However, § 438.10(c)(3) requires each MCO, PIHP, PAHP, and PCCM to make its written information available in the prevalent non-English languages in its particular service area. For potential enrollees and enrollees who primarily speak a non-English language that is not prevalent, the mechanism we are requiring in response to a comment on § 438.10(b) will provide them an avenue for obtaining needed information.

Comment: One commenter contended that requiring States to identify prevalent languages is administratively burdensome and costly. Another commenter found the language requirements problematic, especially for rural States, and believed they would create additional costs for State and plans. Finally, a commenter noted the difficulty of consistently producing materials in prevalent non-English languages in a timely fashion. On the other hand, numerous commenters supported the proposed rule requiring a methodology to identify prevalent non-English languages, and provision of written information in those languages.

Commenters who had concerns about the prescriptiveness of the proposed language requirements recommended more flexibility in the language requirements, including allowing States the flexibility to determine if additional language versions of written information are necessary.

Response: The OCR Guidance we referenced in our earlier response makes clear that all entities that receive Federal financial assistance from the Department of Health and Human Services, either directly or indirectly, must provide meaningful access to its services for beneficiaries with limited English proficiency. This includes providing translated versions of vital documents into non-English languages regularly encountered in the eligible population. The Guidance provides suggested methodologies for identifying prevalent languages, which may be of use to States that do not yet have a methodology in place. It may be that in a rural State, there are no non-English languages that would meet a prevalence test. In those instances, States must still arrange for oral interpretation and have a mechanism (see comment and response on § 438.10(b)) to assist non-English speaking beneficiaries to understand written materials that are not translated.

We believe the proposed rule gives considerable discretion to States in what methodology they use.

Comment: Several commenters expressed support of the proposed rule's reinforcement of existing language requirements under title VI of Civil Rights Act of 1964. Others suggested specifically referencing in the rule guidance issued by the Office for Civil Rights, since it applies to States and plans receiving Federal funding under Medicaid.

Response: We appreciate the commenters' support on this issue. We have disseminated the Guidance to States via a State Medicaid Director letter dated August 31, 2000, and it is also available on our website. We do not believe it necessary to specifically reference the OCR Guidance in the regulation.

Comment: Numerous commenters noted that the definition of ''prevalent'' does not define what constitutes a ''significant number or percentage.'' They believe this is not sufficient guidance, and that there is no compelling need for States to have discretion. On the other hand, a few commenters expressed support for giving States the discretion to define prevalent.

The commenters concerned about lack of guidance uniformly recommended the final rule establish a minimum threshold. Recommendations included defining prevalent as 10 percent or 3,000; incorporating OCR guidance on ''safe harbors,'' and using a threshold of 5 percent in a localized area and a Statewide level of 5 percent as well.

Response: We believe that the language and format requirements are essential elements for ensuring that enrollees and potential enrollees receive the information necessary to make an informed choice and access benefits. While we believe they are essential elements, we also continue to believe that the best methodology for determining the prevalent language spoken by a population in a service area may differ from State to State and therefore we will not be modifying the regulation to mandate a specific methodology. We also note that the OCR policy guidance referenced above gives further examples and guidance on meeting individuals' language needs.

Comment: One commenter noted that § 438.10(c)(2) requires States to *provide* written information in each prevalent language, but § 438.10(c)(3) only requires plans to make translated written material *available.* The commenter believes that this seems to suggest that unlike plans, States cannot simply respond to a request and instead must actually ensure it distributes translated materials to each beneficiary with limited English proficiency. The commenter stated this would be an onerous requirement, and recommended instead that latitude be given to States to respond to an inquiry.

Response: We agree that the wording could be construed to required different levels of effort between the State and plans. In response to this comment, we are revising § 438.10(c)(2) to clarify that States need only make translated materials available. We note that § 438.10(c)(5) still requires States and plans to notify enrollees and potential enrollees that translated materials are available and how to obtain them.

Comment: One commenter noted that the proposed rule required States and plans to identify beneficiaries with limited English proficiency. However, the commenter believed that individuals with limited English proficiency should be able to self-identify and receive appropriate written and oral communication.

Response: We agree that beneficiaries with limited English proficiency should be able to self-identify and receive appropriate written and oral communication, and believe the regulation does allow this. First, anyone who self-identifies as having limited English proficiency would at that point be identified as such by the State as well as a result. Secondly, § 438.10(c)(5) requires States and plans to notify

potential enrollees and enrollees about the availability of oral interpretation, written information in prevalent languages, and how to access those services. Those services are available regardless of whether the State or plan identifies the beneficiary as having limited English proficiency, or the beneficiary self-identifies as such.

Comment: One commenter concurred with the requirement in § 438.10(c)(3) on making translated material available, and limiting it to written information.

Response: We appreciate the commenter's support for this clarification.

Oral Interpretation (Proposed § 438.10(c))

Comment: A few commenters noted that sign language was not specifically referenced in the proposed rule, and that interpretation for persons with hearing impairments is required by the Americans with Disabilities Act and title VI of the Civil Rights Act. One commenter suggested that clarification of this point in the regulation text would avoid confusion about the applicability of ADA requirements. The commenters recommended specifically including sign language and other interpreter services for beneficiaries with hearing impairments.

Response: We agree that sign language interpretation should be available for potential enrollees and enrollees with hearing impairments. However, § 438.6(f) specifically requires MCOs, PIHPs, PAHPs, and PCCMs to comply with the Americans with Disabilities Act and other applicable Federal statutes. We do not believe it would be necessary or appropriate to restate all of the specific requirements of that law in this section of the regulation text.

Comment: A few commenters supported the availability of interpretation services, but believed it would be extremely difficult for most office-based physicians to set up and finance these services. They noted there is little coverage of these services by States, and the cost would be substantial for office-based physicians, often exceeding their reimbursement for the office visit itself. The commenters felt it was critical that we require States to create and fund systems to ensure appropriate interpretation services Statewide. They further stipulated that the services should be funded separately, not bundled into provider or capitation payments.

Response: While we believe that it is appropriate and necessary to require that interpretation and translation services be available for all potential enrollees and enrollees, we also believes that the States should be afforded the flexibility to determine how these translation services are provided and paid for.

Comment: One commenter contended that the requirement in § 438.10(c)(4) to make oral interpretation available for all non-English languages does not take into consideration special circumstances and characteristics of frontier States. To expect a State with a small population to have someone available to speak any possible language would be unreasonable in this commenter's view. This view was based on the commenter's belief that the increased cost and could result in decreased access if providers drop their participation in Medicaid. Another commenter argued that requiring oral interpretation for all languages was administratively burdensome and costly. The commenters recommended allowing State flexibility to determine if oral interpretation was necessary.

Response: We appreciate the difficulties in arranging for oral interpretation for languages that are less frequently encountered. However, we believe the proposed rule does not create any new requirements, but rather clarifies that existing requirements under title VI of the Civil Rights Act apply to Medicaid managed care programs. The OCR guidance reinforces this, but allows for flexibility in how oral interpretation is arranged. For example, it acknowledges that on-site interpretation may not always be realistic, in which case other options such as telephone language lines may be used.

Comment: Numerous commenters supported the requirement for provision of oral interpretation. One commenter specifically supported the provision that it be available free of charge to each potential enrollee and enrollee, but believed the requirement should be strengthened. The commenter suggested adding language stipulating that oral interpretation be provided when needed, and in a manner convenient to the beneficiary.

Response: We appreciate the commenters' support of this provision. We believe that some flexibility is appropriate, as noted in the OCR guidance, which sets forth a variety of factors to take into consideration when determining how to provide meaningful translation.

Alternative Formats (Proposed § 438.10(d)(2))

As noted above, proposed paragraph (d) specified the format for information, and that alternative formats must be available for those with special needs.

Comment: Numerous commenters supported the requirement that written material be available in alternative formats, but objected to the fact that the proposed rule did not expressly identify who was responsible for providing them. They believed that specifying responsibility was essential to ensuring that the information is transmitted in a timely manner. The commenters recommended that the final regulation specify that both the State and health plans have responsibility for making available their respective written materials in alternative formats.

Response: We believe that the proposed rule makes clear that written material must be available in alternative formats. We believe that as drafted, it is clear that this requirement applies to whomever is providing the written material at issue to potential enrollees and enrollees. Therefore, we believe it is unnecessary to list each party in the regulations text.

Required Information — General (Proposed § 438.10 (e) Through (g))

As noted above, proposed paragraph (e) described information requirements for potential enrollees; paragraph (f) set forth the general information requirements for enrollees of MCOs, PIHPs, PAHPs, and PCCMs, and paragraph (g) contained specific information requirements for MCO and PIHP enrollees.

Comment: One commenter noted that requiring specific information for potential enrollees and enrollees would require additional State and contractor financial and staff resources. The commenter believed this would lead to increased costs of production and distribution for both State and plans.

Response: We appreciate that additional resources may be needed to compile, produce, and disseminate the required information. However, we believe this information is critical for potential enrollees to make informed decisions, and enrollees to understand how to access services.

Information for Potential Enrollees (Proposed § 438.10(e)(1)(i))

Comment: Numerous commenters believed the proposed rule would result in a delay in potential enrollees receiving information. The commenters noted that as proposed, the rule would require information be given to potential enrollees when they become eligible to voluntarily enroll in managed care, or face mandated enrollment in managed care. They were concerned this could delay when beneficiaries receive the information, reducing the amount of time they have to digest it. Some

commenters proposed that an additional option should be added, *i.e.,* the time when the potential enrollee first becomes eligible for Medicaid. Others recommended adding the following language to § 438.10(e)(1)(i): ''When eligible to choose among MCOs, PIHPs, PAHPs, or PCCMs in a voluntary program.''

Response: We believe the proposed rule ensures that potential enrollees are provided required information at the earliest appropriate time. We acknowledge that a beneficiary may become Medicaid eligible first, and only later be eligible to enroll in a voluntary program, or required to enroll in a mandatory program. However, we are concerned that the provision of information for which the beneficiary has no immediate use will result in the information being disregarded. In the majority of cases, a beneficiary becomes a ''potential enrollee'' immediately upon Medicaid eligibility determination, and in these instances will get the information at the time suggested by commenters.

Comment: One commenter noted that the proposed rule does not expressly require the State to provide the required information on a plan to all potential enrollees in the plan's service area. The commenter recommended adding this language.

Response: The proposed rule requires the State to provide the required information to all potential enrollees, which already would include all potential enrollees in a particular plan's service area. Therefore, we believe it unnecessary to add the recommended language on ensuring that the information must be provided to all potential enrollees in a plan's service area.

Summary Information for Potential Enrollees (Proposed § 438.10(e)(2)(ii))

Comment: Some commenters supported proposed § 438.10(e)(2)(ii), which provided that States need only provide summary information specific to each plan, with detailed information to be provided upon request. They believe this flexibility allowed States and plans to make better use of their resources by giving specific information only where it is needed to make informed choices, without broadly disseminating voluminous information that will generally receive little attention.

Another commenter was concerned that the requirement for States to provide only summary information—versus providing detailed information—would mean that many potential enrollees may not receive basic information on service areas, cost-sharing, benefits covered, provider information (including family planning), and other benefits not covered under contract. The commenter believed the burden in providing more detailed information is minimal, so the final rule should require the State to provide detailed information to all potential enrollees, not just upon request.

Numerous commenters specifically objected to proposed § 438.10(e)(2)(ii)(E), which required the State to provide to potential enrollees only summary information on State plan services not covered by the contract. They believed this provision eliminated one way potential enrollees learn about the full range of what is available under the State plan. Some commenters were especially concerned that it was important for access to reproductive health services, which plans may not offer. Some commenters were concerned that the delay caused by needing to ask for the information could result in a beneficiary being defaulted into such a plan. Finally, there were commenters who asserted summary information was not adequate to allow potential enrollees to make an informed decision.

Many of the commenters recommended that the final regulation require detailed—not summary—information on all items specific to each MCO, PIHP, and PAHP. Others also suggested the final rule require health plans to refer enrollees to a State sponsored, toll-free number that informs beneficiaries about how and where to access services plan the plan does not provide. They further suggested that this information be provided on an annual basis and at the point of service.

Response: We believe the proposed rule strikes the proper balance between providing needed information and ensuring the information is useful rather than overwhelming. The proposed rule does not preclude a State from providing detailed information. However, if it opts to provide summary information, then it must under § 438.10(e)(12)(ii) ensure potential enrollees and enrollees are informed that more detailed information is available upon request, and how to request it. Lists of Participating Providers (§ 438.10(e)(2)(ii)(D) and § 438.10(f)(6)(i))

These proposed sections required the provision of a list of participating providers, including the name, phone number address, non-English languages spoken, and other information.

Comment: For potential enrollees, one commenter suggested limiting the list of providers on whom information is provided to hospital and primary care. The commenter believed that providing a full specialty provider directory may create confusion on how to navigate the plan's referral process, giving the impression that referrals or authorization are not needed. The commenter recommended potential enrollees who want the specialty network information be directed to call the plan or enrollment broker.

Response: Although we acknowledge that including information on specialists adds to the volume of information and further complicates the process of keeping information current, we do believe that a significant number of potential enrollees rely on this information and therefore continue to believe that, at a minimum, information on provider networks should include information on primary care physicians, specialists, and hospitals.

Comment: One commenter believed that even in summary format, provider information would be too voluminous, and its value for potential enrollees is highly questionable. In the commenter's view, based on experience with managed care, people are more likely to read mailings that contain simple, limited information focusing only on the most important issues. The commenter suggested the requirement be limited to informing potential enrollees how they can obtain this information.

Another commenter was unclear how provider network information could be summarized. Even a summary could be voluminous, especially if it has to be kept up to date. The commenter asserted that States need flexibility to determine the most efficient method that will get accurate information to beneficiaries via the easiest media. The commenter suggested making this information available upon request, with assistance available from both State and plans.

Response: For many potential enrollees, a decisive factor in selecting a plan is whether their current primary care provider is in the network. For beneficiaries with disabilities or chronic illnesses, participating specialists can carry the same weight. We believe the flexibility to summarize provider information will allow States to minimize the volume. For example, clinics or group practices could be identified in lieu of listing individual physicians. States and their contractors must highlight to potential enrollees how to obtain detailed listings or to inquire whether a specific provider is participating.

Comment: A commenter pointed out that identifying non-English languages spoken by providers—as required in

§ 438.10(e)(2)(ii)(D) and § 438.10(f)(6)(i)—is an example of how the proposed rule would impose requirements on managed care programs which are not required in Medicaid FFS programs. In the commenter's view, it would be problematic to obtain this information, and the State could place itself at risk if it is construed that it is in some way ''certifying'' their ability to speak the language. Another commenter noted that maintaining information on non-English languages spoken by specialists and hospitals is extremely difficult due to the frequency with which it changes. The commenter recommended this only be required for PCPs.

Response: We acknowledge that this information may be problematic to obtain and keep current. However, it is our belief that potential enrollees and enrollees need this information to make informed choices. We encourage States and plans to highlight to potential enrollees and enrollees that it is important to verify through a phone call or other means that the information is current.

Comment: A few commenters felt that it would be difficult to keep information on which providers are accepting new enrollees current—as required in § 438.10(f)(6)(i)—especially in a printed format. One of the commenters suggested clarifying that plans may state in their materials that potential enrollees must contact the plan for oral updates of this information, or that they be required to keep the printed information reasonably up to date. Another commenter suggested that the final rule be revised to require the plan to prominently display a toll-free number to get this information. Another recommended the rule be clarified to provide that a plan's best effort would be sufficient, or allow for a phone number to be available to provide the information.

Response: We acknowledge that this information is time sensitive; however, it is our belief that beneficiaries need this information to make an informed selection. Therefore, we encourage States and their contractors to highlight to potential enrollees and enrollees that it is important to verify through a phone call, or other means, that the information is still current. We also expect that States and their contractors will provide updates to provider directories within a reasonable time frame, although the exact time is left to the State to determine.

Required Information—General (Proposed § 438.10(e) through (f))

Comment: One commenter observed that some of the information required before and after enrollment is duplicative.

Response: We agree that the requirement to provide information on benefits, cost sharing, service area, and participating providers required for potential enrollees in § 438.10(e)(2)(ii) duplicates required information for enrollees in § 438.10(f)(6). However, we would note that for potential enrollees, States may provide summary information, with detailed information provided upon request. For enrollees, detailed information is necessary to understand the services for which they are covered and how to access them.

Comment: One commenter believes that all the required information for both potential enrollees and enrollees should be in writing, and should also be available to enrollees through a toll-free telephone number established by the State.

Response: While we expect that the required information will be provided in writing, we do not want to preclude other formats. We note that the ''mechanism'' for assisting enrollee understanding that we are requiring in response to comments on proposed § 438.10(b) will provide another source of information, though as noted above, we believe States and plans are in the best position to determine the most effective mechanism to be used.

Comment: Numerous commenters believed that a core patient protection is access to information on the quality of health plan and providers. This conforms with the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry. The commenters recommended requiring MCOs and PIHPs to provide to potential enrollees and enrollees, upon request, (1) information on licensure, certification and accreditation status of MCOs and health care facilities; (2) information on education, licensure, Board certification and recertification; (3) a description of cost-control procedures; (4) summary descriptions of methods of compensation for physicians; and (5) information on the financial condition of the plan, including the most recent audit.

Response: We believe the provision in § 438.10(g)(4), which requires MCOs and PIHPs to provide certain information upon request to enrollees, including information on the structure and operation of the plan, is sufficient to cover the bulk of the information the commenters specifically mentioned. As a result, we are not revising the regulations text to add additional references.

Notice of Disenrollment (Proposed § 438.10(f)(1))

Comment: One commenter suggested modifying the requirement for annual disenrollment notice to not apply when there is no lock-in, while several other commenters supported the requirement for States to notify enrollees of their disenrollment rights at least annually, and at least 60 days prior to each open enrollment period.

Response: We agree that the proposed rule as written would be awkward for a program with no lock-in provision. However, we believe it important for enrollees to be notified annually of their disenrollment rights under § 438.56, even in a program with no lock-in, and therefore are not eliminating this provision.

Traditionally, States with no lock-in program could still delay the effective date of disenrollment to the beginning of the subsequent month, leading to a de facto lock-in of 1 month. Section 1932(a)(4) of the Act did not eliminate this scenario, but did permit States to lock-in enrollees for up to a year. The Act also provides that if there is a lock-in, enrollees can disenroll without cause for the first 90 days of enrollment in an MCO, which assumes that a lock-in period will be at least 90 days long. Finally, the statute provides that if States have a lock-in, they must notify enrollees at least 60 days prior to each annual enrollment opportunity of the right to disenroll. We are revising the regulation to clarify that the 60-day timeframe for notifying enrollees of the right to disenroll applies solely to programs with lock-ins of 90 days or greater.

Annual Notice (Proposed § 438.10(f)(2) and § 438.10(g))

Comment: Numerous commenters objected to the fact that the annual notice requirement in § 438.10(f)(2) need only notify enrollees of the availability of required enrollee information (that is, that they may receive it upon request) rather than requiring that the information be furnished to all enrollees. Many commenters believed that the result would be that many enrollees would not receive information for many years, and would be unaware of their rights, because they did not bother to specifically ask for the information. Some commenters found this especially problematic in light of the fact that some services may not be provided because of the conscience clause. One commenter

noted that an annual mailing of a full set of information typically is sent to enrollees in private health plans, and believed that Medicaid enrollees deserve no less. Another commenter argued that by actually furnishing all required information yearly, rather than only upon request, enrollees are ensured timely information about their rights, as well as a complete compilation of the previous year's changes or amendments to services provided. Finally, a commenter expressed the view that the information in question is critical for enrollees deciding to remain with a particular plan or switch during an open enrollment season.

On a related issue, numerous commenters supported the MCO and PIHP-specific provisions in § 438.10(g), but recommended the annual notice in § 438.10(f)(2) be amended to require the information be provided in full on an annual basis.

Response: We appreciate the arguments for ensuring enrollees have up-to-date information on the managed care plans with which they are enrolled. However, we believe the proposed rule achieves a balance. The rule ensures enrollees receive detailed information upon enrollment. In § 438.10(f)(4), we require plans to give each enrollee written notice of significant changes at least 30 days prior to the effective date of the change. To ensure that they are updated on all required information, we are adding a requirement at § 438.10(f)(2) and (f)(3) that enrollees be updated on changes to required information in § 438.10(g), regarding MCO- or PIHP-specific information.

Timing of Information to Enrollees (Proposed § 438.10(f)(3) Through (f)(5))

Comment: One commenter expressed concern about the requirement that plans send specified information to enrollees within a reasonable time after plans receive notice of enrollment. The commenter noted that in some cases, notice of enrollment precedes the effective date by a wide enough margin that it will be confusing to send the information that early. The commenter suggested revising the language in the proposed rule to read ''a reasonable time after the MCO received the notice of the recipient's enrollment or the effective date of enrollment, whichever is later.''

Response: The regulation requires that the information be provided within a ''reasonable time after it receives, from the State or the enrollment broker, notice of the recipient's enrollment.'' We believe that the State is in the best position to define this specific time requirement (*i.e.,* what is ''reasonable'') for providing this information.

Comment: One commenter noted that the requirement in § 438.10(f)(4) for 30 days written notice of any significant change, as defined by the State, is not always possible to comply with, since States do not always have 30 days notice of such changes. However, numerous other commenters supported the provision to require plans to give 30 days prior notice of significant changes.

Response: While we understand that there may be instances in which plans receive less than 30 days notice of a change, we believe this would be the rare exception, and that a general rule for 30 days notice would generally be possible to meet. We believe that where it is possible, this timeframe should be satisfied, since we believe that it is needed in order to give enrollees adequate notice of significant changes that could affect their care. As a result, we are not changing this provision.

Comment: One commenter was concerned that the provision in § 438.10(f)(5) requiring 15 days notice to enrollees of their provider's termination from the plan's network was not enough to ensure continuity of care. The commenter recommended requiring 60 days notice, with prior approval by the State. The commenter further suggested that if 60 days notice is not given, the plan should pay for enrollee care from the terminating provider for 60 days or until the enrollee transfers to another plan.

Response: We recognize a more stringent threshold would likely further promote continuity of care, and we believe the proposed rule provides States with the discretion to do so. However, we also recognize the reality that providers often give little notice of their plans to terminate participation in a network. We believe the proposed rule provides a realistic threshold that protects enrollees' interests.

Required Information for All Enrollees (Proposed § 438.10(f)(6))

Paragraph (f)(6) sets forth information that must be provided to all enrollees.

Comment: One commenter found that the requirement in § 438.10(f)(6)(i), to provide the names and other information for hospital and specialists, would be impractical for a PCCM program, since all Medicaid-participating providers are eligible. The commenter observed that specialists also move, change offices, etc., making maintenance of such a list impractical. In addition, the commenter noted that identifying all participating PCCMs for enrollees does not seem necessary or reasonable.

Response: We agree with the commenter, and in response to this comment are conforming the language in § 438.10(f)(6)(i) to the language in § 438.10(e)(2)(ii)(D), which clarifies that information on specialists and hospitals is only required for MCOs, PIHPs, and PAHPs. We are also clarifying the State need only identify participating PCCMs in an enrollee's service area.

Comment: Numerous commenters supported the statement in the preamble to the proposed rule that information provided must (1) clearly indicate which providers are available under any subnetworks with which a plan contracts, and (2) explain the procedures under which an enrollee may request a referral to an affiliated provider not in the subnetwork. These commenters believed that compliance with this requirement was especially important for women who may be obtaining services from a subnetwork that limits access to reproductive health services. The commenters recommended including an explicit requirement in the regulation text, specifically in § 438.10(f)(6)(ii).

Response: While we do not believe it would be appropriate to dictate permissible contracting entities for plans, we do require under § 438.10(e)(2)(iii) that if there are restrictions within a network, the beneficiary be informed of these restrictions as part of the information that they receive.

Comment: Numerous commenters noted that the preamble to the proposed rule specifically discussed the provision of information on pharmaceuticals, mental health and substance abuse benefits. H.R. 2564, as passed by the House, and supported by the President, specifically requires disclosure of prescription drug benefits. If the intent is for plans to disclose this information, the commenters believed that § 438.10(f)(6)(v) should explicitly list them.

Response: We believe that the language in § 438.10(f)(6)(v) already ensures full disclosure of information on all benefits, including prescription drug coverage and mental health benefits. It requires information on the ''amount, duration, and scope of benefits available under the contract in sufficient detail to ensure that enrollees understand the benefits to which they are entitled.'' Since this applies to all contracted benefits, it is unnecessary to single out specific benefits in the regulation text.

Comment: Numerous commenters noted that proposed § 438.62 would require States to ensure continued services to beneficiaries who are transitioning, out of an MCO, PIHP, PAHP, or PCCM, but did not require

that enrollees be provided with information on how to obtain benefits during such a transition. The commenters recommended adding this as required information for enrollees.

Response: The proposed rule requires the State agency to actively arrange for continued services to beneficiaries transitioning in and out of a managed care system. We believe States should be given discretion as to how they fulfill that responsibility.

Comment: Several commenters supported the requirement in § 438.10(f)(6)(vii) to specify the ability to access family planning providers out of network. They recommended clarifying that this requirement applies to all plans, not just those with conscience clauses.

Response: We believe that it is clear that the language in the proposed rule applies to all managed care programs (unless this obligation were ever waived under a section 1115 demonstration), and are not making further revisions.

Comment: With respect to § 438.10(f)(viii)(C), one commenter noted that in some frontier and rural States, 911 is not yet operational throughout the State. The commenter stated that printing and updating materials specific to the system in each locale would increase costs and burden. The commenter observed that this would also lead to another situation in which managed care requirements would be greater than those in fee-for-service.

Response: The requirement for providing information on how to use the 911 service is limited, implicitly, to areas where this service exists to use. For areas that have not yet implemented a 911 system, it would be acceptable for the State to generally instruct the enrollee to call their local emergency number without specifying the actual phone number. We believe that it is important, however, to include information on using 911 wherever this service is available.

Comment: One commenter asked why the requirements in § 438.10(f)(6)(viii)(D) through (f)(6)(viii)(E) concerning the provision of information on emergency services applied to PCCM programs. The commenter believed that in PCCM programs, there were no additional restrictions on which emergency settings PCCM enrollees can use. The commenter believed there was no difference between PCCMs and regular FFS Medicaid on this point.

Response: While enrollees must be able to access emergency care at any hospital setting, MCOs, PIHPs, and PAHPs also often contract with specific hospitals for these services; in those instances, these contracted providers need to be identified. We acknowledge that the only contracted providers in PCCM programs are PCPs. For PCCM programs, it will be sufficient for the State to direct enrollees to the nearest emergency room.

Comment: Numerous commenters supported the requirement in § 438.10(f)(6)(viii) through (f)(6)(ix) that MCOs and PIHPs make certain information available to enrollees regarding how emergency services are covered, and the process for accessing these services. Some of the commenters, however, suggested that plans also be required to send required enrollee information on emergency care to affected providers and hospitals.

Response: Since an enrollee must be able to access emergency services at any hospital setting, it would be virtually impossible for plans to send the information to all such providers. For hospitals and providers with which plans contract to provide emergency services, § 438.230(b)(2)(ii) requires that a subcontract ''[s]pecifies the activities * * * delegated to the subcontractor,'' so this would ensure that at least these providers would be aware of procedures regarding emergency services.

Comment: Numerous commenters believed there was a gap in proposed § 438.10(f)(xii) with respect to how enrollees would be informed of where and how to obtain counseling or referral services that plans do not provide on the grounds of moral or religious objection. As written, these commenters asserted that the proposed rule does not require plans to provide information, nor refer enrollees to a source of information concerning these services. They acknowledged that States are required to provide this information, but did not feel that it should be up to the enrollee to figure this out. Some commenters argued that requiring enrollees to go to two places to obtain information about how and where to access family planning services is confusing, constitutes a barrier to care, and could delay care unnecessarily. These commenters believed this would permit discrimination against women, ignoring their health care needs. Another commenter noted that remedying this problem would reduce State burden in complying with the requirements. A few commenters felt that as written, the proposed rule would permit plans to create ''gag rules'' against physicians and other health providers, who can be barred from even discussing how to find information about certain services. Finally, some commenters believed that this provision violated section 1932(b)(3)(B)(ii) of the Act, which requires plans to inform enrollees about services not covered because of moral or religious objections.

Several commenters recommended that plans be required to refer enrollees to where they can obtain the information addressed in section 438.10(f)(xii). Some commenters suggested that plans specifically provide referral to toll-free line—which States should be responsible for maintaining—that tells beneficiaries how and where to access services the health plan does not provide. A few also suggested that such a toll-free line be used to inform enrollees about the extent to which they can access out of network providers, including family planning (per § 438.10(f)(6)(vii)), and services available under the State plan but not under the contract (per § 438.10(f)(6)(xii)). Other commenters suggested that plans be required to inform beneficiaries of all State plan services not available in the plan but otherwise available in Medicaid, and that this information be provided at point of service and annually.

Response: We believe it would be inappropriate, and inconsistent with the intent of the conscience clause provision, to require a health plan that morally objects to a service to provide information on how and where to access the service. This is why we provided in the regulations that the State should be responsible for doing so. We believe the proposed rule was clear, in stating that information must be ''furnished'' by the State, that the State had the responsibility of providing beneficiaries with this information, not merely making it available to them. It appears, however, that at least some commenters have inferred some lesser level of State responsibility from the fact that the word ''furnish'' was used instead of ''provide,'' which is used elsewhere in the regulation text. While we believe these words to be interchangeable, the commenter seems to believe that furnish, as used here, means only that the materials must be furnished upon request (that is, ''made available''). In order to avoid any such inferences, and to make it clear that States are required actually to provide this information to enrollees, we are revising the text of § 438.10(e)(2)(ii)(E) and § 438.10(f)(6)(xii) to use the word ''provide'' instead of ''furnish'' in describing the State's responsibility. We are also revising § 438.102(d) to clarify the State is responsible for providing the required information not only for potential enrollees, but for enrollees as well. We believe States should be given

discretion as to how they fulfill that responsibility.

MCO/PIHP Specific Information (Proposed § 438.10(g))

Comment: One commenter urged that it be made clear how grievances and appeals work, not only within the health plans, but within State government as well.

Response: Section 438.10(g)(1)(i) requires that plans provide information on the State fair hearing process, as well as their own grievance procedures.

Comment: One commenter recommended that the required information for MCOs and PIHPs should also apply to PAHPs.

Response: The information requirements in § 438.10(g) of the proposed rule reflect requirements elsewhere in the regulation that apply only to MCOs and PIHPs. However, in response to a comment on § 438.2 and 438.8, two additional provisions on which information is required in § 438.10(g) are being imposed on PAHPs. First, under § 438.8(b)(1)(ii), the advance directives requirement in § 438.6(i)(2) now applies to the extent that the PAHP includes any of the providers listed in § 489.102(a). Second, PAHP enrollees are entitled to an affirmation of their right to a State Fair Hearing. In response to this comment, and as noted above, we are adding a new paragraph (h) for PAHP-specific requirements (with proposed paragraph (h) renamed paragraph (i)), and including a reference to it in appropriate parts of § 438.10(f). Finally, § 438.6(h) and 438.8(b) of the proposed rule already extended the Physician Incentive Plan requirements of 434.70 to PAHPs. We are adding in the new paragraph (h) of § 438.10, that this information be provided upon request.

Comment: One commenter was unclear as to why the information on provider appeal rights required by proposed § 438.10(g)(1)(vii) was critical for enrollees. In the commenter's view, enrollees already feel that the amount of information they currently receive is too much, or borders on it. The commenter suggested requiring plans to send notices of provider appeal rights to network providers rather than enrollees.

Response: The requirement in § 438.10(g)(1)(vii) simply reflects the statutory requirement in section 1932(a)(5)(B)(iii) of the Act that information on ''procedures available to * * * a health care provider to challenge or appeal the failure of the organization to cover a service.'' This should not be interpreted as creating a new right in Medicaid for providers to file an appeal. However, should the State, MCO, or PIHP provide for such a right, they must inform enrollees of its availability.

Comment: A few commenters noted that under the grievance and appeals rules in proposed subpart F of part 438, enrollees have the right to representation. These commenters were believed that grievances and appeals are complicated proceedings involving difficult to understand rules, and that enrollees should be made aware they have the option to obtain assistance. In addition, the commenters believed that enrollees should be protected against retaliation for filing an appeal or grievance, and provided with information on this right as well, so they will not forgo appeals out of fear of retaliation. The commenters recommended requiring health plans to inform enrollees they have a right to representation, and that they will not suffer from retaliation for filing an appeal or grievance.

Response: We agree that enrollees need to understand the grievance system for it to be effective. However, we note the proposed rule at § 438.10(g)(1)(iv) already stipulates that enrollees must be informed of the ''availability of assistance in the filing process.'' We believe this is sufficient to ensure enrollees understand the ability to obtain assistance, and are not adding the suggested clarification. We also disagree with the commenter that it is necessary to include an explicit statement that the beneficiary will not face retaliation for appealing. We do not believe that beneficiaries would assume that they would face retaliation in such a case.

Comment: A few commenters questioned the provision of complex information such the information on physician incentive plans provided under proposed § 438.10(g)(3)(B). These commenters believed that many enrollees would not want such information, and may have difficulty understanding it, making its automatic provision counterproductive. The commenters recommended making it available upon request.

Response: We agree that requiring the provision of detailed information on physician incentive plans may be counterproductive. We are revising the regulation to provide at § 438.10(g)(3)(B) to require MCOs and PIHPs to inform enrollees it is available upon request.

Comment: A few commenters objected to the lack of a requirement for plans to notify enrollees of their ability to obtain, upon request, information on requirements for accessing services, including factors such as physical accessibility. These commenters believed that if plans did not furnish this information, the enrollee would have to contact numerous providers to obtain such information. In an emergency, the commenters were concerned that this could delay lifesaving care. One commenter referenced the need for TTY's service. Commenters also specifically noted that the 14th recommendation in CMS' Report to Congress on Special Needs addressed ensuring that plans and providers are physically accessible to those they will serve. Other commenters asserted that this was a requirement of the Americans with Disabilities Act. The commenters urged that plans be required to notify enrollees that this information is available upon request, and that this also be included in the annual notice.

Response: We believe that the overall requirements of this section, in particular the new requirement for a mechanism to assist beneficiaries understand the managed care program and their own plans requirements and benefits, will fulfill the needs identified by the commenters. Further, § 438.6(f) specifically requires MCOs, PIHPs, PAHPs and PCCMs to comply with the provisions of the Americans with Disabilities Act and other anti-discrimination statutes. We do not believe any additional changes to the regulations text are necessary.

Comparative Information Under the State Plan Option (Proposed § 438.10(h)—Current § 438.10(i))

Comment: One commenter noted that there is a common understanding that quality and performance indicators are still evolving. This commenter believed that the reliability of such indicators for comparing plans varies for reasons such as difficulty in adjusting for factors not within the plan's control; reporting inconsistencies; or lack of statistical validity due to small plan size. The commenter recommended requiring States to address these issues as they determine which measures to include, and how the information is presented, explained, and qualified. In addition, the commenter recommended that the final rule advise States whether there are circumstances in which reporting data that is not statistically valid would be misleading.

A few commenters urged that MCO information be consistent with HEDIS standards, and be based on the MCO's overall performance. Another commenter suggested giving States the latitude to develop and apply regional standards for comparative information. Finally, a commenter contended that disenrollment rates are not valid

indicators when auto-assignment is used.

Response: We believe that States are aware of the evolving nature of quality indicators. The proposed rule includes the statutory discretion in section 1932(a)(5)(c)(iii) to provide quality indicators ''to the extent available.'' We believe States are in the best position to determine which quality indicators to use, and that there is no impediment to regional standards for comparative information. With respect to disenrollment rates, we agree that there are valid concerns with respect to their use in a situation with auto-assignment. We note that disenrollment rates were not included in Medicaid HEDIS because of methodological problems, including the fact that most were related to loss of Medicaid eligibility. As a result, in response to this comment, we are revising the regulation at § 438.10(i)(3)(iv) to delete the reference to disenrollment rates.

Comment: One commenter believed that the type, scope, nature, and format of the comparative information that must be furnished in the case of the State plan option would be extremely costly. Another commenter argued that charting this information for individual PCCM providers would unduly complicate comparisons for enrollees, and be confusing for many service areas. This commenter believed that collection and maintenance would be cumbersome and costly to the State. The commenter suggested deleting this requirement for PCCMs.

Response: We recognize these requirements will result in some additional costs, but do not believe compliance will be as onerous as the commenter believes. The information on benefits, cost-sharing, and service area are already available to the State. We do not have any flexibility on the requirement that information be presented in a comparative chart-like format, since this is specifically required by section 1932(a)(5)(C) of the Act. We also do not have flexibility on the applicability of this requirement to PCCMs under section 1932(a)(1) authority, as this is also required under section 1932(A)(5). (Section 1932(a)(5) requires the provision of information on ''managed care entities,'' which includes MCOs and PCCMs.)

There is flexibility for States to provide certain information that is identical across plans or PCCMs only once. For example, the State may provide a list of services provided or coordinated by all entities, and only identify and compare variations such as additional services provided, or services not provided because of the entity's religious or moral objections. The quality indicators are only required ''to the extent available.''

We are, however, clarifying that the State need only provide comparative information on MCOs and PCCMs on a service area basis, to ensure that enrollees do not receive information on entities with which they cannot enroll.

Comment: One commenter believed that it did not make sense to require the comparative information to be provided to potential enrollees at least once a year. The commenter assumed this was an error. The commenter suggested making this information available to enrollees and potential enrollees, rather than furnishing it. The commenter further suggested that States be required to provide the information prior to enrollment or anytime upon request.

Response: The commenter is correct that we made an error. The error, however, was not the fact that the information be provided, rather than merely being made available upon request. Rather, the error was in omitting a reference to enrollees in what is now § 438.10(i)(3). Section 1932(a)(5)(C) provides that ''A State that requires individuals to enroll with managed care entities under paragraph (1)(A) shall *annually* (and upon request) *provide,* directly or through the managed care entity, to such individuals * * *.'' The statute thus requires that information be provided to all potential enrollees *and* enrollees, and contrary to the commenter's suggestion that information only be made available upon request, it requires that this information be ''provid[ed]'' annually. Thus, in this respect, the regulation is not in error. We are making the needed correction to conform § 438.10(i)(3) in this final rule with the statute. Specifically, we are clarifying that the information needs to be provided to potential enrollees in the timeframe required in § 438.10(e)(1) (since enrollment is mandated for potential enrollees under section 1932(a)(1), these individuals would be enrollees when the obligation to provide information after one year occurs), and that enrollees should receive it annually and upon request. Further, we are acknowledging in § 438.10(i) that the comparative information required in this paragraph may duplicate what is required in § 438.10(e) for potential enrollees and § 438.10(f)(6) for enrollees.

Comment: A few commenters supported the idea that access to comparative information on health plans is essential to allow Medicaid beneficiaries to make informed choices. The commenters believed that exempting PIHPs and PAHPs from this requirement would undermine true competition among plans. The commenters recommended including PIHPs and PAHPs.

Response: The requirements in § 438.10(i) (proposed § 438.10(h) apply only to managed care programs operated under State plan amendment, as authorized by Section 1932(a)(1) of the BBA. States may only use this authority for mandatory MCO and PCCM programs; mandatory PIHP and PAHP programs cannot be operated under this authority. Thus, § 438.10(i) applies, PIHPs and PAHPs that are not also PCCMs (if they wee, they would be included as such) would not be among the plans from which beneficiaries could choose. As a result, we are not extending the requirement for comparative information to PIHPs and PAHPs as the commenter suggests.

Technical Corrections

Comment: Some commenters noted areas where technical corrections are needed. In the introductory paragraph of § 438.10(g), the reference should be to ''438.10(f)'' instead of ''§ 438.10(e).'' In § 438.10(h)(1), they noted the correct reference was ''(h)(3),'' not ''(g)(3).'' In § 438.10(h)(3), they recommended changing ''paragraph (d)'' to ''paragraph (e),'' and changing ''paragraph (g)(2)'' to ''paragraph (h)(2).''

Response: We appreciate the commenters pointing out the errors, and are making the recommended corrections. In addition, we are correcting a drafting error in § 438.10(a), in the definition of ''potential enrollee.'' Specifically, we are deleting the words ''in a'' in the phrase ''* * * not yet an enrollee of a specific in a MCO * * *''

6. Provider Discrimination (Proposed § 438.12)

Proposed 438.12 would implement the prohibition on provider discrimination in section 1932(b)(7) of the Act. The intent of these requirements is to ensure that an MCO does not discriminate against providers, with respect to participation, reimbursement, or indemnification, solely on the basis of their licensure or certification. We extended this requirement to PIHPs and PAHPs in proposed § 438.12. These requirements do not prohibit an MCO, PIHP or PAHP from including providers only to the extent necessary to meet their needs. Further, the requirements do not preclude an MCO, PIHP or PAHP from establishing different payment rates for different specialties, and do not preclude an MCO, PIHP or PAHP from establishing measures designed to maintain the quality of services and

control costs, consistent with its responsibilities.

Comment: One commenter agreed that health plans should be prohibited from excluding providers from their networks for reasons that are inconsistent with public policy, such as discrimination against providers serving a high need population or retaliation against providers who advocate on behalf of their patients. However, the commenter stated that the vast majority of health plans' decisions are wholly unrelated to these concerns. The commenter noted that the issuance of a written notice is unlikely to prevent the few cases of improper conduct. The commenter believed that the written notice provision would impose an unnecessary administrative burden and cost on health plans without substantially protecting providers, and therefore should be eliminated.

Response: We continue to believe that such notice is important to help enforce the anti-discrimination requirements in section 1932(b)(7) of the Act and § 438.12. The notice will provide reasons why providers were not included in the MCO's, PIHP's, or PAHP's network and may be used by States in its monitoring efforts. Further, we estimate that it will take one hour to draft and furnish any given notice and on average each MCO, PIHP, and PAHP will only need to produce 10 notices per year.

Comment: One commenter strongly disagreed with this provision, as the commenter believed it was intervening with the ability of the MCO to contract and develop networks without undue restraint. The commenter specified that in a managed care business model, selection of networks is made on the basis of quality and market need and that States should be given the latitude to address these issues as part of their network analysis. The commenter also argued that this provision would handicap MCOs in requiring all providers be credentialed.

Response: We disagree with the commenter. Section 438.12, implementing section 1932(b)(7) of the Act, provides sufficient latitude for MCOs, PIHPs and PAHPs with respect to network selection. This provision does not require MCOs, PIHPs and PAHPs to contract with providers beyond the number necessary to meet the needs of its enrollees. Further, this provision does not preclude these entities from establishing measures for provider selection that are designed to maintain quality of services and control costs and are consistent with its responsibilities to enrollees. Finally, this provision does not require entities to contract with any willing provider. We also would not have the discretion to eliminate this provision even if we agreed with the commenter, as it is set forth in the statute.

Comment: One commenter urged CMS to clarify in this section that Medicaid managed care entities may not prohibit or limit fully licensed physicians, such as psychiatrists from providing services within their scope of practice.

Response: The requirements in § 438.12 are intended to ensure that an MCO, PIHP or PAHP does not discriminate against providers with respect to participation, reimbursement or indemnification solely on the basis of their licensure or certification. We do not believe it is appropriate to include the suggested statement, as this requirement does not pertain to scope of practice. Section 438.214 addresses provider selection and credentialing requirements.

B. State Responsibilities (Subpart B)

Proposed subpart B set forth the State option to implement mandatory managed care through a State plan amendment, as well as other State responsibilities in connection with managed care, such as beneficiary choice, provisions for disenrollment, continuity of care, conflict of interest standards, limits on payment, and monitoring.

1. State Plan Requirements (Proposed § 438.50)

Proposed § 438.50 permits State agencies to enroll most Medicaid beneficiaries in MCOs or PCCMs on a mandatory basis without a waiver under sections 1915(b) or 1115 of the Act, and without being out of compliance with the provisions in section 1902 of the Act for Statewideness, comparability, or freedom of choice. Paragraphs (b) and (c) set forth the requirements for these programs and the assurances that States must provide. Paragraphs (d) and (e) identified populations that cannot be mandatorily enrolled in an MCO or PCCM and address the requirements for a default enrollment mechanism.

Comment: Two commenters viewed proposed § 438.50(b)(2) as a first step in better understanding how managed care organizations pay physicians and recognize that payment to providers in managed care is controlled by the managed care organizations. The commenters recommended that CMS also require managed care plans to specify the manner in which increases in Medicaid payment for services will be passed through to intended physicians.

Response: Section 438.50(b)(2) is a general requirement that a State plan amendment under this authority specify the payment arrangement between the State and its managed care contractor. This section does not require the submission of any information regarding payment mechanisms or amounts between MCOs and their subcontracting providers. CMS does not review these subcontracts. We do not believe that it is necessary to impose these requirements beyond requiring that payments to providers be sufficient to encourage sufficient provider participation.

Comment: Several commenters supported the provisions for public involvement in the design and implementation of the State plan amendment and on-going public participation after implementation of the State plan amendment as proposed in § 438(b)(4). One commenter opposed the requirements for public involvement citing that this requirement is not applied to any other State plan amendment and requires additional State resources. The commenter suggested that latitude be given to States with history of public appearance.

Response: While not all State plan amendments require public involvement, this language is consistent with the public notice requirements of the State Children's Health Insurance Program and reflects the requirements under the section 1115 of the Act demonstration authority.

Comment: Several commenters suggested adding PIHPs and PAHPs, as well as MCOs and PCCMs, to the introductory clause in § 438.50(d), which describes populations that cannot be mandatorily enrolled in an MCO or PCCM under the authority in section 1932(a) of the Act and § 438.50(a).

Response: Section 1932(a)(1) prohibits States from mandatorily enrolling specified groups of beneficiaries in MCOs and PCCMs under the authority in that section, which is implemented in § 438.50. This section of the statute and regulations only permit States to enroll beneficiaries in MCOs and PCCMs, even if the beneficiaries are not in an exempted group. Since this provision is an exception to authority that only permits enrollments in MCOs or PCCMs, it is not appropriate to reference PIHPs or PAHPs in this provision. Unless the PAHP also qualifies as a PCCM, and thus, would already be covered by this latter term, enrollment in a PIHP or PAHP may only be mandated under waiver authority in sections 1915(b) or 1115(a) of the Act.

Comment: We received several comments on the enrollment by default

in proposed § 438.50(f) with one commenter applauding CMS' effort to maintain existing relations that recipients may have with providers. Another commenter recommended that CMS delete the specific requirements to take relationships with existing providers into account. Two commenters believe that the default enrollment process discourages health plans and providers who have not traditionally served Medicaid beneficiaries. Another commenter inquired as to how the default enrollment process should function if the individual's provider is part of more than one MCO network. One commenter recommended that the default enrollment process consider geographic location, family relations and special needs of the individual.

Response: Section 1932(a)(4)(D) of the Act clearly states that the default mechanism must consider existing relationships or ''relationships with providers that have traditionally served beneficiaries under this title.'' We believe that the States should have the flexibility to consider other factors in the design of a default enrollment process that best meets the needs of the individual, including factors suggested by the commenter. Therefore, we have not added any new requirements to § 438.50(f).

Comment: A few commenters requested clarification of the phrase in proposed § 438.50(f)(2), ''must distribute the recipients equitably.'' One commenter recommended that the regulation be restated to explicitly grant States the right to determine what is an equitable distribution.

Response: This provision requires States to have a process whereby they can assign beneficiaries to MCOs or PCCMs, if the beneficiary does not exercise his or her right to choose. When the State is unable to make an assignment based on an existing provider-recipient relationship or a relationship with a provider that has traditionally serviced the Medicaid population, it must do so by distributing ''the recipients equitably among qualified MCOs and PCCMs available to enroll them.'' The State is the only party that can determine when it is unable to make an assignment based on its records of an existing relationship or traditional service to the Medicaid population. Further, we agree with the commenter that the State is best suited to determine how to make an equitable distribution of default-assigned beneficiaries. This may be done through a specific assignment algorithm or as a simple distribution among all qualified providers up to any limits established. We have added language to the text of § 438.50(f)(2) to clarify this.

Comment: To help ensure the best quality of care, one commenter recommended that the proposed requirement for ''existing provider-recipient relations'' in § 438.50(f)(3) be based on the provider being the main source of Medicaid services for the recipient in the last 2 years.

Response: We believe that a 1-year period allowed in § 438.50(f)(3) is sufficiently long to identify an existing provider-recipient relationship. This provision only applies to the default assignment of individuals who did not take the opportunity to choose their MCO or PCCM, and we would assume that most individuals would make this selection if their relationship with a particular provider is important to them.

Comment: One commenter expressed concerns that these provisions in § 438.50 do not directly address the importance of ensuring that families are able to choose among health plans and health care providers when enrolling in mandatory managed care plan. The commenter believes that the process of auto-assigning can cause problems with the assignment of different family members of the same family to numerous providers and the assignment of certain individuals to providers many miles away and recommended that States be required to make every effort to ensure that families make their own selections.

Response: Through a mandatory assignment under § 438.50(f), or any mandatory managed care arrangement under a waiver authority, it is possible that individuals in a family may be assigned to different providers. We do not believe that this should be prohibited, since the arrangement may be in the best interest of the individuals in the family based on their specific health care needs. If this assignment is problematic, all enrollees are free to disenroll without cause during the first 90 days of their enrollment period. Consequently, we do not believe any changes are warranted in this provision.

2. Choice of MCOs, PIHPs, PAHPs, and PCCMs (Proposed § 438.52)

Proposed § 438.52 implements the requirement in section 1932(a)(3) of the Act that States must permit an individual to choose from at least two MCOs or PCCMs, but would have permitted States to offer a single MCO in a rural area under certain conditions, and to offer a single HIO in certain counties.

Comment: Several commenters were concerned about the impact of these regulations on States with a single carve-out PIHP contract, such as a mental health carve-out in a non-rural area, because the requirement for choice in this section would appear to prohibit this type of program.

Response: Although we are extending the choice requirement in § 438.52 to PIHPs and PAHPs under the authority of this regulation, the Secretary will continue to have the discretionary authority to grant waivers for the operation of managed care programs contracting with single PIHPs or PAHPs on a case-by-case basis.

As under current provisions, these entities can operate under waivers of the freedom of choice requirement in section 1902(a)(23) of the Act, which permits a State to establish or continue a program. For the purposes of PIHPs and PAHPs, this waiver could extend to the requirement for choice in section 1932(a)(3) of the Act. All requirements that apply to PIHPs and PAHPs, including the choice requirement, are based only upon the regulatory authority for the existence of these entities, which is derived from section 1902(a)(4) of the Act, which can be waived under section 1915(b). The waiver would not be possible for MCOs or PCCMs since this section of the Act cannot be waived under section 1915(b).

Therefore, under these rules, as before, CMS can grant States a waiver to operate a program with a single PIHP or PAHP, in a rural or non-rural area.

Comment: One commenter pointed out that a State could not restrict enrollment in one plan as a sanction in non-rural areas where only two plans exist, because the State would not be in compliance with this requirement for choice.

Response: The commenter is correct that a State cannot impose a sanction that would leave only one plan available in a non-rural area unless the State then offers fee-for-service as an alternative.

Comment: A few commenters suggested there should be no exception to allow a State to limit choice in rural areas. Another commenter felt that allowing a choice in a rural area of two primary care providers as opposed to two managed care systems, would limit choices that might in fact be otherwise available to an enrollee.

Response: The exception allowing a State agency to restrict choice of coverage to a single MCO or PCCM system in rural areas is specified in section 1932(a)(3)(B) of the Act and cannot be revoked by this regulation. Even without the rural exception to the choice requirement permitted by section 1932(a)(3)(B), a State may limit a beneficiary's freedom of choice of providers in a rural or any other area

through a waiver under section 1115 or 1915(b) of the Act, or a State plan amendment under section 1932(a)(1) of the Act. Both these waivers and the exception permitted under this rule may have the impact of limiting beneficiary choices, which would otherwise be available, as suggested by the commenter. However, the limitation in this rule is specifically authorized by section 1932(a)(3) of the Act.

We have specified conditions that must be met in order for this exception to be implemented. These include the requirement in § 438.52(b)(2) that a beneficiary in a rural area who has been receiving services from a provider that is not part of the managed care network can receive out-of-plan treatment from that provider on a limited basis, as specified in that paragraph. Thus, we believe that the statute and this final rule contain sufficient beneficiary protections when the choice of managed care entity is restricted in rural areas.

Comment: One commenter was concerned that rural area PIHPs and PAHPs that do not include primary care services would not qualify for a rural exception because of the requirement to permit beneficiaries to choose from at least two physicians or case managers.

Response: If either of these entities operating in a rural area do not include primary care services, then the requirement would not apply to them. These primary care services would be available through another source.

Comment: One commenter was concerned about what the commenter saw as a contradiction in the preamble in the statement that, allowing beneficiaries in a single rural plan to choose another primary care provider in the network would make it unnecessary for a State agency to operate a parallel fee-for-service system for those individuals who disenroll for cause.

Response: The commenter is correct that this statement is misleading, and a State may not always be able to be relieved from operating a fee-for-service system in this situation. The State may be obligated to cover out-of-network services on a FFS basis in the situations described in § 438.52(2)(b)(ii)(A) through (b)(ii)(D). Further, enrollees in a program operated under the rural exception to the choice requirement, have the right to disenroll from their primary care providers, but not necessarily from the single entity providing health care in the rural area (except for instances when the enrollee moves out of the entity's service area). When the enrollee no longer resides in the rural area served by the single entity, he or she may be required to re-enroll in a managed care entity serving his or her new area of residence.

However, the commenter is correct that there may always be individual instances when States must maintain the ability to make FFS payments to providers even if an entire parallel FFS system is no longer necessary.

Comment: There were several commenters who appreciated requiring MCOs to solicit enrollment of providers who are the source of service to a new enrollee, and to transition the enrollee within 60 days to other providers in the MCO network if the provider chooses not to participate. These commenters were concerned that rural area enrollees would otherwise remain out-of-network indefinitely. One commenter suggested a transition period shorter than 60 days and a few suggested a longer period. Many commenters felt that it was not appropriate to require a rural provider to join an MCO in order to continue to serve a patient with whom there was a prior relationship, particularly for pregnant women. They indicated belief that rural providers would choose not to enroll and, therefore, enrollees' choices would be severely restricted. Some commenters questioned if this section meets the requirement of section 1396u–2(a)(3)(B)(ii) U.S.C. to allow for consideration of when using an out-of-plan provider is ''appropriate.'' Some commenters opposed requiring MCOs to offer contracts to ''any willing provider'' because it would prevent MCOs from building networks that are the correct composition for their enrollees and would undermine the financial viability of MCO networks.

Response: We believe that in establishing the ''appropriate circumstances'' for allowing an enrollee to go out of network when there is a rural exception to choice, we need to balance the needs of enrollees with supporting good managed care practices. By requiring an MCO to offer a contract to any qualified provider who is the main source of service to the recipient, we prohibit the MCO from barring the client's access to that provider. The 60-day period provides sufficient time to assure that a provider has the option to continue to serve an enrollee with whom they have an existing relationship. Allowing a recipient to continue indefinitely (that is, as long as an acute medical condition exists) to see a non-participating provider could encourage providers to not contract with MCOs and not continue their participation in the Medicaid program. We especially want to encourage, rather than discourage, the continued participation of providers who treat pregnant women, and we believe that this provision helps to accomplish that goal.

We disagree with the commenter that this provision requires MCOs to offer contracts to ''any willing provider.'' Section 438.52(b)(2)(ii)(B)(2) specifically recognizes that a provider ''may not meet the qualification requirements to join'' the managed care network. If this is the case, there is no requirement that the provider be offered a contract, and the beneficiary must be transitioned into the managed care network.

Comment: Two commenters were concerned that the definition of ''rural'' at § 438.52(b)(3) does not recognize that a Metropolitan Statistical Area may be largely rural although it has a large city, and due to the rural nature outside the city it would be appropriate for an exemption to the choice of two MCOs requirement. They suggested that the State should apply its own definition of ''rural'' subject to approval of CMS.

Response: We initially proposed three possible definitions of rural, and asked for comments. There was no clear consensus among the comments we received at that time, and CMS decided to use the single definition of rural based on being outside of an MSA. We believe that this definition best assures that States can use the exemption when appropriate but it reasonably limits the extent to which an area is considered rural, and is consistent with the Medicare definition for the purpose of defining rural hospitals.

3. Enrollment and Disenrollment (Proposed § 438.56)

Proposed § 438.56 implements the provision in section 1932(a)(4) of the Act, and sets forth a number of requirements relating to enrollment and disenrollment in Medicaid managed care programs.

Comment: One commenter questioned the authority to apply the provisions of this section to voluntary managed care programs.

Response: Section 1932(a)(4) of the Act contains new requirements that apply to the enrollment and disenrollment of beneficiaries in MCOs and PCCMs. In addition to applying directly to the mandatory programs under section 1932(a)(1)(A) of the Act, these requirements are incorporated under section 1903(m)(2)(A) of the Act for MCOs and section 1905(t) of the Act for PCCMs. In addition, through this regulation we are extending these provisions to PIHPs and PAHPs.

Comment: Several commenters were pleased that the proposed § 438.56(b) was consistent with the Medicare+Choice requirements restricting disenrollment by a plan. One

commenter was concerned that there was no guidance as to what would constitute acceptable grounds for disenrollment.

Response: We believe that § 438.56(b)(2) clearly identifies the reasons an MCO, PIHP, PAHP, or PCCM may *not* request disenrollment of a beneficiary. We have not provided other limits as long as beneficiaries are not disenrolled for these reasons. States may wish to establish specific instances in which entities may request disenrollment of a beneficiary in their contract provisions.

However, we note that § 438.56(b)(2) as set forth in the proposed rule omitted the word ''adverse,'' describing a change in an enrollee's health status, as contained in the prior section governing disenrollment by the plan in § 434.27(a)(2). We inadvertently omitted this term, and we have inserted ''adverse'' in the final rule to clarify that the prohibition on requests for disenrollment under this section applies only to adverse changes in health status, not where an enrollee's health status has improved.

Comment: Several commenters expressed concern that the ability to disenroll without cause during the 90 days following initial enrollment would disrupt continuity of care and was contrary to HEDIS reporting timeframes. Several other commenters were concerned that 90 days was not enough time and there should be more flexibility to change without cause.

Response: Under section 1932(a)(4)(A) of the Act, beneficiaries must be able to disenroll without cause from an MCO or PCCM within the first 90 days of initial enrollment. We have no authority to modify this requirement by this regulation, but we believe that represents a reasonable time period for enrollees to decide whether the managed care entity in which they are enrolled will best meet their needs.

Comment: One commenter suggested that all States with ongoing programs should be required to provide a right to disenroll without cause, immediately upon implementation of these regulations. The commenter also suggested that disenrollments for cause should be applied retroactively.

Response: Nearly every State (that is not operating under the authority of a section 1115 demonstration) has already implemented the BBA rules regarding enrollment and disenrollment in accordance with the guidance contained in the letter to all State Medicaid Directors letter dated January 21, 1998. As discussed elsewhere, provisions of this rule will become effective 60 days following publication of this final rule and must be implemented by 1 year from the effective date of this final rule.

We believe that an automatic disenrollment without cause for all of the over 25 million Medicaid managed care enrollees upon implementation of the regulation would create a chaotic situation disrupting current patterns of care, and is not justified by any evidence of problems in States' existing Medicaid managed care programs. We do not understand how the commenter envisions implementing retroactive disenrollments for cause, but we do not believe there is any justification for the suggested provision.

Comment: Many commenters suggested that homelessness or being a migrant worker should be added as a cause for disenrollment at any time.

Response: We do not believe it is necessary to add these conditions as a cause for disenrollment. A beneficiary in one of these circumstances, like all other Medicaid enrollees, is entitled to disenroll, without cause for the first 90 days of enrollment in an MCO, PIHP, PAHP, or PCCM. Further, he or she may still disenroll for cause after that date, if one of the conditions in § 438.56(d)(2) listed is met. Section 438.56(d)(2)(i) specifies that an enrollee's movement out of an MCO, PIHP, PAHP, or PCCM service area is one of the required examples of cause for disenrollment. We believe that this option will often be available to migrant workers. In addition, a State may include additional reasons, such as homelessness as a cause for disenrollment under § 438.56(d)(2)(iv).

Comment: One commenter was supportive of the reasons allowed for disenrollment with cause. Another commenter was concerned that the broad definition of cause for other reasons at §§ 438.56(d)(2)(iv) was too broad and could lead to disenrollment on demand, particularly if MCOs may approve disenrollment through the grievance process.

Response: CMS has specified three specific circumstances where cause for disenrollment exists and permitted States to develop other reasons, including but limited to, the examples in § 438.56(d)(iv). It is not our intent in this provision to permit disenrollment on demand. States will make determinations on request for disenrollment based on these requirements and any others they select, and beyond these limited requirements, have the flexibility to implement this provision as best serves their beneficiaries and the Medicaid program.

Comment: One commenter suggested that the timeframe for processing disenrollments should be more flexible to accommodate situations where more time is needed to make a determination.

Response: We believe that the fixed timeframe will assure that all information is properly collected and evaluated in a timely fashion. Making the timeframe flexible could create an incentive to delay in accumulating necessary information. This timeframe reflects the time permitted for the determinations previously, and we do not believe it was problematic.

Comment: One commenter suggested that the requirement in §§ 438.56(f)(1), that enrollees be given written notice of their disenrollment rights at least 60 days before the end of each enrollment period, would confuse enrollees and seem to encourage disenrollment. The commenter suggested that including disenrollment rights in enrollment materials, and providing information through the enrollment broker should be sufficient.

Response: Section 1932(a)(4) requires an annual notice at least 60 days before the beginning of an individual's annual opportunity to disenroll. We believe that this information will be provided to enrollees along with all other enrollment materials that must be provided in this time frame. The purpose of this requirement is to ensure that enrollees have sufficient information in order to make a decision whether or not to continue enrollment in their current MCO, PIHP, PAHP, or PCCM within the time allotted for a change in enrollment.

Comment: One commenter applauded the requirement to automatically reenroll a recipient who was disenrolled solely because he or she lost Medicaid eligibility for a period of 2 months or less.

Response: We appreciate the commenters' support.

4. Conflict of Interest Safeguards (§ 438.58)

Proposed § 438.58 requires as a condition for contracting with MCOs that States establish conflict of interest safeguards at least as effective as those specified in section 27 of the Office of Federal Procurement Policy Act. We received no comments on this section.

5. Limit on Payment to Other Providers (Proposed § 438.60)

Proposed § 438.60 prohibits direct payments to providers for services available under a contract with an MCO, PIHP, or PAHP.

Comment: Many commenters asked what type of payments to providers are exempt from this prohibition on direct payments, based on exceptions in title XIX of the Act or Federal regulations,

and whether this exemption applies to graduate medical education (GME) payments to teaching hospitals, requiring GME payments to be included in capitation rates.

Response: The exemption in proposed § 438.60 applies to two types of providers—disproportionate share hospitals (DSH) and Federally qualified health centers (FQHCs). Section 1902(a)(13) of the Act specifically requires direct payments to these providers when they are part of an MCO provider network. The proposed provision would prohibit States from making direct payments to teaching hospitals for GME when their Medicaid patients are enrolled in, and their services are provided under a contract between the State and an MCO or PIHP. Proposed § 438.60 would require any GME payments to be included in the capitation rates paid the MCO or PIHP.

Comment: Numerous commenters opposed this limitation on GME payments in managed care arrangements, arguing that States should be permitted to maintain their current payment methodology for GME. A number of these commenters stated that this prohibition on GME is directly contradictory to the Medicare managed care requirements, for GME be carved out and paid directly to the teaching hospitals, and asked for CMS' rationale for this inconsistency.

Many commenters stated that this requirement would adversely impact teaching hospitals and discourage them from participating in managed care. Others indicated that including GME payments in capitation rates would not work since payments vary widely by provider and therefore by MCO network. They added that including GME in capitation rates would take away States' control over whether and to what extent teaching hospitals receive payments intended to go to them.

Most commenters suggested that approved GME payments should be made an exception to this provision, like DSH and FQHC payments.

Response: The intent of proposed § 438.60 was to prevent duplicate and inappropriate supplemental payments to providers. Under the new rules governing payments under risk contracts in § 438.6(c), States are expected to make actuarially sound payments to MCOs, PIHPs, and PAHPs that include amounts for all services covered under the contract. In most instances, we do not believe there should be a need for payments directly from the State to providers who are delivering all of their services to Medicaid MCO enrollees. The Congress has made a statutory exception to require States to pay directly to the two types of providers identified above, when their services are delivered through a Medicaid-contracting MCO. As some commenters pointed out, the Congress also made an exception for Medicare GME, where amounts are required to be carved out of Medicare managed care payments and paid directly to teaching hospitals. A rationale for treating GME differently in Medicaid would be that the Medicare statute specifically authorizes payment of GME, while the Medicaid statute does not contain a similar provision.

However, we recognize that GME payments have become a common payment practice in State Medicaid programs. In response to the concerns raised, we are amending § 438.60 to allow an exception to this prohibition on direct payment to providers, ''where the State agency has adjusted the actuarially sound capitation rates paid under the contract in accordance with § 438.6(c)(5)(v), to make payments for graduate medical education.'' The aggregate amount of allowable payments under this exception would be limited to the total amount that would have been paid under the approved state plan for FFS. We believe that this is an equitable approach that mirrors the requirements in Medicare managed care and addresses State concerns of preventing harm to teaching hospitals and Federal concerns of ensuring the fiscal accountability of these payments. As part of our larger strategy of improving the fiscal integrity of Medicaid payments, we also plan to study existing Medicaid GME payment arrangements and may issue additional policies in the future.

6. Continued Service to Recipients (Proposed § 438.62)

Proposed § 438.62 requires States to arrange for continued services to beneficiaries who were enrolled in an MCO, PIHP, PAHP, or PCCM whose contract was terminated, or for any enrollee who is disenrolled for any reason other than ineligibility for Medicaid.

Comment: Many commenters recommended adding provisions to require mechanisms to assure continued access for enrollees with ongoing health care needs who move from FFS to managed care, between one managed care entity and another, or from managed care to FFS. These commenters wanted the requirements to apply to all special needs children, beneficiaries over age 65, pregnant women, and other groups identified by the State and include procedures for notification regarding the State's transition mechanisms and assurances that enrollees' ongoing health care needs would be met.

These commenters felt that enrollees may not understand how to access continued services during transition and this could be dangerous for those with special health care needs for which continuity of care is necessary. For example, an enrollee who requires home health services may find himself unable to receive care while being transferred from one MCO to another.

Another commenter stated that it was important to have some type of mechanism to insure that individuals may be treated by their current provider for a reasonable period of time. One commenter also suggested requiring a period of up to 60 days for beneficiaries going through one of these transitions, during which they could continue an ongoing course of treatment with a nonparticipating health care provider.

Several commenters supported the proposed provision.

Response: The goal of our proposed rule is to ensure that there are adequate protections for managed care enrollees, while providing flexibility to States to determine how to best implement these protections. Most States, in their waiver programs under sections 1115 or 1915(b) of the Act already have mechanisms in place to transition enrollees into managed care from fee-for-service (FFS) and from one MCO to another. Further, we are concerned that it would be very difficult to enforce the requirement when a recipient moves from managed care to FFS as there are few mechanisms in the FFS delivery system for care coordination and follow-up.

7. Monitoring Procedures (Proposed § 438.66)

Proposed § 438.66 is a redesignation of § 434.63, with non-substantive revisions and appropriate changes in terminology, and requires States to have in place procedures for monitoring MCOs, PIHPs, and PAHPs.

Comment: One commenter stated that since Medicaid provides care to many low income children, monitoring should include a focus on pediatric services. A recent General Accounting Office report (*GAO–01–749,* published July 2001) found that States have done a poor job in complying with EPSDT requirements, particularly in the area of managed care. The commenter urged CMS to implement the GAO recommendations to work with States to develop a timetable for improving their compliance, and for highlighting best practices.

Response: We have initiated a number of projects that address the GAO recommendations, and are working to improve our monitoring of States as well as identifying and providing needed technical assistance to them.

C. Enrollee Rights and Protections (Subpart C)

Proposed subpart C set forth a variety of enrollee protections, including enrollee rights (proposed § 438.100), protection of provider-enrollee communications (proposed § 438.102), limits on marketing activities (proposed § 438.104), limits on enrollee liability for payment (proposed § 438.106) and cost-sharing (proposed § 438.108), rights in connection with emergency and post-stabilization services (proposed § 438.114), and solvency standards (proposed § 438.116).

1. Enrollee Rights (Proposed § 438.100)

As part of these standards, proposed § 438.100, required that each MCO and PIHP have written policies with respect to enrollee rights, and that each MCO, PIHP, PAHP, and PCCM ensure compliance with Federal and State laws affecting the rights of enrollees, and ensure that its staff and affiliated providers take these rights into account when furnishing services. Under proposed § 438.100(b), States were required to ensure that each enrollee of an MCO, PIHP, PAHP, or PCCM has the right to (1) receive information regarding his or her health care; (2) be treated with respect and with due consideration for enrollee dignity and privacy; (3) receive information on available treatment options and alternatives that is presented in a manner appropriate to the enrollee's condition and ability to understand; (4) participate in decisions regarding his or her health care, including the right to refuse treatment; and (5) be free from any form of restraint or seclusion used as a means of coercion, discipline, convenience, or retaliation. Further, enrollees of MCOs or PIHPs were given the right to (1) be furnished health care services in accordance with proposed §§ 438.206 through 438.210; (2) obtain a second opinion from an appropriately qualified health care professional; (3) request and receive a copy of his or her medical records, and to request that they be amended or corrected. The State also had to ensure that each enrollee is free to exercise his or her rights, and that the exercise of those rights does not adversely affect the way the MCO, PIHP, PAHP, or PCCM and its providers or the State agency treat the enrollee. Proposed § 438.100(d) required that States ensure compliance with various civil rights laws.

Comment: Several commenters provided support for the enrollee rights provisions as proposed. Several other commenters felt that all of the rights in this section should apply to PAHPs as well as PIHPs, or that the differences between these two types of plans should be narrower.

Response: In response to the latter comments, we have expanded the enrollee rights to be provided for PAHP enrollees. We have clarified that PAHP enrollees have the right to request and receive a copy of their medical records, and to request that they be amended, as specified in 45 CFR part 164. Further, we have revised § 438.100(b)(3) to provide that PAHP enrollees, consistent with the scope of the PAHP's contracted services, have the right to be furnished health care services in accordance with §§ 438.206 through 438.210. We also removed from the regulation text the language referring to the right to obtain a second opinion from an appropriately qualified health care professional in accordance with § 438.206(b)(3) to avoid duplication. Please note, this language was only removed to avoid duplication, we did not remove the right to a second opinion, as it is subsumed within § 438.100(b)(3) as one of the health care services enrollees of MCOs, PIHPs and PAHPs have the right to be furnished under § 438.206.

Comment: One commenter suggested that CMS should consider HIPAA privacy rules before finalizing this rule to ensure that there is no conflict.

Response: The Health Insurance Portability and Accountability Act of 1996 (HIPAA) included comprehensive health privacy legislation. HHS published the final privacy rule on December 28, 2000 (65 FR 82462). The final rule took effect on April 14, 2001 and applies to covered entities as that term is defined at 45 CFR 160.103. Most health plans and providers must comply with the new requirements by April 14, 2003. Enforcement of the privacy rule requirements will not occur until April 2003. The compliance date for small health plans is April 14, 2004. The privacy rule gives patients greater access to their own medical records and more control over how their personal health information is used. Specifically, the privacy rule gives patients the right to access their records, request a change or challenge a particular part of the medical record, and have that challenge be included in the permanent records. The privacy rule also covers permissible uses and disclosures of protected health information and requires that appropriate safeguards are used to ensure against misuse of such information. This final rule neither conflicts with the privacy rule, nor does it impose any privacy provisions of its own. Moreover, nothing in this final rule affects a State's or any other covered entity's responsibilities under the privacy rule. We reference the privacy rule at §§ 438.100(b)(2)(vi), 438.208(b)(4), and 438.224, to the extent that it is applicable.

Comment: One commenter expressed concern that proposed § 438.100(a)(2) specifies that all MCOs and PCCMs must comply with any applicable Federal and State laws that pertain to enrollees rights. The commenter was concerned that State laws on enrollee rights might be in conflict with this section. The commenter expressed the concern that requiring MCOs to comply with two sets of regulations addressing the same operational areas is unnecessarily confusing and burdensome for MCOs and for managed care enrollees. The commenter requested that this provision be restated such that if State law on enrollee rights is consistent with section 1932(b) of the Act, CMS does not have the authority to impose additional regulation.

Response: As Federal law supercedes State law, all States must conform with Federal regulations for Medicaid managed care enrollees, so there would not be a situation in which two conflicting sets of requirements would apply, and this concern of the commenter is not valid. We proposed these standards because interpersonal aspects of care are highly important to most patients and closely related to quality of care. Enrollees' interactions with the organization and its providers can have an important bearing on their willingness and ability to understand and comply with recommended treatments and hence on outcomes and costs. While many States have requirements in place that would assure these rights, not all States do. We believe that these minimum standards are justified for all Medicaid beneficiaries. We accordingly do not accept the commenter's suggestion that we defer totally to State law with respect to enrollee rights. However, we note that these Federal regulations set a floor for the level of enrollee standards. States may establish more stringent standards that are not inconsistent with these requirements.

2. Provider-Enrollee Communications (Proposed § 438.102)

Medicaid beneficiaries are entitled to receive from their health care providers the full range of medical advice and counseling that is appropriate for their

condition. Section 1932(b)(3)(A), added by the BBA, clarifies and expands on this basic right by expressly precluding an MCO from establishing restrictions that interfere with enrollee-provider communications, and expressly ensuring the right of a health care professional to give medical advice, without regard to whether the course of treatment advised is covered under the MCO's plan. In § 438.102 of the proposed rule, we provided a definition of the term ''health care professional'' (as discussed above, in this final rule, the definition is located at § 438.2), and outlined the general rule prohibiting interference with provider-enrollee communications. We also included language reflecting the provision in section 1932(b)(3)(B) specifying that the requirements in section 1932(b)(3)(A) should not be construed to require the MCO cover, furnish or pay for a particular counseling or referral service if the MCO objects to the provision of that service on moral or religious grounds, and provides information to the State, prospective enrollees, and to current enrollees within 90 days after adopting the policy with respect to objections of any particular service. In proposed § 438.102, under the authority in section 1902(a)(4), we extended both the explicit right to give advice in section 1932(b)(3)(A) and the moral or religious objection exception in section 1932(b)(3)(B) to PIHPs and PAHPs.

Comment: Several commenters believe that enrollees should receive information from their providers about treatment options in a culturally competent manner so that enrollees can better understand information about their health care. One commenter suggested that if information about treatment options is not delivered in a culturally sensitive way, it could affect patient compliance with medical advice, and trigger health conditions and medical care episodes that escalate the cost of care. The commenter also felt that this would adversely affect not only patients' health status, and ultimately health plans, but States' and CMS' combined efforts to eliminate ethnic and racial health disparities. Another commenter pointed out that many enrollees who have disabilities come from another country and do not speak English, or have a low education level that limits their ability to understand their medical care and insurance. In other instances enrollees have disabilities that can be a barrier to engaging a health care provider. The commenter believes that this could be true for people with mental disabilities, making it difficult for certain enrollees to get the health care that they need. Several of the commenters recommended that we include a provision, which mirrors a Medicare+Choice requirement, to require that MCOs, PIHPs, and PAHPs take steps to ensure that health professionals furnish information about treatment options (including option of no treatment) in a culturally competent manner, and ensure that enrollees with disabilities have effective communication in making decisions with respect to treatment options.

Response: We believe it is important for enrollees to receive information in a culturally competent manner, however, we do not agree that additional regulatory provisions are necessary. The regulation already requires, at § 438.206(c)(2), that each MCO and PIHP participate in the State's efforts to promote the delivery of services in a culturally competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds. It is up to each State to design its own cultural competency efforts to fit its individual needs and place responsibilities on its providers. In addition, we require at § 438.10(b) that information be provided to all enrollees in a manner and format that may be easily understood, taking into consideration cultural and linguistic needs and disabilities of enrollees. Finally, at § 438.100(b)(2)(iv), MCO, PIHP, and PAHP enrollees have the right to participate in decisions regarding his or her care, including the right to refuse treatment. We believe these provisions address the commenters' concerns.

Comment: One commenter suggested that § 438.102 make clear that States have the affirmative responsibility to provide race, ethnicity, and language data to health plans.

Response: It is not clear why the commenter believes that such a requirement would belong in the section dealing with provider-enrollee communications. In any event, § 438.204(b)(2) already requires that the State quality strategy identify the race, ethnicity and primary language spoken of each Medicaid enrollee, and that States provide this information to MCOs and PIHPs for each Medicaid enrollee at the time of enrollment. We therefore do not believe it is necessary to include additional regulatory requirements in this section of the regulations.

Comment: We received numerous comments on the definition of health care professional. One commenter recommended that language be added that would permit expansion of the disciplines based on recognition of new medical providers/additional licensed individuals offering services. Others recommended a more general definition, that does not rely on identifying specific disciplines, or at a minimum adding ''and any other health care professional identified by the State'' at the end of the definition. Commenters were concerned that the definition in the proposed rule did not include all health care professionals authorized to provide care in all States, and that as the health care industry continues to evolve, the list will become outdated.

Response: We recognize the commenters' concerns, however we will not be making any changes to the definition, as section 1932(b)(3)(C) of the Act provides an exact list of professions that are covered under this provision. As noted above, we have moved the definition of health care professional to § 438.2.

Comment: A few commenters noted that the provisions in paragraphs (c)(1), (c)(1)(ii)(B) and (c)(2) of § 438.102 make references to a paragraph (b)(3), which does not exist.

Response: We appreciate these comments and have corrected the erroneous references.

Comment: A few commenters raised concerns about the fact that under proposed § 438.102(b)(2), health plans that exclude coverage of certain counseling or referral services on moral or religious grounds are not required to provide information on how and where to obtain information about the service. One commenter believes that any responsibility to provide information to beneficiaries eliminates what the commenter saw as the crucial means for women to access information at the point of service. The commenter felt that this provision discounts the moral and religious beliefs, and health care needs, of female Medicaid beneficiaries. Another commenter pointed out that the proposed rule transfers the responsibility for providing information on services the MCO declines to cover under § 438.102(b)(2) to the State, with no mention on how the State would provide that information to enrollees on a timely basis. The commenter urged that health plans be required to inform enrollees that it does not provide certain services on moral or religious grounds, and at a minimum, provide a referral to a State-sponsored toll-free number that informs beneficiaries about how and where to access these services.

Response: Ultimately, it is the State's responsibility to deliver information on, and furnish, these services. As discussed above in section A., § 438.10(e) requires that information on each MCO, PIHP, or PAHP, be provided

to potential enrollees (at the time the potential enrollee is first required to enroll in a mandatory enrollment program and within a timeframe that enables the potential enrollee to use the information in choosing among available MCOs, PIHPs, or PAHPs), including the benefits covered by the MCO, PIHP, or PAHP and the benefits available under the State plan, but not covered under the MCO's, PIHP's, or PAHP's contract. In addition, § 438.10(f) provides that for a counseling or referral service not covered because of moral or religious reasons, the State must furnish information about how and where to obtain the services. Section 438.102(b) requires the MCO, PIHP or PAHP to notify potential enrollees of services it does not cover because of moral or religious reasons. Further, this provision does not preclude health providers from providing information on how and where to obtain services, if they so choose. In addition, we do not believe that these provisions compromise the needs of female Medicaid beneficiaries, as the Medicaid statute guarantees freedom of choice for family planning services. An enrollee may seek family planning services out-of-network. We also permit enrollees to disenroll if services are not covered because of moral or religious objections, though because of the freedom of choice provisions, disenrollment is not necessary in order to access family planning services.

3. Marketing Activities (Proposed § 438.104)

Consistent with the rules in section 1932(d)(2) of the Act that apply to MCOs and PCCMs, and in part under our authority in section 1902(a)(4), proposed § 438.104 set forth requirements for, and restrictions on, marketing activities by MCOs, PIHPs, PAHPs and PCCMs. Proposed § 438.104 included definitions of ''cold-call marketing,'' ''marketing,'' and ''marketing materials.'' It also set forth requirements and prohibitions for MCO, PIHP, PAHP or PCCM contracts, specifically: (1) The entity must not distribute any marketing materials without first obtaining State approval; (2) the entity must distribute the materials to its entire service area as indicated in the contract; (3) the entity complies with the information requirements of § 438.10 to ensure that before enrolling, the beneficiary receives from the entity or State, the accurate oral and written information he or she needs to make an informed decision on whether to enroll; (4) the entity does not seek to influence enrollment in conjunction with the sale or offering of any other insurance; and (5) the entity does not, directly or indirectly, engage in door-to-door, telephone, or other cold-call marketing activities. Proposed § 438.104(b)(2) requires that MCOs, PIHPs, PAHPs, and PCCMs specify the methods by which the entity assures the State agency that marketing plans and materials are accurate and do not mislead, confuse, or defraud the beneficiaries or State agency. Finally, § 438.104(c) proposed to require the State to consult with a Medical Care Advisory Committee or an advisory committee with similar membership in reviewing marketing materials.

General Comments

Comment: Several commenters believe that proposed § 438.104 should apply to current enrollees rather than just potential enrollees, and that the fact that it does not do so is inconsistent with the marketing requirements in the BBA.

Response: We have defined marketing as any communication, from an MCO, PIHP, PAHP, or PCCM to a Medicaid beneficiary who is not enrolled in that entity, that can reasonably be interpreted as intended to influence the beneficiary to enroll in that MCO, PIHP, PAHP, or PCCM, or either to not enroll in, or to disenroll from, another MCO's, PIHP's, PAHP's, or PCCM's Medicaid product. We believe that MCOs, PIHPs, PAHPs, and PCCMs are not engaged in marketing for the purposes of influencing enrollment or disenrollment when communicating with current enrollees. We do not believe this is a violation of the BBA marketing provisions in section 1932(d)(2), as this section does not address to whom the marketing covered by its provisions is directed. We believe that our interpretation of the word marketing is reasonable, and consistent with section 1932(d)(2).

Cold-Call Marketing

Proposed § 438.104(a) defines cold-call marketing as any unsolicited personal contact by the MCO, PIHP, PAHP, or PCCM with a potential enrollee for the purpose of influencing the individual to enroll in that particular MCO, PIHP, PAHP, or PCCM. Cold-call marketing includes door-to-door, telephone or other related marketing activities performed by MCOs, PIHPs, PAHPs, or PCCMs and their employees (that is, direct marketing) or by agents, affiliated providers, or contractors (that is, indirect marketing). In the preamble to the proposed rule, we noted that cold-call marketing included such activities as a physician, other member of the medical staff, a salesperson, other MCO, PIHP, PAHP, or PCCM employees, or independent contractors approaching a beneficiary in order to influence his or her decision to enroll with a particular MCO, PIHP, PAHP, or PCCM. In proposed § 438.104(b)(1)(v), we expressly prohibited MCOs, PIHPs, PAHPs, or PCCMs from directly or indirectly engaging in door-to-door, telephone, or other cold-call marketing activities.

Comment: Numerous commenters stated that the definition of cold-call marketing is too broad and might impede legitimate marketing efforts.

Response: The prohibition on cold-call marketing only applies to unsolicited contact by the MCO, PIHP, PAHP, or PCCM. For example, if a beneficiary attends a health fair or similar event, he or she would be seeking out information about health care and, therefore, the contact between the MCO, PIHP, PAHP, or PCCM and the beneficiary would not be considered unsolicited. We note, however, that MCO, PIHP, PAHP, or PCCM participation in health fairs and other community activities is considered marketing and, therefore, must have State approval.

Section 1932(d)(2)(E) of the Act prohibits direct or indirect door-to-door, telephonic, or other cold-call marketing of enrollment. Our interpretation of Congressional intent is that the statutory language was meant to minimize the potential for abusive marketing practices in both voluntary and mandatory programs. There are several other types of marketing that are permitted under section 1932(d) and this regulation. For example, States may permit the use of billboards, newspaper, television, and other media to advertise MCOs, PIHPs, PAHPs, or PCCMs. Mailings are also permitted as long as they are distributed to the MCO's, PIHP's, PAHP's, or PCCM's entire service area covered by the contact. States may also provide marketing materials on behalf of MCOs, PIHPs, PAHPs, and PCCMs.

This regulation does not prohibit educational activities on the part of MCOs, PIHPs, PAHPs, or PCCMs. However, any contacts other than patient counseling by any MCO, PIHP, PAHP, or PCCM staff or representative, would be considered marketing subject to State oversight. The regulation does not prohibit States from permitting MCOs, PIHPs, PAHPs, or PCCMs to market to groups in schools, churches, day care centers, etc. States are responsible for approving and monitoring these types of presentations and ensuring that beneficiaries attend

voluntarily with knowledge that they are attending a marketing presentation.

States may permit and establish rules for marketing in public places. However, States may not permit uninvited personal solicitations in public places such as eligibility offices and supermarkets. Some States allow representatives of available MCOs, PIHPs, PAHPs, and PCCMs to be in eligibility offices or other locations on certain days or on a rotating basis to answer questions and provide information to beneficiaries. In these situations, there should be provisions to monitor contacts to ensure that unbiased information is available about all options and that beneficiaries are not coerced. However, marketing or other MCO, PIHP, PAHP, or PCCM representatives who approach beneficiaries as they enter or exit eligibility offices or other public places, call at residences uninvited, etc., are considered cold-call contacts and are not permitted.

We believe the regulation gives States broad authority to determine what marketing activities are permitted, with the exception of unsolicited personal contacts by MCOs, PIHPs, PAHPs, and PCCMs or their representatives. States are free to use MCOs, PIHPs, PAHPs, and PCCMs in community-based efforts. However, those efforts are considered marketing; therefore the materials (activities, materials, presentations, etc.) are subject to State review and approval.

Service Area

Proposed § 438.104(b)(1)(ii) required that marketing materials be distributed to the entire service area as indicated in the contract.

Comment: Some commenters believe that the proposed requirement was unnecessary, unduly burdensome and costly. One commenter suggested that MCOs should not have to distribute marketing materials to areas they already serve and should be allowed to limit distribution to new areas only. Another commenter thought it reasonable to require materials be sent only to those who are eligible or potentially eligible for Medicaid in a given service area and recommended that we require MCOs, PIHPs, PAHPs, and PCCMs to distribute materials to all eligible enrollees in a specified county or region to avoid confusion to those in a particular sector in which the marketing materials do not apply.

Response: Section 1932(d)(2)(B) of the Act requires that marketing materials be distributed to the entire service area. The intent of this provision is to prohibit marketing practices that favor certain geographic areas over those thought to produce more costly enrollees. Section 438.104(b)(1)(ii) requires that each MCO, PIHP, PAHP, and PCCM contract must provide that the entity ''distributes the materials to its entire service area *as indicated in the contract.*'' (Emphasis added.) The phrase ''as indicated in the contract'' is intended to provide States and MCOs, PIHPs, PAHPs, and PCCMs with some flexibility in designing and implementing marketing plans and in developing marketing materials. We expect that when States review MCO, PIHP, PAHP, and PCCM marketing and informing practices, they will not only consider accuracy of information, but also factors such as language, reading level, understandability, cultural sensitivity, and diversity. In addition, State review should ensure that MCOs, PIHPs, PAHPs, and PCCMs do not target or avoid populations based on their perceived health status, cost, or for other discriminatory reasons.

For example, a State may permit distribution of materials customized for a Hispanic population group as long as the materials are comparable to those distributed to the English speaking population. While the presentation and formats of the information may be varied based on the culture and distinct needs of the population, the information conveyed should be the same, in accordance with § 438.10. In the above example, the materials for the Hispanic population group must be distributed to all those Medicaid eligibles or enrollees who require or request Hispanic-related materials. States that use this flexibility to allow selective marketing may permit distribution by zip code, county, or other criteria within a service area if the information to be distributed pertains to a local event such as a health fair, or provider, such as a hospital or clinic. However, States must ensure that health fairs are not held only in areas known to have or perceived as having a more desirable population. We have chosen not to limit the distribution requirement only to mailings because broadcast advertising and other marketing activities can also be done selectively. All marketing activities should be conducted in a manner that provides for equitable distribution of materials and without bias toward or against any group.

Sale of Other Insurance

Proposed § 438.104(b)(1)(iv) requires MCO, PIHP, PAHP, and PCCM contracts to assure that the entity does not seek to influence enrollment in conjunction with the sale or offering of any other insurance. We interpreted this provision to mean that MCOs, PIHPs, PAHPs, and PCCMs may not entice a potential enrollee to join the MCO, PIHP, PAHP, or PCCM by selling or offering any other type of insurance as a bonus for enrollment. However, we invited comment on this provision, because we did not have any legislative history to consider when developing our interpretation.

Comment: Several commenters strongly recommended that CMS clarify that this provision does not apply to Medicaid enrollees who are eligible for Medicare. As it is worded, commenters believe that this section precludes a Medicare sales representative from telling a potential enrollee eligible for Medicare and Medicaid services about Medicare. Another commenter indicated that this section could impede coordination efforts between Medicare and Medicaid programs. Another commenter stated that the section should not apply to Medicare, since the Medicare program is subject to marketing regulations.

Response: We agree with the commenters that the proposed regulatory text could impede the interaction of marketing to dual eligibles by MCOs, PIHPs, PAHPs or PCCMs. We have clarified the regulation text at § 438.104(b)(1)(iv) by adding language clarifying that this provision applies to the sale or offering of any private insurance. This would not preclude a Medicare sales representative from telling a dually eligible beneficiary about the health plan's Medicare+Choice benefits. Rather, it is intended to apply to such types of insurance as burial insurance.

State Agency Review

Proposed § 438.104(c) provides that, in reviewing the marketing materials submitted by MCOs, PIHPs, PAHPs, and PCCMs, the State must consult with its Medical Care Advisory Committee (MCAC) or an advisory committee with similar membership. Section 431.12, of existing rules, sets forth the requirements for establishment of an MCAC. The MCAC must include Board-certified physicians and other representatives of the health professions who are familiar with the medical needs of low-income populations and with the resources available and required for their care. The MCAC must also include the Director of the Public Welfare Department or the Public Health Department, whichever does not head the Medicaid agency, as well as members of consumer groups including Medicaid beneficiaries and consumer organizations such as labor unions, cooperatives, and consumer-sponsored prepaid group practice plans.

Comment: Several commenters felt that the MCAC review of marketing materials would be cumbersome, an administrative burden to the States, and may create delays in distributing marketing information to potential enrollees. The commenters indicated that States should consult the MCAC on marketing policy, regulations, and guidelines, rather than review each piece of marketing materials submitted. One commenter felt that if the MCAC were to review pieces of marketing material, then it should be done in a timely manner.

Response: We did not intend to require that the committee itself review and approve marketing materials. Rather, we intend to reflect section 1932(d)(2)(A)(ii) of the Act, which requires the State to *consult* with the committee during the State's own process of review and approval. The State is not required to obtain the committee's approval of, or consensus on, the materials. The State has flexibility in determining how to consult with the committee. A State may elect to require the committee to review the actual marketing materials. If so, in order to expedite the total review time, the State could permit the committee members to conduct their review concurrently with the State's review.

States may also consult with the committee in the development of standardized guidelines or protocols that are intended to facilitate State review. States may consult with the committee to develop suggested language and deem approval of an MCO's, PIHP's, PAHP's, or PCCM's materials if that language is used. MCOs, PIHPs, PAHPs, and PCCMs could also use some of the suggested language and then identify areas where different language has been used, and States could then limit review and/or consultation to that particular portion of the materials.

4. Liability for Payment (Proposed § 438.106)

Proposed § 438.106, consistent with section 1932(b)(6) of the Act, requires MCOs, PIHPs, and PAHPs to provide that their Medicaid enrollees will not be held liable for (a) the debts of the MCO, PIHP, or PAHP in the event of insolvency; (b) covered services provided to the enrollee for which the State does not pay the MCO, PIHP, or PAHP; or (c) payments for covered services furnished under a contract, referral, or other arrangement, to the extent that those payments are in excess of the amount that the enrollees would owe if the MCO, PIHP, or PAHP provided the services directly.

Comment: One commenter expressed support for this provision.

Response: We acknowledge and thank the commenter for their support.

5. Cost Sharing (Proposed § 438.108)

Prior to the enactment of the BBA, MCOs were prohibited from imposing cost sharing on enrollees. The BBA eliminated this prohibition, and provided that copayments for services furnished by MCOs may be imposed in the same manner as they are under fee-for-service. In § 438.108, we proposed that the contract must provide that any cost sharing imposed on Medicaid enrollees is in accordance with § 447.50 through § 447.58 of the existing regulations.

Comment: Two commenters supported this provision. One commenter expressed concern about the inappropriate use of hospital emergency rooms. The commenter recommended that we allow and encourage States to charge beneficiaries a $25 copayment per visit for inappropriate use of the emergency room. Under the commenter's recommended approach, MCOs would require that hospitals collect the copayment at the time of the visit; provided, however, that enrollees would not be denied care because of inability to pay the copayment. Under the commenter's suggested policy, if it was determined that a true emergency existed, the copayment would be refunded. The commenter believes that this would serve as an incentive to enrollees to seek care in the appropriate setting, at the appropriate time and would allow the primary care physician to establish a medical relationship with the beneficiary.

Response: Under § 447.53(b)(4), emergency services are exempt from cost sharing. Specifically, copayments may not be imposed on ''[s]ervices provided in a hospital, clinic, office, or other facility that is equipped to furnish the required care, after the sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) that the absence of immediate medical attention could reasonably be expected to result in—(i) Placing the patient's health in serious jeopardy; (ii) serious impairment to bodily functions; or (iii) serious dysfunction of any bodily organ or part.'' We emphasize that as long as the enrollee seeks emergency services that could reasonably be expected to have the above effects, a copayment may not be imposed, even if the condition was determined not to be an emergency.

We believe that allowing the collection of an ''upfront'' copayment in a hospital emergency room as the commenter suggested violate § 447.53(b)(4), and be inconsistent with the enrollee's right to coverage of emergency services when a ''prudent layperson'' would reasonably believe that an emergency exists (see discussion above). However, enrollees should be aware that if they seek services in an emergency room when it is clear that the standard in § 447.53(b)(4) is not met, coverage of these services may be denied entirely.

6. Emergency and Post-Stabilization Services (Proposed § 438.114)

Section 4704(a) of the BBA added section 1932(b)(2) to the Act to assure that Medicaid managed care beneficiaries have the right to immediately obtain emergency care and services, and the right to post-stabilization services following an emergency medical condition under certain circumstances. (Post-stabilization services are medically necessary services related to an emergency medical condition that are received at the site at which the patient is treated for an emergency medical condition, after the individual's condition is sufficiently stabilized that he or she could alternatively be safely discharged or transferred to another facility.) Each contract with an MCO and PCCM must require the organization to provide for coverage of emergency services and post-stabilization services as described below. In section 1932(b)(2)(A)(i) of the Act, while the Congress required MCOs and PCCMs to provide coverage of emergency services, it did not define the word ''coverage,'' even though these health care models generally do not cover emergency services in the same manner. In proposed § 438.114, we interpreted the obligation in section 1932(b)(2)(A)(i) of the Act to provide for coverage of emergency services to mean that an MCO or State (as payer in the case of a PCCM) that pays for hospital services generally, must pay for the cost of emergency services obtained by Medicaid managed care enrollees. We interpreted coverage in the PCCM context to mean that the PCCM must allow direct access to emergency services without prior authorization. We applied different meanings to the word ''coverage'' because while PCCMs are individuals paid on a fee-for-service basis, they receive a State payment to manage an enrollee's care. Unlike MCOs, PCCMs would not likely be involved in a payment dispute involving emergency services, though

they could be involved in an authorization dispute over whether a self-referral to an emergency room is authorized without prior approval of the PCCM. Accordingly, in proposed § 438.114(c)(2), we provided that enrollees of PCCMs are entitled to the same emergency services coverage without prior authorization that is available to MCO enrollees under section 1932(b)(2) of the Act.

Section 1932(b)(2)(A)(i) stipulates that emergency services must be covered without regard to prior authorization, or the emergency care provider's contractual relationship with the organization. This assures a Medicaid enrollee of the right to immediately obtain emergency services at the nearest provider when and where the need arises.

Section 1932(b)(2)(B) of the Act defines emergency services as covered inpatient or outpatient services that are furnished by a provider qualified to furnish these services under Medicaid that are needed to evaluate or stabilize an ''emergency medical condition.'' An ''emergency medical condition'' is in turn defined in section 1932(b)(2)(C) of the Act as a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in placing the health of the individual (or for a pregnant woman, the health of the woman or her unborn child) in serious jeopardy, serious impairment to body functions, or serious dysfunction of any bodily organ or part. While this standard encompasses clinical emergencies, it also clearly requires MCOs to base coverage decisions for emergency services on the apparent severity of the symptoms at the time of presentation, and to cover examinations when the presenting symptoms are of sufficient severity to constitute an emergency medical condition in the judgment of a prudent layperson. The above definitions are set forth in proposed § 438.114(a).

In some cases, the ''emergency'' services required to diagnose or treat an ''emergency medical condition'' may fall within the scope of services that a PIHP, or even a PAHP, is required to cover under its contract. In this case, we believe that enrollees should have the same rights to have these services covered without delay, and ''out of plan'' as in the case of services covered by an MCO or through a PCCM. Accordingly, through our authority in section 1902(a)(4) of the Act, we provided in proposed § 438.114(f) that the requirements in § 438.114 apply to PIHPs and PAHPs to the extent that the services required to treat the emergency medical condition, or the required post-stabilization services in question, fall within the scope of the services for which the PIHP or PAHP is responsible.

Proposed § 438.114(b) requires that MCOs, PIHPs, PAHPs (to the extent applicable), at-risk PCCMs, or the State agency pay for emergency and certain post-stabilization services without prior authorization (other than the pre-approval of post-stabilization services no later than within one hour of a request for approval).

Proposed § 438.114(c)(1)(i) provides that an MCO or, to the extent applicable, a PIHP or PAHP, must pay for emergency services regardless of whether the entity that furnishes the services has a contract with the MCO, PIHP, or PAHP. In proposed § 438.114(c)(1)(ii), MCOs, PIHPs, or PAHPs may not deny payments if, on the basis of symptoms identified by the enrollee, he or she appeared to have an emergency medical condition, but turned out not to have a condition in which the absence of immediate medical care would have resulted in serious jeopardy to the health of the individual or, in the case of a pregnant woman, the health of her unborn child, serious impairment of bodily function, or serious dysfunction of any bodily organ or part. Likewise, the MCO, PIHP, PAHP, or PCCM cannot deny payment if the enrollee obtained services based on instructions of a practitioner or other representative of the MCO, PIHP, or PAHP. Proposed § 438.114(c)(2) provides that if a PCCM contract is a risk contract that covers the services, a PCCM system must allow enrollees to obtain emergency services outside of the PCCM system.

Proposed § 438.114(d) further clarified financial responsibility. Proposed § 438.114(d)(1) provided that MCOs, PIHPs and PAHPs (to the extent applicable), at-risk PCCMs, or States may not limit what constitutes an emergency medical condition through lists of symptoms or final diagnoses/conditions and may not refuse to process a claim because it does not contain the primary care provider's authorization number. Proposed § 438.114(d)(2) provided that an enrollee who, based on the treating emergency provider's determination, has an emergency medical condition, may not be held liable for payment concerning the screening and treatment of that condition necessary to stabilize the enrollee. Proposed § 438.114(d)(3) provided that the attending physician or practitioner actually treating the enrollee determines when the enrollee is sufficiently stabilized for transfer or discharge, and that this determination is binding on the MCO, PIHP, or PAHP for coverage purposes.

Section 1932(b)(2)(A)(ii) of the Act also provides MCO and PCCM enrollees with the right, under certain circumstances, to coverage of ''post-stabilization'' services after they have been ''stabilized'' (that is, they no longer have an emergency medical condition, and could be safely discharged or transferred to another facility) following an admission for an emergency medical condition. Specifically, the services that must be covered are those that must be covered under Medicare rules implementing section 1852(d)(2) of the Act, in the same manner as these rules apply to M+C plans offered under Part C of Title XVIII. In section 1932(b)(2)(A) of the Act, this requirement was effective 30 days after the Medicare rules were established, which was August 26, 1998. The Medicare+Choice post-stabilization requirements referenced by section 1932(b)(2)(A)(ii) of the Act are set forth in proposed § 438.114(e), which referenced § 422.113(c) of the Medicare+Choice final regulation. Post-stabilization care means covered services, related to an emergency medical condition, that are provided after an enrollee is stabilized in order to maintain the stabilized condition, and under the circumstances described in paragraph § 422.113(c)(2)(iii), to improve or resolve the enrollee's condition. Under these latter circumstances, either the health plan has authorized post-stabilization services in the facility in question, or there has been no authorization and (1) the hospital was unable to reach the health plan; or (2) the hospital reached the health plan, but did not get instructions within an hour of a request.

The above emergency provisions are consistent with most of the emergency services provisions in the Medicare+Choice regulations. However, these regulations deviate from Medicare in two ways. First, the Medicare statute has specific provisions for non-emergency, but urgently needed services, while the Medicaid statute does not contain any similar references. Second, the PCCM, PIHP, and PAHP models are delivery systems unique to Medicaid; and there is no Medicare counterpart to the special rules described above that apply to PCCM enrollees.

Comment: One commenter urged that the applicable definitions, including an emergency medical condition and post-

stabilization services, be set forth in § 438.114, rather than simply referencing § 422.113. The commenter felt this would make the Medicaid regulations easier to understand.

Response: We agree. In response to this comment, we have set forth the full definitions of emergency medical condition, emergency services and post-stabilization services in § 438.114.

Comment: Several commenters noted that the Emergency Treatment and Active Labor Act (EMTALA) requires hospitals and emergency providers to screen and treat those Medicaid enrollees that present at the emergency room, and argued that managed care organizations (MCOs) and States should have to cover costs that EMTALA mandates. A few commenters expressed the view that EMTALA was being enforced on hospitals with more vigilance than the prudent layperson standard is on MCOs, PIHPs, and States.

Response: While MCOs, PIHPs, and States are responsible for covering emergency medical conditions, this is not the same mandate as the services that must be covered under EMTALA. For example, if a prudent layperson would not reasonably believe that an emergency medical condition existed, MCOs, PIHPs, or States would not be liable for costs when the individual presents at an emergency room without prior authorization. Under EMTALA, however, obligations to at least perform screening exist regardless of the condition of the presenting individual. Hence, the scope of a hospital's obligations under EMTALA is broader than the scope of an MCO's or State's obligation under section 1932(b)(2) (or, by extension under this regulation, a PIHP where applicable). However, we agree that the mandates under each rule overlap significantly in most cases. We encourage parties who have concerns about violations or enforcement to contact either the State or CMS regional office responsible for the area in question.

Comment: One commenter suggested that we remove the provision which precludes an MCO, PIHP or State from refusing to cover services without the primary care provider's (PCP) authorization number. The commenter was concerned that without such a number, there was not a practical mechanism to alert a State or health plan that its enrollee had presented to the emergency room. The commenter also said that its computer system would have to be reconfigured in order to leave out this information, costing a significant amount of money.

Response: Originally, we added this requirement because we were concerned that MCOs, PIHPs, and States could attempt to avoid their obligations under § 438.114 by refusing to pay claims based on technicalities concerning the submission of claims. However, we agree with the commenter that there is a vested interest in MCOs, PIHPs, and States tracking individual enrollees' emergency room presentation rates. Therefore, we are allowing MCOs, PIHPs, and States to require the PCP number to be on a claim before it will be processed for payments. However, we have provided in § 438.114(d)(1)(ii) that MCO, PIHPs, and States must provide hospitals, emergency room providers, or their fiscal intermediaries, when applicable, a minimum of 10 business days to notify the primary care provider or other designated contact before a payment may be denied for a failure to provide notice.

Comment: One commenter was concerned about the prohibition against denying claims based on lists of symptoms or final diagnosis codes. A number of States require MCOs to pay a screening fee even if there was no emergency, but do not require them to pay for the service based on their emergency services fee schedule. The commenter wanted to know if there was a conflict with the regulation.

Response: There is no conflict in this situation if the determination was made taking into account the presenting symptoms rather than the final diagnosis. We prohibit the use of codes (either symptoms or final diagnosis) for denying claims because there is no way a list can capture every scenario that could indicate an emergency medical condition as required in the BBA. An MCO, PIHP, or State may pay claims using those lists and require coverage of screens even if no emergency medical condition exists. However, we do not require coverage of a screen if it reveals no emergency medical condition (as opposed to EMTALA requirements on Medicare participating hospitals).

Comment: A few commenters were concerned that the Federal rules provide little State flexibility when it comes to setting State rules involving claims coverage, or educating enrollees about emergency room use. One commenter was concerned that, if read literally, the rule prohibits denial of a claim for any reason other than not meeting the prudent layperson standard. The commenter stated that under the proposed rule, reasons for denial could include claims not submitted in a timely manner, claims that are not clean, or claims submitted by providers who refuse to sign provider agreements.

Response: We never intended this rule to prevent States from setting reasonable claim filing deadlines, asking for charts or other information before making a decision, or covering claims submitted by providers refusing to sign provider agreements. The purpose of the rule is to ensure that enrollees have unfettered emergency room access for emergency medical conditions, and that hospitals receive payment for those claims meeting that definition without having to navigate through unreasonable administrative loopholes. However, as long as filing deadlines specifically outlined for an appeals process are not used to deny initial claims, a State may set its own filing timeframes and other administrative rules (as long as it is not contrary to specific Federal provisions such as the 10 business day post-notification minimum timeframe requirement).

Comment: One commenter was concerned about the application of proposed § 438.114 to situations involving mental health emergencies. The commenter felt that the present definition cannot be readily understood in the context of emergencies related to mental disorders.

Response: We agree that the present definition is primarily designed to cover physical rather than mental health. However, since the definition comes directly from the BBA, we do not have the legal authority to expand or change it. The present definition does apply to mental health as well when its standards are met (for example, ''placing the health of the individual in serious jeopardy'').

Comment: A few commenters believe that the one-hour rule for MCOs to notify hospitals before post-stabilization services may be performed is too short a timeframe, and is contrary to their own State rules. One commenter indicated that it follows a 2-hour timeframe before post-stabilization services may be performed, finding it much more reasonable in order to give MCOs and PCPs an opportunity to coordinate an enrollee's non-emergent care.

Response: Section 1932(b)(2)(a)(ii) of the Act requires MCOs and PCCMs to comply with guidelines established under section 1852(d)(2) of the Act regarding coordination of post-stabilization care in the same manner as the guidelines apply to Medicare+Choice plans under Part C of title XVIII. Therefore, according to statute, we must follow the rules that apply under the Medicare+Choice program. In this case, that is a 1-hour timeframe for MCOs or PCCMs to notify a hospital before post-stabilization services may begin.

Comment: A few commenters pointed out that proposed § 438.114(c)(1) contains an error by referring to entities identified in subparagraph (c) when it should refer to paragraph (b).

Response: The commenters are correct. We have made the change in the final rule.

7. Solvency Standards (Proposed § 438.116)

Section 4706 of the BBA added new solvency standards to section 1903(m)(1) of the Act, requiring that an MCO's provision against the risk of insolvency meet the requirements of a new section 1903(m)(1)(C)(i), unless exceptions in section 1903(m)(1)(C)(ii) apply. Under section 1903(m)(1)(C)(i), the organization must meet ''solvency standards established by the State for private health maintenance organizations'' (or be ''licensed or certified by the State as a risk-bearing entity.'') The exceptions to this new requirement in section 1903(m)(1)(C)(ii) apply if the MCO, (1) is not responsible for inpatient services, (2) is a public entity, (3) has its solvency guaranteed by the State, or (4) is, or is controlled by FQHCs, and meets standards the State applies to FQHCs. Section 4710(b)(4) of the BBA provided that the new solvency standards applied to contracts entered into or renewed on or after October 1, 1998. Proposed § 438.116 reflects these statutory provisions. We received no comments on this section and are implementing it as proposed.

D. Quality Assessment and Performance Improvement (Subpart D)—Background

Section 4705 of the BBA added section 1932(c) to the Act. Section 1932(c)(1) requires State agencies that contract with Medicaid MCOs under section 1903(m) of the Act to develop and implement quality assessment and improvement strategies that are consistent with standards established by the Secretary. Subpart D would implement this provision. We proposed that the requirements be applied to PIHPs and, in some cases, to PAHPs.

1. Scope (Proposed § 438.200)

Proposed § 438.200 set forth the scope of subpart D. Proposed subpart D would implement section 1932(c)(1) by setting forth specifications for quality assessment and performance improvement strategies that States must implement. Subpart D also proposed standards that would apply to States, MCOs, Prepaid Inpatient Health Plans (PIHPs), and in some cases, Prepaid Ambulatory Health Plans (PAHPs).

Comment: One commenter stated that the provisions of subpart D were appropriate overall but that more flexibility is needed for smaller States and MCOs because their administrative burden is greater. Many commenters supported the approach taken in the August 2001 proposed rule and the balance struck between requirements and flexibility. They stated their belief that subpart D avoids the imposition of requirements with administrative burden and serves the interest of beneficiaries.

Response: We believe that § 438.204 provides the structure for State quality strategies consistent with the intent of the Congress when it addressed quality in section 4705(a) of the BBA. We also believe that we have provided sufficient flexibility for States to design and implement quality strategies that will best meet their needs. We do not relax the requirements for smaller States or MCOs because we do not believe that quality should be compromised due to the size of an organization. However, we do not believe the burden on States is excessive, even for smaller States, and we believe that States may impose the appropriate activities on MCOs and PIHPs. For example, a State might require less in the way of quality assessment and performance improvement activities for smaller plans. The State also might contract with an organization that does external quality review for the State pursuant to section 1932(c)(2) of the Act, to calculate performance measures or design quality improvement projects. (See 64 FR 67223, December 1, 1999 for the proposed rules that would govern ''External Quality Review Organizations,'' or ''EQROs.'')

Comment: Many commenters stated that the provisions of subpart D should apply to PAHPs, including dental plans, as well as to MCOs and PIHPs. They believe that all capitated programs, including those that provide transportation, should be subject to the quality provisions. Other commenters stated that exempting ''mental health carve out'' plans from the quality requirements is inconsistent with the findings of the General Accounting Office (GAO) report of September, 1999 on mental health carve out programs in Medicaid managed care.

Response: We agree with the commenter. Therefore, in this final rule, we have applied additional sections of the regulation to PAHPs. (See § 438.8(b).) In subpart D, we now apply the provisions of §§ 438.206, 438.207, 438.208, 438.210, 438.214, 438.230, and 438.236 to PAHPs. These sections address access to care and the provision of quality care. We believe that the protections of these sections should be extended to enrollees in PAHPs. We do not apply the other provisions of subpart D related to a quality strategy and quality improvement activities, as we believe these requirements would impose a burden on States and PAHPs that is unreasonable given the scope of PAHP activities.

The terms ''mental health carve out program'' or ''behavioral health carve out program'' refer to prepaid plans that provide only mental health services. Under a waiver, a State Medicaid managed care program can contract with such a program. The GAO Report issued on September 17, 1999, indicated that CMS needs to oversee mental health carveouts more systematically, and noted approvingly that we were developing a rule that would include a requirement for annual external quality reviews. Mental health carve out programs that provide hospital as well as ambulatory care are PIHPs, and are subject to all the subpart D requirements. We believe that most of the large mental health carve out programs fall into this category, and that this final rule is therefore consistent with the intent of the September 1999 GAO report.

2. State Responsibilities (Proposed § 438.202)

Proposed § 438.202 set forth the State's responsibilities in implementing its quality strategy. Specifically, proposed § 438.202 required that each State (1) have a written strategy for assessing and improving the quality of managed care services, (2) provide input by stakeholders into the strategy, (3) ensure compliance with State-established standards, (4) periodically review the strategy for its effectiveness and update as needed, and (5) submit to CMS a copy of the initial and revised strategies and regular reports on their implementation and effectiveness.

Comment: One commenter suggested that in § 438.202 ''strategy'' be replaced with ''policy.''

Response: Section 1932(c)(1) of the Act requires a State to develop and implement a quality assessment and improvement strategy if it contracts with an MCO. Therefore, we retain the term ''strategy'' in § 438.202 of the final rule to be consistent with the term used in the statute.

Comment: One commenter believes that the provisions regarding a State quality strategy are heavy handed, over controlling, and result in CMS substituting its judgment regarding quality for the State's.

Response: We believe the regulation provides a balance between an appropriate amount of detail needed to ensure that States develop and implement sound quality strategies and flexibility for States to determine the best approach for developing these strategies.

Comment: One commenter said that the State's quality strategy should clearly outline the relationship between the MCO and PIHP quality requirements and the strategy components. Each MCO and PIHP requirement should clearly support a component of the strategy.

Response: The MCO and PIHP quality requirements of subpart D (§§ 438.206 through 438.242) are incorporated as an element of the State's quality strategy (§ 438.204(g)). Specifically, § 438.204(g) requires that the State quality strategy include information on how the State plans to make MCOs and PIHPs comply with State access standards, structural and operational standards, and measurement and improvement standards. We do not believe we need to revise § 438.204 to provide clarifying language to show the relationship between the quality strategy and the MCO and PIHP quality requirements under § 438.240.

Comment: Many commenters stated that the requirement in proposed § 438.208(c) and (d) (now § 438.208 (b) and (c)) for States to assess the quality and appropriateness of care and services furnished to all Medicaid enrollees, including those with special health care needs, is ambiguous. Commenters believe it can be read to mean that the overall population must be measured, including special needs populations, rather than that the quality for special needs populations be measured separately. They see this as a problem because the results may yield no specific information about persons with special health care needs.

Response: Our intent for the proposed provision was to have States assess the quality and appropriateness of care and services to all Medicaid enrollees as well as to assess separately the quality and appropriateness of care and services for individuals with special health care needs. For clarification purposes, we have revised § 438.208(b) and (c).

Comment: One commenter objected to the inclusion of the word ''all'' in § 438.204(b) because States do not have the budgets or staffs to assess the needs of all Medicaid enrollees.

Response: Section 438.204(b) requires the State to identify in the quality strategy how it plans to implement procedures to assess the quality and appropriateness of care and services furnished to all Medicaid beneficiaries. We disagree with the commenter because States have the flexibility to determine the methods and timeframes that will work best to assess the quality and appropriateness of care and services to all Medicaid beneficiaries. There are a variety of options States can choose from to meet this requirement. For example, States can use findings from performance measures collected, performance improvement projects conducted, reviews for compliance with State standards, consumer surveys, or the analysis of grievance and appeal information. States can conduct these activities, use a State contractor to conduct these activities, and/or use findings from MCO and PIHP quality assessment and performance improvement programs.

Comment: One commenter questioned if there are specific quality measures for individuals with special health care needs, other than surveys, that can be used to meet the requirement of the regulation that States assess the appropriateness of care of these enrollees.

Response: As stated above, there are numerous activities that can be conducted to assess the appropriateness and quality of care and services provided to beneficiaries. When targeting an assessment of individuals with special health care needs States can stratify the data by identified categories or conduct activities specifically targeted to a specified population. For example, a State could conduct or have their MCOs and PIHPs conduct a performance improvement project on access to care for individuals needing substance abuse services.

Comment: Many commenters suggested that proposed § 438.208(b) (now § 438.208(c)) should require States to provide information to MCOs and PHPs about Medicaid enrollees known by the agency to have special needs, as this step is crucial to assessing the quality and appropriateness of care provided to these beneficiaries.

Response: We agree with the commenters. Therefore, we have revised § 438.208(c) to require that States implement mechanisms that identify individuals with special health care needs. The State or its enrollment broker may determine which individuals have special needs, and then inform the MCO, or the State may require that the MCO, PIHP, or PAHP apply the mechanisms to identify these individuals.

Comment: Many commenters expressed support for the requirement that State quality strategies be in writing. One commenter mistakenly believed that the proposed rule did not include the requirement that the strategy be in writing and asked that this requirement be included.

Response: We agree with the commenters and we will retain the requirements in § 438.202(a). We believe it important that the quality strategy be in writing to provide a document for stakeholders to react to, as well as, for the States to assess on a regular basis and update as necessary.

Comment: Several commenters stated that the regulation appears to contemplate a formal solicitation of public input to the quality strategy. A formal public process is costly and administratively burdensome. One commenter said that they have found a public process to solicit input ineffective. The commenter asked that we clarify in text or preamble language that a less formal process is permissible. Another urged its deletion. Several commenters supported the requirement for public input into the State quality strategy.

Response: Our intent is that there be a formal process to obtain input from beneficiaries and other program stakeholders in the development of the State quality strategy. We leave it to the State to define this process. We believe public input provides for the integration of various perspectives and priorities and will facilitate a more useful end product. Therefore, we retain the requirement in § 438.202(b) of this final rule.

Comment: One commenter expressed concern that the regulation will require a continual process of formal comments on a State's quality strategy because it will change frequently as new quality tools become available, laws and regulations change, and CMS places conditions on States when approving waivers.

Response: As stated above, we intend for States to obtain public comments on updated quality strategies when significant changes are made. We do not expect States to obtain public comments when modifications are made to the strategy that are not considered significant, as defined by the State.

Comment: Many commenters believe that CMS should specify a timeframe for States to update their quality strategies, such as annually or every 3 years. They believe that ''periodic'' is insufficient, as the term is not defined. One commenter stated that the review should be conducted annually, the review should identify the degree to which the MCO or PIHP interventions continue to support the goals of the strategy, and the findings should be reported annually to CMS and to the public.

Response: We do not agree that we should require a specific time period for States to update their quality strategies. We have provided States with the flexibility to determine these timeframes. We believe that a State's review and evaluation of the effectiveness of the strategy will guide the State's decision as to when and how the strategy should be revised. Therefore, we retain the requirement in § 438.202(d).

Comment: One commenter said that the requirement that States submit their quality strategies to CMS implied a role for CMS in approving the strategy. Another commenter requested a provision stating that CMS' review will be limited to verification that each required element is addressed.

Response: As part of the CMS regional office review of Medicaid managed care programs, regional office staff will assess State quality strategies to ensure compliance with this rule. We have not yet determined the scope of review activities that regional office staff will undertake. As we develop this process, we will work in collaboration with States and other stakeholders.

Comment: One commenter suggested that a provision be included to require States to review health plans' quality strategies at least every 3 years.

Response: MCOs and PIHPs are not required to develop quality strategies. MCOs and PIHPs are required to have a quality assessment and performance improvement program as specified under § 438.240. The State is required to review this program annually to determine the impact and effectiveness of the program.

Comment: One commenter stated that progress toward goals in the quality strategy should be shared by States with their MCOs and PIHPs to reinforce collaboration, monitor progress, and make needed revisions.

Response: We encourage States to share findings of the effectiveness of the State quality strategy with MCOs and PIHPs. We are not requiring this, however, in regulation.

3. Elements of State Quality Strategies (Proposed § 438.204)

Proposed § 438.204 set forth the elements of a State quality strategy, including, in § 438.204(a), contract provisions that incorporate the standards specified in this subpart. Section 438.204(b) required that the State strategy must include procedures that (1) assess the quality and appropriateness of care and services furnished to all Medicaid enrollees, including those enrollees with special health needs; (2) identify and provide to MCOs and PIHPs information on the race, ethnicity, and primary language spoken of each Medicaid enrollee; and (3) monitor and evaluate the compliance of MCOs and PIHPs with these standards.

Section 438.204(c) provided that the State quality strategy must include any performance measures and levels developed by CMS in consultation with States and other stakeholders. ''Performance measures'' or ''measures'' refer to how often a desired action or result is achieved or produced, such as the percent of two-year olds who are immunized. ''Levels'' refers to a specified percentage to be achieved or a measure.

Section 438.204(d) required an annual, external independent review of the quality outcomes and timeliness of, and access to, the services covered by the MCO or PIHP contract.

Section 438.204(e), (f), and (g) required that State strategies use intermediate sanctions; include an information system to support the operation and review of the strategy; and include standards for access to care, structure and operations, and quality measurement and improvement, all consistent with the requirements of other sections of this subpart.

Comment: One commenter suggested that States be required to use the definition of children with special health care needs established by the Bureau of Maternal and Child Health and, through monitoring the use of services, identify children who received subspecialty care.

Response: There are numerous definitions for individuals with special health care needs. However, health services research is still in the process of developing conceptual models, screening tools, and approaches to identifying these individuals. We, therefore, do not agree that this regulation should require States to use a particular definition. We provide States with the flexibility to define individuals with special health care needs. This regulation requires that States identify procedures to assess the quality and appropriateness of care provided to individuals with special health care needs and that States conduct reviews to evaluate the effectiveness of the strategy, including quality activities targeting individuals with special health care needs.

Comment: Many commenters strongly supported the provision that States be required to identify the race, ethnicity, and primary language spoken of each Medicaid enrollee and provide this to the MCO or PIHP upon enrollment. This supports the HHS goal of eradicating racial and ethnic disparities in health care by the year 2010. It also ensures that MCOs and PIHPs have the information necessary to comply with title VI of the Civil Rights Act of 1964. They allege that it has been long recognized that effective recording and reporting of data is the basis used to determine that Federal fund recipients are in compliance with the law.

Response: To ensure that Medicaid services are provided in a manner that meets the needs of beneficiaries, we retain the provision in § 438.204(b)(2) in the final rule.

Comment: One commenter urged that the regulation permit the collection of information on race, ethnicity, and primary language at both the State and MCO and PIHP level. They note that State data is not always accurate.

Response: In addition to the information provided to MCOs and PIHPs by the States, MCOs and PIHPs have the option to collect information on race, ethnicity and primary language. We are not requiring this in regulation but we note that States may do so.

Comment: One commenter asked for clarification on the level of specificity that would be required to meet the requirement to collect data on ethnicity.

Response: We are providing States with the flexibility to determine how they would like to define and categorize ethnicity. Ethnicity information is collected for census purposes and we encourage States to consider using standard categories used by the Bureau of the Census.

Comment: One commenter noted that race data in State eligibility systems is not always accurate and that identifying primary language will cost money to make required systems changes.

Response: We recognize that some States will need to modify their Medicaid Management Information Systems (MMIS) to collect data on primary language. We will allow States sufficient time to modify their systems to capture these data. We also recognize that the race data collected by States may not always be accurate and that it will always be subject to omission due to a variety of factors including beneficiary unwillingness to provide the information.

Comment: One commenter said that information on race, ethnicity, and primary language is not available from the Social Security Administration (SSA) for Supplemental Security Income (SSI) beneficiaries or that States do not control what information SSA collects. States should not be required to provide this information to MCOs unless it is available from SSA.

Response: Information on race is available from SSA on SSI beneficiaries and is available to States through the State Data Exchange (SDX) file. Information on ethnicity and primary language, however, is not available from SSA. We encourage States to pursue methods to collect information on ethnicity and primary language spoken for these beneficiaries. The information may be available in files of other State programs. We recognize that this information may not be complete for a variety of reasons.

Comment: One commenter said that the State has no legitimate interest in the primary language spoken by beneficiaries, as this does not indicate that use of English presents a barrier.

Response: We disagree with the commenter. We believe that the primary language spoken by a beneficiary indicates that there could be a potential barrier to appropriate use of health care services.

Comment: Several commenters said that data on race, ethnicity, and primary language are difficult to collect and unreliable due to the reliance on self-reporting. One commenter noted that undocumented parents may be reluctant to apply for benefits if this question is asked. The commenter further suggested that this provision be deleted or not required.

Response: Self-report data are used for numerous purposes including consumer satisfaction surveys and initial screening of beneficiary needs. There are methodological pros and cons to using any types of data, including self-report data. While we realize that self-report data about race, ethnicity, and language will not always be completely reliable, we believe that collecting it will allow MCOs, PIHPs, and PAHPs to take into account the cultural barriers that may undermine the delivery of health care to particular populations enrolled in the MCO. We do not believe that collection of this information will discourage undocumented parents from applying for benefits for eligible children because the question will be in reference to the children.

Comment: One commenter said that requiring beneficiaries to disclose race or ethnicity constitutes a potential violation of the Civil Rights Act.

Response: This rule does not require beneficiaries to disclose race or ethnicity. It requires States to make an effort to identify this information. In addition, the Civil Rights Act of 1964 does not prohibit a State or any other Federally assisted entity from asking a beneficiary to disclose his or her race or ethnicity. The failure to disclose the requested information, however, cannot be used as a basis to deny services or benefits to the beneficiary.

Comment: Several commenters noted that the requirement for States to collect information on race, ethnicity, and primary language would require systems modifications and training of intake staff. The commenter expressed the hope that CMS, when conducting compliance reviews, would be sensitive to the time it will take for States to fully implement this provision. Another commenter suggested that States may need technical assistance.

Response: We recognize that some States will need to modify their MMIS systems to capture these data, although we believe most States are already capturing data on race and ethnicity. We will allow States sufficient time to modify their systems to capture these data. We also recognize that training of intake staff may need to occur and that technical assistance to State may need to be provided. We plan to conduct training pertaining to the implementation of the provisions in this rule shortly after its publication.

Comment: One commenter suggested that the regulation require States to furnish MCOs and PIHPs with the age of children being enrolled along with information on race, ethnicity, and primary language spoken.

Response: The purpose of requiring States to identify race, ethnicity, and primary language is to facilitate the appropriate delivery of health care services. We believe that MCOs and PIHPs can adequately obtain age information from the enrollee and are, therefore, not requiring that the age of enrolled children be provided.

Comment: One commenter appreciated that we are permitting States to develop strategies for identifying race, ethnicity, and primary language, rather than requiring States to identify these factors.

Response: We believe the commenter misunderstood the provision. The regulation *requires* States to identify the race, ethnicity, and primary language of enrollees.

Comment: One commenter asked that States be required to provide the date of redetermination for new enrollees to MCOs and PIHPs. This would allow MCOs and PIHPs to outreach to enrollees to ensure that eligible beneficiaries continue to receive services.

Response: We do not agree that this regulation should require States to provide the date of redetermination for new enrollees to MCOs and PIHPs. If MCOs and PIHPs would find this information useful to provide continuity of services and do not currently receive it, we suggest that they raise this issue with their State.

Comment: One commenter asked that the requirement in proposed § 438.204(b)(3) for ''continuous'' monitoring be changed to ''periodic'' monitoring as continuous means nonstop, and this is an unreasonable requirement.

Response: We agree with the commenter and have revised § 438.204(b)(3) of the regulation text to provide for regular monitoring, as opposed to continuous monitoring.

Comment: Many commenters applauded the provision that performance measures and levels be identified and developed by CMS in consultation with States and other stakeholders. Some recommended that beneficiaries and groups that represent them should be among the stakeholders consulted. One commenter suggested that CMS ask the American Association of Health Plans (AAHP) to obtain recommendations and comments about proposed measures from MCOs. Others urged that performance measures be implemented in a way that allows MCOs to meet a realistic schedule. They further recommended that CMS take into consideration nationally demonstrated performance levels in both MCOs and in State fee-for-service (FFS) programs. One commenter recommended that any new measures be tested for one year to assess the data and results before States, MCOs and PIHPs are considered out of compliance.

Response: We anticipate that States, beneficiary advocacy groups, and MCOs and PIHPs would all be invited by CMS to participate in the process to develop standard measures. The implementation process would be discussed at this time and would include issues such as measure specifications, testing of measures, and measure reporting. States would need to ensure that their contracting MCOs and PIHPs collect any measures specified by CMS. We would encourage States to also use standard measures in their FFS programs. If CMS prescribes any national performance measures, it will consider a testing phase. Finally, should CMS consider setting levels for performance measures, we would consider levels used in both managed care and FFS programs.

Comment: One commenter suggested that the number of national measures be limited so as not to unnecessarily increase costs or burden or interfere with State efforts.

Response: We agree that national measures should be limited in number.

Comment: One commenter suggested that quality improvement initiatives must be recognized as long-term efforts

and that States and MCOs must partner to identify meaningful topics that should be measured, and track these over time. Continual, capricious changes to quality initiatives are not conducive to meaningful study and improvement.

Response: We agree with the commenter and acknowledge that a quality improvement initiative (the process of measuring performance, implementing interventions to respond to identified quality problems, and then remeasuring performance) needs sufficient time to be implemented and for findings to be made available. We do not prescribe the duration in which performance improvement projects must be completed. We expect States to require that a project be completed in a reasonable time period and that information be provided on the project's progress annually.

Comment: One commenter requested detailed standards to ensure that Medicaid children are receiving the care to which they are entitled. Specifically, the commenter recommended the regulation include standards for accreditation of MCOs and PIHPs, consumer satisfaction and quality of care ''report cards,'' and use of criteria consistent with national standards for assessing outcomes of care of children. In addition, the commenter suggested that CMS work with states to develop criteria and a timetable for improving the reporting of early and periodic, screening, diagnosis and treatment (EPSDT) services.

Response: The provisions under subpart D provide for access standards, structural and operational standards, and measurement and improvement standards. These standards apply regardless of the composition of the Medicaid population that is provided health care services through a State Medicaid managed care program. A review of these standards will be conducted as specified in the forthcoming final External Quality Review (EQR) regulation (64 FR 67223). As part of EQR, we have proposed that States may contract with external quality review organizations (EQROs) to conduct consumer surveys and validate and calculate performance measures and obtain a 75 percent enhanced Federal matching rate. Alternatively, States can have a contractor that is not an EQRO conduct these activities, and obtain the 50 percent administrative matching rate. States, the EQROs they contract with, or other State contractors will be able to extract information obtained from these quality measurement activities in a way that allows them to look at the quality of care of specified populations, including children. Regarding the comment about EPSDT, we do not believe that this is within the scope of this regulation.

Comment: Many commenters suggested that only non-medical PHPs (that is, transportation and dental) be excluded from the requirement for EQR and that a State audit substitute for the EQR for these entities.

Response: We have proposed to exclude all PAHPs, including transportation and dental PAHPs, from the EQR requirements. We believe that requiring EQR for PAHPs would impose an unreasonable burden given the limited scope of their services.

Comment: One commenter stated that many States conduct extensive quality reviews, either though another State agency or through an accreditation organization. These reviews, the commenter contended, are similar to or more rigorous than the CMS required external review and he suggested that, if a review is done by another State agency or an accreditation organization, that the MCO or PIHP be exempt from the EQR.

Response: We plan to address when an MCO or PIHP can be exempt from certain EQR activities or from EQR in its entirety in the final EQR regulation.

Comment: One commenter asked if it will be permissible to contract with State medical and allied health professional schools for EQR.

Response: We plan to address who is qualified to be an EQRO in the final EQR regulation.

Comment: One commenter mistakenly believed that we deleted the EQR requirement from the quality strategy and was in agreement with this deletion arguing that the requirement was excessive and costly.

Response: Section 1932(c)(2) of the Act requires an EQR of managed care activities. While we have included the EQR requirement as part of the quality strategy under this subpart, specific requirements regarding compliance with the EQR provision were published in a separate EQR Notice of Proposed Rulemaking on December 1, 1999 (64 FR 67223). The final EQR rule is forthcoming.

Comment: One commenter stated that some PIHPs have enrollments of less than 200 and serve fewer than 10 beneficiaries a year. The commenter is concerned that for these PIHPs the cost of an EQR could exceed the costs of providing health care services. The commenter suggested that for PIHPs include an option for Section 1115 and 1915(b) waiver programs allowing the use of the independent assessment of the waiver program in lieu of an EQR.

Response: The independent assessment requirement only applies to programs operated under section 1915(b) waivers, and if the assessment is found to be acceptable, is generally required for only the first two waiver periods. It does not apply to a managed care program conducted under section 1932(a) or section 1115 of the Act or one that enrolls beneficiaries in managed care on a voluntary basis. We therefore do not agree that this option is a suitable replacement for the EQR requirement. If a PIHP contracts with a State to provide services to Medicaid beneficiaries it will be required to comply with the provisions in this rule including the EQR requirements.

Comment: One commenter recommended that § 438.204(e), which requires the use of intermediate sanctions, be amended to indicate that it is applicable to MCOs only and not to PIHPs because subpart I does not apply to PIHPs.

Response: We agree with the commenter and have deleted the reference to PIHPs under § 438.204(e). In addition, to clarify the applicability of § 438.204(c), we have included language that clarifies that this provision applies to both MCOs and PIHPs.

4. Availability of Services (Proposed § 438.206)

Section 1932(c)(1)(A)(i) of the Act, as added by section 4705 of the BBA, requires each State that contracts with MCOs under section 1903(m) of the Act to develop and implement standards for access to care under its quality assessment and improvement strategy. Section 438.206 of the proposed rule established standards for access to care. Paragraph (a) required that States ensure that all covered services are available and accessible to enrollees. Paragraph (b) proposed new requirements for the delivery networks of MCOs and PIHPs. These requirements would be imposed on State agencies, which in turn would enforce these requirements on MCOs and PIHPs through contract provisions.

Specifically, paragraph (b)(1) proposed that all MCOs and PIHPs maintain and monitor a network of appropriate providers that is supported by written arrangements and is sufficient to provide adequate access to covered services. In establishing and maintaining such a network, the proposed rule required MCOs and PIHPs to consider (1) anticipated enrollment; (2) the expected utilization of services, considering enrollee characteristics and health care needs; (3) the numbers and types of network providers required to furnish contract

services; (4) the number of network providers who are not accepting new patients; and (5) the geographic location of providers and enrollees, considering distance, travel time, the means of transportation normally used by enrollees, and whether the location provides physical access for enrollees with disabilities.

In § 438.206(b)(2) we proposed that the State be required to ensure that MCOs and PIHPs allow women direct access to a woman's health specialist for women's routine and preventative services. Proposed § 438.206(b)(3) required that MCOs and PIHPs provide for a second opinion from a qualified health care professional within the network, or arrange for the enrollee to obtain one outside the network, at no cost to the enrollee. In paragraph (4), we proposed that the MCO or PIHP must cover medically necessary services for enrollees obtained outside the network if, and for as long as, they cannot be obtained from within the network. Paragraph (5) of the proposed rule required out-of-network providers to coordinate with the MCO and PIHP with respect to payment and ensure that the cost to the enrollee is no more than it would be if the services were provided within the network. In paragraph (6), we proposed that MCOs and PIHPs demonstrate that their providers are credentialed in accordance with § 438.214(b).

Paragraph (c)(1) required MCOs and PIHPs to meet State standards for timely access to services and to require that their providers also meet these standards. It also required MCOs and PIHPs to (1) ensure that network providers offer hours of operation that are no less than the hours of operation offered to commercial enrollees or comparable Medicaid fee-for-service, if the provider serves only Medicaid enrollees; (2) make services available 24 hours a day, 7 days a week, when medically necessary; (3) establish mechanisms to ensure compliance with these requirements; (4) monitor for compliance continuously; and (5) take corrective action if there is a failure to comply.

Paragraph (c)(2) required that the State ensure that each MCO and PIHP participate in State efforts to promote the delivery of services in a culturally competent manner to all enrollees with limited English proficiency and diverse cultural and ethnic backgrounds.

Comment: Many commenters said that the provisions in proposed § 438.206 should apply to all PHPs because PAHPs should have the same requirements for an adequate provider network as applies to MCOs and PIHPs. One commenter said that this section should apply to dental plans.

Response: We agree with the commenters that the availability of services provisions should apply to PAHPs. Therefore, in § 438.206 of the final rule, we have added ''PAHP'' in each instance in which the terms ''MCO or PIHP'' appeared in the proposed rule. Therefore, these requirements will now apply to dental PAHPs. We note that the types of providers that a PAHP must include in its network is limited to those needed to provide the services under its contract.

Comment: Several commenters supported the provisions at § 438.206(a) requiring that all covered services be available and accessible.

Response: We agree with the commenters and believe that these provisions are consistent with the intent of the Congress concerning the development and implementation of standards for access to care.

Comment: Many commenters said that proposed § 438.206(b) fails to provide for direct accountability by States in that it provides only that States ensure compliance *through their contracts.* These commenters believe that this wording does not require States to ensure that the contract provisions are carried out in practice.

Response: We agree with the commenter. We now specify in the regulation that § 438.206 be reflected in contracts with MCOs, PIHPs, and PAHPs, because it is essential that these requirements be included in the contract to be enforceable by the State. The regulation also requires, at § 438.204(b)(3), that States ''monitor and evaluate the MCO, PIHP, and PAHP compliance with the standards''.

Comment: One commenter said that a requirement that MCOs have a network ''sufficient to provide adequate access to all services under the contract'' is a significant departure from 1902(a)(30)(A) of the Act that requires the State to establish methods, procedures, and payments ''sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in a geographic area''. The commenter is concerned that the language in the proposed regulation obligates the State to guarantee that all covered services are available at all times, which may be beyond the ability of the State due to shortages of service providers.

Response: Section 1902(a)(30)(A) is a requirement that applies to the State's fee-for-service program, operated pursuant to the State plan. The provision that specifically governs the availability of services under a State's managed care program is section 1932(c)(1)(A)(i) of the Act, which requires that services be available ''in a manner that ensures continuity of care and adequate primary and specialized services capacity.'' We believe that the provisions of § 438.206(b)(1) carry out the intent of the Congress under section 1932 to provide access standards that will ensure the availability of care in MCOs, PIHPs and PAHPs.

Comment: One commenter expressed support for the provision requiring networks to have experienced providers.

Response: We agree that it is important that MCOs, PIHPs, and PAHPs have experienced providers in order to provide quality care to Medicaid enrollees. This is especially true for enrollees with special health care needs, whose needs may be sufficiently rare or complex due to multiple conditions that a provider, even one who is a specialist, may have little or no experience in treating the enrollee's condition or conditions. Accordingly, in section 438.206(b)(1)(iii) we specify that the MCO, PIHP, or PAHP must consider the training, experience, and specialization of providers.

Comment: One commenter recommended adding language to require MCOs and PIHPs that serve children with special health care needs to include appropriately trained physicians in their network, including pediatric specialty and subspecialty physicians.

Response: We do not believe it necessary to include an explicit requirement for specific specialty and subspecialty physicians for particular groups of enrollees. The general requirement that a network be adequate to provide access to all services under the contract, taking into account the anticipated enrollment and the expected utilization, is sufficient to ensure that the network will be adequate to meet all needs. Inclusion of language related to particular groups may even be detrimental in that it would be impossible to list the particular requirements of all groups.

Comment: One commenter suggested that we add an explicit requirement that MCOs and PHPs pay particular attention to the needs of enrollees with disabilities when developing and maintaining networks. Without such a provision, the commenter is concerned that specialized psychiatric treatment for children and adults with severe mental illness may not be available. The commenter believes that the inclusion of such a requirement has the potential

to bring psychiatrists who refuse to treat FFS Medicaid beneficiaries into the program because MCOs would use their market power to recruit these providers.

Response: As stated above, we do not agree that we should address the special needs of particular groups of enrollees for specialty providers. We believe that the requirement of the regulation for adequate provider networks will cause the States to include appropriate requirements in their contracts with MCOs, PIHPs, and PAHPs and that the assurances of adequate capacity and services, provided under § 438.207 of this regulation, will further ensure that provider networks include the range of providers necessary to meet the needs of their enrollees.

Comment: Several commenters suggested that the regulation include a provision that MCOs and PIHPs pay particular attention to pregnant women and individuals with special health care needs because MCO and PIHPs may interpret a general requirement to require only an overall survey of enrollees, rather than a targeted assessment of the needs of the most vulnerable and ill patients.

Response: For the reasons stated above, we do not agree that the regulation should include a specific provision for these groups. We believe that the intent of this regulation is clear, that is, that the needs of all enrollees must be met through the provider network.

Comment: One commenter said that the regulation should require States to ensure that MCOs and PIHPs consider and address existing underutilization problems when establishing and monitoring their service networks.

Response: The regulation places an affirmative obligation on States and MCOs, PIHPs, and PAHPs to consider the needs of their anticipated enrollees and provide an adequate provider network to meet those needs. We believe that this requirement makes it unnecessary to include a provision to address existing underutilization problems.

Comment: Several commenters said that the regulation should require MCOs and PIHPs that seek to expand their service areas to demonstrate that they have sufficient numbers and types of providers to meet the anticipated volume and types of services enrollees in those areas will require. Failure to include this provision could violate sections 1902(a)(19) and 1932(b)(5) of the Act which require State plans to provide safeguards to assure that services be provided, and MCOs to provide assurances that they have the capacity to serve the expected enrollment, respectively.

Response: We do not agree that it is necessary for the regulation to specifically require that MCOs, PIHPs, and PAHPs that seek to expand their service areas have sufficient numbers and types of providers to meet the expected increased enrollee volume. The general requirement that MCOs, PIHPs, and PAHPs have adequate networks applies whatever the service area. Furthermore, § 438.207(c) requires that MCOs, PIHPs, and PAHPs submit documentation to the State at any time there has been a significant change in their operation, including changes to the geographic service area.

Comment: Many commenters asked that a provision be included in the regulation to require States to make available all services included in the State plan and make information available to beneficiaries on how to access these benefits. The commenter is concerned that without this requirement important community services that many State plans include through the Rehabilitation Option, such as services that are part of the assertive community treatment model, will not be accessed by beneficiaries.

Response: States are required to make available to all beneficiaries all services covered in the State plan. States may use voluntary or mandatory managed care to provide some or all of these services. If the beneficiary is enrolled in an MCO that does not provide all Medicaid services, or is enrolled in a PIHP or PAHP (which, by definition, is not a comprehensive risk contract), the State remains responsible for making available all Medicaid services not covered in the contract. The regulation provides that both potential enrollees and current enrollees be informed about the services not covered under the contract and how and where they can be obtained. See § 438.10(e)(2)(ii)(E) and (f)(6)(xii).

Comment: Many commenters said that the rule should require States to notify enrollees how and where to obtain services, including transportation, for services covered by the State plan but not included in the MCO, PHP, or PCCM contract.

Response: Section 438.10(f)(6) requires the State, it's contracted representative, or the MCO, PIHP, PAHP, or PCCM to notify enrollees annually of their right to request this information. In addition, § 438.10(e)(2)(i)(E) requires that this information be provided to potential enrollees at the time the potential enrollee first becomes eligible to enroll in a voluntary program or is first required to enroll in a mandatory program.

Comment: One commenter expressed concern that use of a distance standard for urban enrollees could force travel to outlying suburban areas or neighboring counties. The commenter would like the final rule to include language to protect urban enrollees from needing to make lengthy trips to obtain services.

Response: The regulation provides that the State must ensure through its contracts that the provider network is accessible to enrollees, taking into account several factors related to geographic location of providers and enrollees. Depending on State and local circumstances, we believe that the significance of the factors listed—distance, travel time, and means of transportation ordinarily used by Medicaid enrollees—will differ. For urban enrollees, States may find that the latter two factors are more important considerations than distance. When using distance for enrollees in urban areas, we believe that States will factor in the other elements and select a distance criterion that meets the overall intent of the regulation. We believe that the State is in the best position to determine how these criteria should be applied in each of its service areas.

Comment: Many commenters applauded the use of the term ''women's health care specialist'' because they believe that it recognizes the important role played by a variety of health care professionals in addition to physicians. These commenters asked that ''routine and preventative'' be defined in order to ensure that MCOs and PIHPs do not place barriers to impede women's access to women's health specialists. According to the commenters, the definition should include initial and follow up visits for prenatal care, mammograms, pap tests, family planning, and treatment of vaginal and urinary tract infections and sexually transmitted diseases.

Response: We believe that the use of the words ''routine and preventative'' in the regulation is sufficient to categorize the types of services that women can access directly through a women's health specialist.

Comment: One commenter seeks inclusion of a requirement that children have direct access to pediatricians, including specialists. The commenter noted that the regulation provides for direct access to women's health specialists and that the patient's rights legislation endorsed by the Administration provides for direct access to pediatricians.

Response: We do not believe that it is appropriate to require direct access to

pediatricians. While we believe that most children enrolled in Medicaid managed care will have pediatricians as their primary care physicians, pediatricians are not locally available in all areas of the country, and some children will use other physicians, such as family physicians, as their source of primary care. We believe that direct access should generally be to the primary care physician. For women's routine and preventative care we make an exception to this rule because we think it appropriate that women have the choice to see a women's health specialist for routine and preventative care rather than a generalist or other specialty physician.

Comment: One commenter said that the regulation should require direct access to psychiatrists.

Response: We do not agree that the regulation should provide direct access to psychiatrists. We are concerned about coordination of care and believe that States should have the option to require that patients be referred to psychiatrists by their primary care physician. This helps to ensure that the primary care physician is cognizant of both the physical and mental health needs of patients and has the information needed to coordinate the care needed by patients.

Comment: One commenter asked that we retain the provision for out-of-network second opinions from health care professionals, which are not currently available. The commenter stated that a second opinion for a denied service from an in-network provider is a meaningless right.

Response: We disagree with the commenter. The proposed rule provided for a second opinion from a provider in the network, if one is available, and from a provider outside the network only if there is not another qualified provider within the network. We believe that it is important to provide an enrollee with the right to a second opinion, but we believe that this does not require access to a second opinion from a provider who is out of the network.

Comment: Several commenters believe that second opinions should be given by participating physicians when one in the specialty is available. Enrollees would then only be allowed to go out of network when no qualified alternative exists with the network.

Response: As stated in the previous response, the proposed and final rule provide enrollees the right to a second opinion from a provider within the network if a qualified health care professional within the network is available to provide the second opinion. When a qualified health care professional is not available within the network to give a second opinion, the enrollee may obtain it from a health care professional who is not in the network.

Comment: One commenter suggested that the regulation require that second opinions regarding care for a child be provided by physicians with appropriate pediatric education and training. This would be consistent with the pending patient's bill of rights.

Response: The rule specifies that the health care professional giving the second opinion must be qualified to do so. We leave to the States the responsibility for determining the qualifications to be used. States best know their health care markets and are responsible for setting provider qualifications and, therefore, are in the best position to make this decision.

Comment: One commenter suggested that the regulation limit second opinions from out-of-State providers to instances in which a qualified professional is not available within the State. In addition, the commenter asked that the regulation require that the nearest out-of-State provider be used.

Response: The regulation provides that second opinions be obtained from a provider in the network if such a qualified provider is available. This limitation applies when the desired out-of-network provider is within or outside of the State. We have not added other requirements to this provision, as recommended by the commenter. This allows States to decide, or to allow MCOs, PIHPs, and PAHPs to decide, who is to provide a second opinion when one is to be obtained from an out-of-network provider.

Comment: One commenter believes that CMS should conduct studies to determine if second opinions routinely result in a change of treatment plan and in better outcomes. Unless it can be established that second opinions result in better outcomes, they do not warrant the extra cost.

Response: We disagree that CMS should study if second opinions result in a change of treatment plan or in better outcomes to document their benefit before establishing them as an enrollee right. Second opinions are widely used and accepted in both FFS and managed care service delivery systems. In FFS, Medicaid beneficiaries can freely access a second opinion by simply seeing another physician. Likewise, in FFS, insurance companies often require confirmatory second opinions before authorizing certain services or procedures. We believe that second opinions are well established in the practice of medicine in this country and should be available to Medicaid managed care enrollees.

Comment: Two commenters asked that the regulation limit payment to non-participating providers to the Medicaid FFS fee schedule.

Response: We do not require that non-participating providers be paid according to the Medicaid FFS fee schedule. We believe that States are in the best position to determine whether payment limits should apply to out-of-network providers or if the MCO, PIHP, and PAHP should be free to negotiate rates.

Comment: One commenter asked that we retain the requirement that MCO and PIHPs pay for services received out of network when they are not available in the network because this will lead to less disenrollment. Another commenter supported inclusion of this provision.

Response: We agree that it is the responsibility of the MCO, PIHP, or PAHP to pay for services, covered under their contracts, received out of network when they are not available from within the network. The MCO, PIHP, or PAHP must arrange for all services needed by their enrollees. We agree that establishing this as an MCO, PIHP, and PAHP responsibility will decrease enrollee disenrollments. We retain this provision in the final rule.

Comment: Many commenters supported the provision that services received out of network may not result in costs to the enrollee greater than would have been within the network. One commenter asked that the wording be revised so that MCOs and PIHPs would not be responsible for actions by out-of-network providers in relation to fees charged to enrollees.

Response: We believe that it is important that Medicaid enrollees not be placed at a financial disadvantage should their MCO, PIHP, or PAHP refer them to an out-of-network provider for a covered service because a qualified provider is not available in the network. The MCO, PIHP, or PAHP must negotiate the amount they will pay the provider and, as part of this negotiation, can best ensure that the enrollee does not incur out-of-pocket costs.

Comment: One commenter expressed the opinion that the hours of operation offered commercial enrollees is not relevant to the Medicaid contract. He believes that this requirement is impossible to oversee or enforce and could result in a decrease in the number of providers available to serve Medicaid beneficiaries. Another commenter believes that it is not realistic for Medicaid to achieve this standard because Medicaid reimburses providers significantly less than commercial