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

plans. And another commenter said that it is not usual practice for States to track providers' hours of operation if they do not treat Medicaid patients. One commenter said that the requirement should be that services are available and accessible to the same extent that they are for FFS beneficiaries or the general public. Another commenter supported the provision as written.

Response: In the final rule we have retained the provision related to hours of operation as proposed. The purpose of this requirement is to make certain that Medicaid enrollees have the same access to providers as do enrollees of other payers. We believe that the provision is appropriate and is enforceable by MCOs, PIHPs, and PAHPs through their contracts with providers. Access can be monitored by the State or the MCO, PIHP, or PAHP by reviewing patient appointments or by monitoring enrollee grievances. The commenter who stated that States do not track providers' hours of operation if they do not treat Medicaid patients misunderstood the provision. It applies only to providers in Medicaid managed care networks. For those providers who serve only Medicaid patients, we set the hours of operation for FFS Medicaid patients as the standard that must also be applied to managed care enrollees.

Comment: One commenter suggested that proposed § 438.204(b)(3) should not require States to ''continuously'' monitor hours of operation, as this represents an increased burden on States. Rather the regulation should require that States monitor for this requirement ''regularly''.

Response: We agree that the use of the term ''continuously'' may be confusing and that ''regularly'' better conveys our intent. We have revised § 438.204(b)(3) of the regulation to reflect this change.

Comment: Many commenters said that the requirement that MCOs participate in States' efforts to promote the delivery of care in a culturally competent manner is not sufficient. They believe that systems of care must be designed to be respectful of and responsive to cultural and linguistic needs in order to provide equal access to quality health care. Failure to provide information about treatment options in a culturally sensitive way could affect patient compliance, lead to declines in the patient's health, and escalate costs.

Response: We agree that health care needs to be delivered in a culturally competent manner for it to be most effective. However, in the final regulation we have retained the provision of the proposed rule, that MCOs, PIHPs, and PAHPs participate in State efforts to promote the delivery of care in a culturally competent manner, because we believe that it is through this requirement that MCOs, PIHPs, and PAHPs, will gain the knowledge and experience to provide culturally competent care.

Comment: Several commenters supported the approach taken in the NPRM regarding cultural competency and believe that the State is in the best position to lead initiatives on cultural competency. This allows States to advance initiatives crossing FFS and managed care.

Response: We agree with the commenters and have retained this provision in the final rule.

Comment: Many commenters said that MCOs, all PHPs, and PCCMs should be required to provide services in a culturally competent manner because, as recipients of Federal funds, they are all required to do this.

Response: This regulation requires MCOs, PIHPs, and PAHPs to participate in State efforts to promote cultural competency in order to comply with the requirements of section 1932 of the Act. It does not address requirements of other statutes that might also apply.

Comment: One commenter objected to the Medicaid rule having what he viewed as weaker requirements relating to cultural competency than the Medicare+Choice rule. He noted that in the preamble to that rule CMS stated that the M+C provisions are consistent with title VI of the Civil Rights Act, recommendations from the President's Race Initiative, and the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry.

Response: Medicaid is a State/Federal program and States retain responsibility for much of the program and operational policy of their programs. We believe that States can best decide how to advance cultural competency in their managed care programs. We are working with the Medicare program to develop tools for managed care organizations to use to improve the delivery of culturally competent health care. When these tools are available, we will share them with States so that they can use them at their option.

Comment: One commenter suggested that the new standards developed by the Office of Minority Health (National Standards on Culturally and Linguistically Appropriate Services) be referenced as a more detailed document that clarifies the regulatory provision.

Response: We agree that these guidelines are a valuable tool and we encourage States to review them and consider their use.

Comment: Many commenters suggested the addition of a provision to prohibit discrimination by providers toward Medicaid enrollees. One commenter noted that the President's Commission on Consumer Protection and Quality in the Health Care Industry opposed discrimination on the basis of source of payment.

Response: We have decided not to include a provision in the regulation to prohibit providers from discriminating against Medicaid enrollees. We do not believe that this provision is needed in this regulation. States remain responsible for ensuring Medicaid enrollees adequate access to providers and are in the best position to choose the mechanisms they believe will be effective to ensure this result. We also have a provision in the regulation that requires that network providers offer Medicaid enrollees the same hours of operation offered to commercial enrollees. We believe that this requirement will help ensure equal access for Medicaid enrollees to providers.

Comment: Many commenters recommended inclusion of a provision to require States that limit freedom of choice to comply with the requirements of § 438.52.

Response: The requirements related to freedom of choice at § 438.52 apply in accordance with the provisions of that section. It is unnecessary to reiterate or cross reference those requirements in this section.

5. Assurances of Adequate Capacity and Services (Proposed § 438.207)

Under the authority of section 1932(b)(5) of the Act, proposed § 438.207(a) required that the MCO and PIHP provide the State with adequate assurances that the MCO or PIHP has the capacity to serve the expected enrollment in the service area. Proposed § 438.207(b) required that documentation submitted to the State must be in a format set by the State and acceptable to CMS and must demonstrate that the MCO or PIHP offers an appropriate range of services, including preventative services, primary care services, and specialty services. The MCO and PIHP was also required to document that it maintains a network of providers sufficient in number, mix, and geographic distribution.

Section § 438.207(c) specified when documentation must be provided including (1) at the time the MCO or PIHP enters into a contract with the State, and (2) whenever there has been a significant change in the MCO's or PIHP's operations that would affect adequate capacity and services such as

changes in services provided, benefits, geographic service areas, payments, or enrollment of a new population.

Comment: One commenter recommended that this section apply to dental plans.

Response: We agree that it is important for PAHPs, including dental plans, as well as MCOs and PIHPs to have adequate provider networks and to provide the State with assurances as to the adequacy of their networks. Therefore, in the final rule, we extend the provisions of this section to PAHPs. We note that the provider network for PIHPs and PAHPs need only include provider types necessary to provide the services included in their contracts.

Comment: One commenter stated that MCOs and PIHPs need to contract with the appropriate number and mix of pediatric-trained specialists and tertiary care centers for children in order to ensure that they have adequate capacity to serve their expected enrollment. If a plan fails to contract with an adequate number of these providers, the plan should be required to provide these services out of network at no additional cost.

Response: As we stated earlier in this preamble, we have chosen not to specify types of specialists or other providers that health plans must contract with in order to meet the requirements of the regulation. Rather, in § 438.206(b)(1), we retain the general requirement that provider networks must be adequate to provide adequate access to all services covered under the contract. In § 438.206(b)(4), we provide that necessary medical services not available within the network, must be covered by the MCO, PIHP, or PAHP out of network.

Comment: One commenter suggested that this provision be revised to require the State to ensure, through its contracts, that MCOs provide a full range of psychiatric services and have a sufficient number of psychiatrists participating in the plan.

Response: As stated above, in the final rule we are not specifying specific provider types needed by MCOs, PIHPs, and PAHPs, but rather providing a general requirement that the networks be sufficient to provide adequate access to covered services to all enrollees.

Comment: One commenter disagreed with CMS' decision to interpret ''adequate assurances'' to require extensive documentation suggested in the preamble. The commenter believes that extensive and detailed data are often of little use in determining the adequacy of the provider network and that network deficiencies are often found when an enrollee changes primary care physicians, calls enrollee services, or files a grievance.

Response: We continue to believe that it is necessary and appropriate for the regulation to require that each MCO, PIHP, and PAHP document that it has adequate provider capacity to provide necessary medical services. The heading for section 1932(b)(5) of the Act is ''Demonstration of Adequate Capacity and Services.'' We believe that the MCO, PIHP or PAHP cannot demonstrate that it has the capacity to serve its expected enrollment without providing documentation. In addition, we require that the State have documentation to support its certification to the Secretary under § 438.207(d). This documentation is required prospectively to avoid problems that may otherwise not be detected until an enrollee complains or takes other steps to address a situation caused by the lack of an adequate provider network.

Comment: Many commenters objected to the omission of a provision to require MCOs and PIHPs to have in place policies and procedures to respond to situations in which there is an unanticipated need for providers with particular types of expertise or an unanticipated limitation on the availability of such providers. The commenters believe that such a provision is necessary to meet the statutory requirement for a quality strategy that includes access standards to ensure that covered services are available within reasonable timeframes and in a manner that ensures continuity of care and adequate primary care and specialty care. Another commenter supported the omission of such a provision.

Response: We have not included a provision in the final rule to require MCOs, PIHPs, and PAHPs to have policies and procedures in place to respond to situations in which there is an unanticipated need for providers or a limitation on the availability of needed providers. We again rely on the requirement in § 438.206(b)(1) and § 438.206(b)(4) that MCOs, PIHPs, and PAHPs must have adequate provider networks or, if the MCO, PIHP, or PAHP is unable to provide them, must adequately and timely provide these services out of network.

6. Coordination and Continuity of Care (Proposed § 438.208)

Proposed § 438.208 contained provisions specifying how the care of Medicaid beneficiaries enrolled in MCOs and PIHPs is to be provided in order to promote coordination and continuity of care, especially with respect to individuals with special health care needs. In proposed paragraph (a) we allowed for two exceptions to some of these coordination and continuity of care provisions. In the first instance, provisions pertaining to some screening, assessment and primary care requirements would apply to PIHPs as the state determines appropriate, based on the scope of the PIHP's contracted services and the way the state has organized the delivery of managed care services. In the second instance, for Medicaid-contracting MCOs that serve certain Medicaid enrollees also enrolled in Medicare+Choice plans and receiving Medicare benefits, the State similarly determines, based on the services it requires the MCO to furnish to dually eligible enrollees, the extent to which the MCO must meet certain screening, assessment, referral, treatment planning, primary care and care coordination requirements. In proposed paragraph (b) we put forth requirements for the state Medicaid agency to identify certain enrollees with special health care needs and to further identify these enrollees to its enrollment broker, if applicable, and contracting MCOs and PIHPs. In proposed paragraph (c) we specified requirements for the screening and assessment of individuals with special health care needs. In proposed paragraph (d) we specified requirements for referrals and treatment plans for MCO and PIHP enrollees determined to have ongoing special conditions that require a course of treatment or regular care monitoring. These requirements addressed access to specialists and the development of treatment plans. In proposed paragraph (e) we specified requirements pertaining to MCO and PIHP care coordination programs, including requirements that these programs: provide each enrollee with an ongoing source of primary care, coordinate each enrollee's health care services, appropriately share with other MCOs and PIHPs the results of any screenings or assessments in order to prevent unnecessary burden on the enrollee, and protect enrollee privacy and confidentiality.

One commenter heartily endorsed § 438.208 of the proposed rule and urged CMS to preserve it in the final rule and monitor for compliance with it. However, many other commenters recommended that this section of the regulation include more specific or stronger requirements for States and managed care entities, particularly with respect to the care of individuals with special health care needs. Most commenters offered specific

recommendations for changing this section of the regulation. We agree with these comments and have revised § 438.208 as discussed below, in response to these comments.

Identification of ''At Risk'' Individuals

Comment: Many commenters recommended that we require States to identify individuals ''at risk'' of having special health care needs. Many of these commenters identified these individuals as: children and adults who receive SSI benefits; children in foster care; enrollees over the age of 65; enrollees in relevant, state-established, risk-adjusted, higher-cost payment categories; and any other category of recipients identified by CMS. A few commenters recommended that we allow States to use additional State-identified categories of people who are ''at risk'' for having special health care needs. One commenter stated that children under age 2 and pregnant women should be identified as being ''at risk'' of having special health care needs. Another commenter stated that children enrolled in a State's Title V program for children with special health care needs should be included in a regulatory definition of persons ''at risk'' of having special health care needs.

Response: The proposed rule at § 438.208(b) required States to identify individuals ''with'' (as opposed to individuals ''at risk of having'') special health care needs. For several reasons, we believe it is appropriate to retain this distinction in this final rule, and not additionally require States to identify individuals ''at risk of having'' special health care needs. First, States already well appreciate the increased risk that certain populations (for example, children and adults who receive SSI benefits; children in foster care; enrollees over the age of 65; and enrollees in relevant, state-established, risk-adjusted, higher-cost payment categories) have for needing special services or high levels of service. States can also readily identify these individuals. We do not believe that regulations are necessary to call States' attention to these individuals or that States need encouragement or assistance in identifying these individuals. To additionally require States to create a new administrative mechanism in order to categorize as ''at-risk'' those individuals who are already well-known to State Medicaid agencies and can be easily identified, would dilute the attention paid to individuals who actually have special health care needs. Instead, in § 438.208(c) of this final regulation we require States to focus their attention more closely on identifying individuals who actually have special health care needs. Second, the concept of ''at risk'' of having special health care needs (beyond the categorical groups discussed above) is widely recognized as difficult to put into operation. Well-known researchers in this field have explicitly declined to address the concept of ''at risk'' when developing screening tools to identify children and adults with special health care needs. Because the science in this area is still elementary, we believe it is premature to ask States to implement this concept at this time. Finally, we note that commenters did not agree among themselves on which populations should be included in a category of ''at risk of having'' special health care needs. For these reasons, in this final rule we do not require States to identify individuals ''at risk'' of having special health care needs.

Definition of Individuals With Special Health Care Needs

Comment: Many commenters recommended that proposed § 438.208(b) should specify certain groups of individuals as ''having'' special health care needs. Many of the recommended groups were identical to the groups identified by other commenters as individuals who should be considered ''at risk'' of having special health care needs. Specifically, the following groups were recommended by many commenters: children and adults who are receiving SSI benefits; children in foster care; enrollees over the age of 65; enrollees in relevant, state-established, risk-adjusted, higher-cost payment categories; and any other category of recipients identified by CMS. Many commenters also identified children under age 2 and other enrollees known by the State to be pregnant or having other special health care needs as categories of persons requiring special attention and about whom the State should notify the MCO/PIHP of their having a special health care need.

Other commenters stated that proposed § 438.208(b) should specify a threshold or minimum definition of persons with special health care needs. One commenter stated that the definition should be as follows, ''Individuals with special health care needs include adults and children who daily face physical, mental, or environmental challenges that place at risk their health and ability to fully function in society (for example, individuals with mental retardation or serious chronic illnesses, pregnant women, children under the age of 7, children in foster care or out-of-home placement, and individuals over age 65).'' Other commenters stated that children with special health care needs should be defined consistent with the Department's Maternal and Child Health Bureau's definition which reads, ''Children with special health care needs are those who have or are at elevated risk for chronic physical, developmental, behavioral, or emotional conditions and who also require health and related services of a type or amount not usually required by children.''

In contrast, several commenters expressed support for allowing States to define which populations need to be identified and how to identify them. One commenter asked us to confirm that the proposed rule would allow States the flexibility to define ''individuals with special health care needs.'' Another commenter stated that the requirement for States to identify enrollees with special health care needs and identify these enrollees to its enrollment broker (if applicable) and MCOs should be eliminated. The commenter stated that this requirement is neither feasible nor practical because (1) the State does not have a mechanism to identify persons with special health care needs—other than individuals who receive SSI; (2) enrollees may not choose to reveal information about their health, which should be held between the enrollee and his or her provider, and possibly the health plans; and (3) the appropriate mechanism for identifying a person with a special health care need is through an assessment which is required elsewhere in the regulation.

Response: In our report to the Congress, Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care, dated November 6, 2000, we identified, ''the presence or increased risk of disability,'' as a shared characteristic of populations with special health care needs. We identified 6 populations as examples of groups that had an increased prevalence or risk of disability: (1) Children with special health care needs; (2) children in foster care; (3) individuals with serious and persistent mental illness and/or substance abuse; (4) individuals who are homeless; (5) older adults with disabilities; and (6) non-elderly adults who are disabled or chronically ill with physical or mental disabilities. However, this same report, while calling these groups to the attention of States, recognized the difficulty that States face in identifying not just population *groups* that have an increased prevalence or risk of disability, but in identifying *individuals* who actually have a special health care need. Because of this, we entered into a contract with

the Foundation for Accountability (FACCT) to produce a reference manual for State Medicaid agencies and other interested parties. The manual will present and discuss reliable and valid approaches to identifying individuals who have special health care needs. In addition, we asked FACCT to develop a new screening tool that can be used to help identify adults with special health care needs. This adult screener has now been developed and tested. It, along with other valid and reliable approaches to identifying adults and children with special health care needs, will be included in the reference manual for States. Because this research conducted for us by FACCT has documented that there are different ways (with varying degrees of sensitivity, specificity, and resource implications) to identify individuals with special health care needs, we do not believe it appropriate to require one approach, and thereby one definition. Rather, we encourage States to review these different approaches, in conjunction with beneficiaries and stakeholders, as a part of their State quality strategy developed under § 438.204, and select the approach or approaches to identifying individuals with special health care needs that best complements the design of the State's Medicaid program and managed care initiatives.

Comment: Many commenters recommended that States also be required to identify enrollees with special health care needs to PAHPs and PCCMs.

Response: We agree with the commenters and we have revised § 438.208(c) to include PAHPs. However, we have not applied these provisions to PCCMs because, as noted elsewhere in this preamble, the statutory provisions of the BBA, which authorized these quality requirements, apply only to prepaid, capitated forms of managed care.

Screening and Assessment

Comment: Many commenters expressed confusion over the use of the words ''screening'' and ''assessment'' in § 438.208(c) of the proposed rule. One commenter erroneously stated that the provisions for screening and assessment of special needs individuals were not contained in the proposed regulation. Many commenters stated that the proposed rule did not differentiate between the words, ''screening'' and ''assessment.'' One commenter urged us to specify that an initial screen must be sufficient to identify individuals with special health care needs and facilities that can meet those needs, and that a health assessment must be comprehensive and include a physical examination.

Response: We agree that the proposed rule provisions at §§ 438.208(b) and (c) respectively calling for ''State responsibility to identify certain enrollees with special health care needs,'' and ''Screening and assessment'' are confusing, in part because of some redundancy. The proposed rule intended to convey that identification of individuals with special health care needs should be accomplished through some form of screening. Therefore, we have revised § 438.208(c) and replaced the word ''screening'' with the words, ''mechanisms to identify.'' This change is supported by information from several experts in screening who reminded us that screening tools by their very nature are not perfect, and that subsequent follow-up through a more intensive assessment is needed in order to better determine if an individual's special health care needs actually require a course of therapy or monitoring. We also made other changes to the organization of this section in order to better distinguish the identification activity from the assessment function.

However, we did not, as requested by one commenter, specify that an initial screen (identification mechanism) must be sufficient to identify facilities that can meet an individual's special needs. We believe that determining appropriate facilities, when care in a facility is needed, should not be based on the results of a screen or identification mechanism, but upon an assessment and ongoing communication between the patient and his or her health care provider(s). We further did not explicitly state in § 438.208(c)(2) that the enrollee's health assessment must be comprehensive because we believe that ''comprehensive'' is subject to varying interpretations, and therefore is not readily able to be reliably monitored or consistently enforced by CMS. Further, the provisions in § 438.208(c)(2) already require assessments to ''identify any ongoing special conditions of the enrollee that require a course of treatment or regular care monitoring'' and that the assessment mechanisms must use appropriate health care professionals. We also have not required that the assessment include a physical examination, because we believe that for some individuals, a course of treatment or regular care monitoring might be determined to be unnecessary without a physical examination. We therefore defer to States to set further standards for assessment, noting that these standards for identification and assessment are included as part of a State's quality strategies under § 438.204. Therefore, any State standards for assessment will be developed with the input of Medicaid beneficiaries and other stakeholders. We believe that any greater specificity in requirements pertaining to assessments should be developed as a part of this process.

Comment: One commenter stated that proposed § 438.208(c) failed to quantify what will be substantial burden associated with the requirements for screening and assessment.

Response: It would be very difficult to more accurately quantify the overall impact and burden of this provision of the regulation because of the variation in State programs and how States will choose to implement these provisions. In § 438.208(c) of the final rule we have retained State flexibility in identification, assessment, treatment planning for individuals with special health care needs, and with respect to how provisions will be applied to MCOs, PIHPs, and PAHPs that serve dually eligible enrollees. Because of our desire to allow States to have this flexibility, and the variations in practice that currently exist within the managed care industry, it is not possible to more accurately quantify the burden of these provisions.

Comment: One commenter stated that it could not comply with the requirement stated in the preamble to proposed § 438.208 that in instances when an MCO is not able to meet requirements for screening or assessment for an individual enrollee, because, for example, it is not possible to contact the enrollee or the enrollee refused to respond to the MCO, that the MCO ensure that the reason why the enrollee could not be screened or assessed be documented in the enrollee's medical record. The commenter stated that it does not own its contracted providers and does not have the ability to enforce the requirement.

Response: We disagree with the commenter. We believe that MCOs can include this as a requirement in their written agreements with participating providers. However, the commenter is incorrect in indicating that we have required this in the preamble. Rather, the preamble states that an MCO or PIHP ''should'' take steps to ensure that this information is documented.

Identification

Comment: One commenter asked us to clarify CMS's goal with respect to individuals with special health care needs given the commenter's

observation that these individuals will have great variability in the coverage and care they will receive between States. One commenter stated that § 438.208(b) of the proposed rules did not emphasize clearly the importance of identifying all persons with special health care needs. A few commenters expressed concern that the proposed rule did not contain provisions that would require the State to have a strategy to identify enrollees with special health care needs. One commenter stated that the regulation does not contain requirements that MCOs have procedures in place to identify individual enrollees with serious and multiple medical conditions, ''whether they be physical-health, mental health, or substance-abuse related in nature.'' The commenter maintained that CMS must include these provisions. A few commenters stated their support for a requirement that MCOs must screen all enrollees to detect special health care needs. A few commenters also stated that each MCO and PHP should be required to implement a mechanism to identify enrollees who develop special health care needs after they enroll in the MCO or PIHP. One commenter asked if CMS would be monitoring States with respect to the requirement in § 438.208(b) pertaining to State's responsibility to identify certain enrollees with special health care needs, and if so, if the monitoring will use a tool that has been developed for CMS by FACCT.

Response: We have revised § 438.208(c)(1) and (c)(2) to clarify our goals with respect to individuals with special health care needs and emphasize the importance of identifying the individuals. We did not, as one commenter directed, require MCOs to have procedures in place to identify individual enrollees with serious and multiple medical conditions, ''whether they be physical-health, mental health, or substance-abuse related in nature,'' because we believe that the State should be the one to consider the issues as it develops its mechanism to identify individuals with special health care needs, as part of its quality strategy, and with the input of Medicaid recipients and other stakeholders. In our revisions, we also did not require each MCO and PIHP to implement a mechanism to identify enrollees who develop special health care needs after they enroll in the MCO or PIHP. We believe that the extent to which this should occur should be considered by the States in the context of the States' overall strategy and mechanism for identifying individuals with special health care needs. Finally, we affirm that CMS will be monitoring States with respect to the requirement to identify enrollees with special health care needs. However, we note that the tool that has been developed for CMS by FACCT is a screening tool, not a monitoring tool. Additionally, it is one of several screening tools that will be shared with States for their discretionary use. Therefore, the FACCT tool is not likely to be used by CMS for monitoring activities.

Assessment

Comment: One commenter stated that the proposed rule does not contain provisions that MCOs assess the condition of individual enrollees with serious and multiple medical conditions. The commenter maintained that CMS must include these provisions. Another commenter stated that the regulation should specify groups of beneficiaries for whom special health assessments should be required so that there will not be significant variation in access and quality of care among the various state Medicaid programs. In contrast, other commenters expressed support for the provisions of the regulation pertaining to assessment of people with special health care needs and for allowing states and plans to develop timelines and procedures that meet the needs of their enrolled population. Still other commenters further expressed support for allowing States to determine how to assess individuals with special health care needs.

Response: The final regulation contains requirements that MCOs (and also PIHPs and PAHPs at the discretion of the State) assess individual enrollees with special health care needs. We believe that individuals with ''serious and multiple medical conditions'' are included in the concept of special health care needs, and intend that States' mechanisms to identify individuals with special health care needs will identify individuals with serious and multiple medical conditions. However, in § 438.208(c)(1) we allow States the discretion of determining how to identify individuals with special health care needs, and therefore how to implement this concept. Consistent with this position, we do not believe that we should specify groups of beneficiaries for whom special health assessments should be required.

Initial Assessments

Comment: One commenter expressed concern that the proposed regulation does not require MCOs or PHPs to conduct initial assessments of all new Medicaid enrollees, noting that Medicare+Choice plans are required to conduct the assessments.

Response: We used the term ''initial assessment'' in a Medicaid proposed rule published on September 29, 1998 (63 FR 52022) to implement these same statutory provisions. Since that time, we have received numerous and ongoing comments that the purpose and scope of an ''initial'' assessment has not been well understood. The words ''initial assessment'' do not appear in widespread use in the private sector or in health services research or policy studies. We have attempted to address this problem in subsequent versions of the regulation, and in § 438.208(c)(1) and (c)(2) of this final regulation, by dropping the terminology ''initial assessment'' and separating out what we believe are the two essential activities; that is, identifying individuals who have special health care needs, and assessing their needs. We do not believe it necessary to further specify the need for primary care providers operating under the auspices of an MCO, PIHP, or PAHP to assess the health of their patients, because we believe this to be a well-established component of primary health care.

Timeframes

Comment: One commenter stated that the regulation must ensure that people with identifiable risks for having special health care needs receive an expedited review of their health care needs. Many commenters stated that the final rules should include a health assessment soon after enrollment to identify pregnant women's health care needs and course of treatment. Many other commenters stated that the regulation should specify timeframes for managed care entities to screen and assess individuals with special health care needs, individuals ''*at risk*'' of special health care needs, and other enrollees. Many of these commenters recommended a variety of specific timeframes as follows. MCOs and PHPs should be required to: (1) Screen enrollees identified as ''*at risk*'' by the State within 30 days of the enrollees being so identified; (2) screen all other enrollees within 90 days of enrollment to determine whether the enrollee is pregnant or has a special health care need; (3) for any screened enrollee identified as being pregnant or having special health care needs, provide a comprehensive health assessment as expeditiously as the enrollee's health condition requires, but no later than 30 days from the date of the identification;

(4) for enrollees identified by the State as being pregnant, or who have self-identified as being pregnant or having special health care needs, provide a comprehensive health assessment within 30 days without needing an initial screen. Other commenters stated that screening should be performed on enrollees identified by the State as having special health care needs within 30 days after having been so identified by the State. One commenter stated that the regulation should require initial assessment of each pregnant woman by her MCO as soon as possible, but always within 30 days of enrollment. The commenter also stated that standards for individuals with complex and serious medical conditions should be similarly revised. Another commenter recommended that each MCO and PHP be required to make a best effort to screen the following individuals within 30 days of their being identified: Children and adults who receive SSI, children in Title IV–E foster care, enrollees over the age of 65, and enrollees in relevant, state-established, risk-adjusted, higher cost payment categories, and other categories identified by CMS. This commenter also recommended that each MCO and PHP be required to make a best effort to assess individuals who are pregnant or who have a special health care need within 30 days of their being identified. Another commenter recommend that disabled children and adults, foster children, enrollees over the age of 65, pregnant enrollees and infants and toddlers be screened by their MCOs within 30 days; other MCO enrollees should be screened within 90 days. Several other commenters, however, did not recommend a specific timeline. One commenter stated that timelines should be specified in advance by the State and approved in advance by CMS.

In contrast, one commenter stated that proposed § 438.208(c) and (d) that pertain to assessment and treatment of people with special health care needs are realistic and allow States and plans to develop timelines and procedures that meet the needs of their enrolled population. Another commenter expressed support for allowing States the authority to determine workable timeframes for their individual programs.

Response: We have carefully reviewed all the suggestions, and we do not believe it best for the Federal government, rather than the States, to establish timeframes specifying when all managed care entities are to screen and assess individuals with special health care needs, individuals ''at risk'' of special health care needs, and other enrollees. We believe that it would be more appropriate and effective for screening and assessment timelines to be established by the State agency, in consultation with beneficiaries and other stakeholders, taking into consideration access and availability standards set by the State, the definitions and mechanisms chosen by the State agency to identify individuals with special health care needs, the character of the state's managed care marketplace, and State and/or local standards in both the public and private marketplace. With respect to the comment that timelines should be specified in advance by the State and approved in advance by CMS, we note that because we believe that any necessary timelines should be established by the State based on State considerations, CMS would not likely have more relevant information than the State, on existing access and availability standards set by the State, definitions and mechanisms chosen by the State agency to identify individuals with special health care needs, the character of the State's managed care marketplace, and State and/or local standards in both the public and private marketplace. We therefore decline to require prior Federal approval of State timelines.

Treatment Plan

Comment: Many commenters supported our proposed § 438.208(d) that pertains to a treatment plan for enrollees with special health care needs, but disagreed with the provision in § 438.208(d)(2) that states that the decision is left to the discretion of the enrollee's MCO/PHP of whether or not an individual with special health care needs would receive a treatment plan. Many commenters further stated that the regulation should indicate the individuals for whom health plans must develop and implement treatment plans, including individuals with special health care needs and pregnant women, particularly those pregnant women at high risk such as those with gestational diabetes or with a history of miscarriages.

Many commenters also suggested a number of additional provisions be added to the requirements for a treatment plan; specifically, that treatment plans: (1) Be appropriate to the enrollee's identified and assessed conditions and needs; (2) be for a specific period of time and updated periodically; (3) specify a standing referral or an adequate number of direct access visits to specialists; (4) ensure adequate coordination of care among providers; (5) be developed with enrollee participation and (6) ensure periodic reassessment of each enrollee as his or her health condition requires. A few commenters stated that the treatment plan should be required to be appropriate to the standard of care for the enrollee's condition and identified needs. Other commenters noted that the Medicare+Choice regulations require a treatment plan for all enrollees with serious medical conditions. One commenter stated that the regulation should add a new provision requiring that, ''the MCO or PHP must continue the existing treatment plan of an enrollee until an initial assessment of that enrollee occurs.'' The commenter stated that this provision would address the adverse effects that individuals can experience when there is an interruption in the ongoing clinical treatment of their illness or health condition. One commenter recommended the inclusion of requirements that treatment plans include direct access to specialists as required by the treatment plan and that the treatment plan be updated periodically by the physician responsible for the overall coordination of the enrollee's health.

In contrast, a few other commenters supported the provisions of the regulation pertaining to assessment and treatment of people with special health care needs, stating that the provisions are realistic and reasonable and allow states and plans to develop timelines and procedures that meet the needs of their enrolled population. One commenter stated that the enrollee, provider, and MCO clinical staff should determine the provisions that need to be included in a member's treatment plan. One commenter expressed support for allowing states to determine the extent to which MCOs must put in place mechanisms to allow enrollees to participate in the development of the treatment plan. One commenter recommended that an additional exemption be created in paragraph (a) with respect to the requirement that there be consultation with the primary care provider in the development of the treatment plans. The commenter noted that in his or her State, fee-for-service primary care providers are not a part of the specialty managed care network, and are not responsible for coordinating their primary care with mental health professionals. The commenter recommended that a new exception be added as section 438.208–(a)(2) (iii) ''to consult with the enrollee's primary care provider in the development of a treatment plan as specified in paragraph (d)(2) of this section.''

Response: We have revised § 438.208(c)(2) of this regulation, that

left the decision of whether or not an individual with special health care needs receives a treatment plan up to the discretion of the enrollee's MCO, PIHP, or PAHP. We agree with many of the commenters that this decision should not be left up to the MCO, PIHP, or PAHP and have revised the regulation to give States the authority to determine the extent to which treatment plans would be required. States will be required to address this as a component of their quality strategy and to develop these standards with input from Medicaid recipients and other stakeholders.

For a variety of reasons, we disagree with commenters that we should add certain other requirements for treatment plans; that is that treatment plans be required to: (1) Be appropriate to the enrollee's identified and assessed conditions and needs; (2) be for a specific period of time and updated periodically; (3) ensure periodic reassessment of each enrollee as his or her health condition requires; and (4) be required to be appropriate to the standard of care for the enrollee's condition and identified needs. We found a number of these requirements to be vague and therefore difficult to monitor and enforce, and not providing significant benefit to beneficiaries; for example, ''be for a specific period of time and updated periodically,'' ''appropriate to * * * conditions and needs'' and ''appropriate to the standard of care for the enrollee's condition and identified needs.'' In addition, we note that two of these proposed additions to treatment plan requirements are more strongly addressed elsewhere in this section. The recommended requirement that the treatment plan specify a standing referral or an adequate number of direct access visits to specialists is addressed in paragraph (c)(4), Direct Access to Specialists, which states that, ''For enrollees determined through assessment to need a course of treatment or regular care monitoring, each MCO, PIHP, and PAHP must have a mechanism in place to allow enrollees to directly access a specialist (for example, through a standing referral or an approved number of visits) as appropriate for the enrollee's condition and identified needs.'' The recommended requirement that the treatment plan ensure adequate coordination of care among providers is addressed in paragraph (b), *Primary care and coordination of health care services for all MCO, PIHP, and PAHP enrollees.* We also did not add a requirement that, ''The MCO or PHP must continue the existing treatment plan of an enrollee until an initial assessment of that enrollee occurs.'' We believe that the situation, which the commenter has identified, is addressed by the provisions at § 438.208(b) pertaining to primary care and coordination of health care services.

Direct Access to Specialists

Comment: One commenter stated that proposed § 438.208(d) that pertains to direct access to specialists should be clarified that direct access to a specialist should be a determination made in concert with the primary care physician, health plan, patient, and specialist based on each patient's specific circumstances, not made through a screening instrument that identifies an individual as having special health care needs. Another commenter expressed support for the regulatory provisions allowing States to determine MCOs mechanisms through which Medicaid enrollees with special health care needs will have direct access to specialists.

Response: We agree that a decision about access to specialists should not be based on the results of screening. In § 438.208(c)(4) of the final rule, we clarify that access to specialists should be made as a result of a more detailed assessment using (consistent with § 438.208(c)(2)) ''appropriate health care professionals.'' We believe appropriate health care professionals include the enrollee's primary care provider, but not necessarily the MCO or a specialist. Participation of the enrollee in this decision is guaranteed under the provisions in § 438.100 (b)(2)(iv) pertaining to the enrollee's right to participate in decisions regarding his or her health care.

Exemptions

Comment: One commenter expressed support for the exemption allowing State Medicaid agencies to determine to what extent any MCO that serves enrollees who are also enrolled in a M+C plan and receive Medicare benefits must meet the screening and assessment, referral and treatment plan, and primary care and coordination requirements of proposed § 438.208(c), (d), and (e)(1) (now § 438.208(b) and (c)). The commenter recommended that dual eligible enrollees receive one screening and assessment that satisfies requirements for Medicare+Choice.

Response: We appreciate and agree with the commenter's support for the provision in § 438.208(b) and (c) that allow State Medicaid agencies to determine to what extent any MCO that serves enrollees who are also enrolled in a M+C plan and receive Medicare benefits must meet requirements pertaining to coordination, identification, assessment, and treatment planning. We agree that it is desirable for dual eligible enrollees to receive one screening and assessment that satisfies requirements for both Medicaid and Medicare+Choice, but we are not imposing this requirement at this time, in recognition of the operational and policy issues that first must be addressed in order to accomplish this and because it may not be feasible in all instances.

Patient Confidentiality and Sharing of Information

Comment: One commenter expressed concern about the provision of proposed § 438.208(e)(3) which would require MCOs and PIHPs to share with other MCOs and PIHPs serving an enrollee, the results of its screening and assessments so that those activities need not be duplicated. The commenter understood of the intent of the provision but expressed concern over possible effects on patient confidentiality. The commenter offered no specific recommendation to address these competing concerns. Another commenter noted that the requirements might present concerns about patient confidentiality if MCOs are not able to obtain enrollee consent for the sharing of information. One commenter supported the proposed regulation's provision in § 438.208(e)(4) pertaining to the protection of enrollee privacy.

Response: We also share commenters' concerns about protecting the privacy of patient information. For this reason, we have retained the provision, now at § 438.208(b)(4), that states that, ''* * * in the process of coordinating care, each enrollee's privacy is protected in accordance with the privacy requirements in 45 CFR parts 160 and 164, subparts A and E, to the extent that they are applicable.

Primary Care and Coordination Program

Comment: One commenter noted that the proposed regulations in § 438.208(e) allowed primary care coordination to be conducted by ''a person or entity.'' The commenter stated that it is inappropriate to allow MCOs or PHPs to delegate management of an enrollee's health care to an unlicensed or non-credentialed person or entity. The commenter recommended that primary care coordination be performed by a health care professional, as that term is defined in proposed § 438.102. One commenter recommended that CMS should describe in the regulation necessary coordination efforts and include specific references and examples.

Response: We have retained the wording, ''a person or entity'' in this final rule to acknowledge that sometimes care coordination might be performed by an organization, such as a Federally Qualified Health Center (FQHC), as opposed to an individual. We have not described in the regulation necessary coordination efforts and specific references and examples because we believe that there are more appropriate vehicles than this regulation for disseminating best practices, reference materials and examples of care coordination.

Monitoring

Comment: One commenter recommended that CMS: (1) Closely monitor State agency and managed care entity procedures to identify any problems or disruptions in the continued treatment of patients with mental illness, including a substance abuse disorder; (2) provide direction to the State or State agency to facilitate effective solutions; and (3) use CMS resources to assure that continuity and coordination is maintained.

Response: We will closely monitor State agencies and their managed care initiatives to identify any problems or disruptions in the services or treatment of all Medicaid enrollees, including enrollees with special health care needs such as mental illness and/or substance abuse. When deficiencies are found, we typically direct the State agency to undertake solutions and use our resources to assure that the solutions are effective.

Factors That Hinder Access

Comment: Many commenters recommended an addition to MCO/PIHP coordination provisions at proposed § 438.208(e) to require plans to have in effect procedures to address factors, such as lack of transportation, that may hinder enrollee access to health care treatments or regimens.

Response: We do not agree with this recommendation. We know that many States and MCOs, PIHPs, and PAHPs in the absence of federal regulations, have in effect procedures to address factors, such as lack of transportation, that may hinder enrollee access to health care treatments or regimens. However, we believe that the extent to which these procedures should be the responsibility of the MCO, PIHP, or PAHP in contrast to the State agency or other agent of the State, is a decision best made by the State agency.

Maintenance of Health Records

Comment: Many commenters recommended that a provision be added to require each MCO and PHP to ensure that its providers have the information necessary for effective and continuous patient care and quality improvement, consistent with certain confidentiality and accuracy requirements. Many commenters also recommended that each MCO and PHP be required to ensure that each provider maintains health records that meet professional standards and that there is appropriate and confidential sharing of information among providers.

Response: We believe that both of these issues are already addressed in other sections of the regulation. Section 438.242, *Health Information Systems,* requires the MCO and PIHP to maintain a health information system that ''collects, analyzes, integrates, and reports data and can achieve the objectives of this subpart'' and ''ensures that data received from providers is accurate and complete.'' We believe that this requirement is a stronger and more effective standard than a requirement that each provider maintain health records that meet professional standards. In addition, § 438.224, *Confidentiality,* requires each MCO and PIHP to establish and implement procedures in accordance with confidentiality requirements in 45 CFR parts 160 and 164. We believe these provisions more strongly address confidential sharing of information among providers.

7. Coverage and Authorization of Services (Proposed § 438.210)

Proposed § 438.210 set forth requirements to ensure that each contract with an MCO or PIHP identifies all services offered under the contract, and that the MCO or PIHP establishes and follows written policies and procedures for processing requests for services in a manner that ensures appropriate beneficiary access to these services. Further, the proposed requirements would ensure that utilization management activities are not structured in a manner that is detrimental to enrollees. These standards implement sections 1932(b)(1) and (b)(4) of the Act.

In § 438.210(a) we proposed that the State, in its contracts with MCOs and PIHPs, identify, define, and specify the amount, duration, and scope of all Medicaid benefits that the MCO or PIHP must furnish. Furthermore, the contract must specify what constitutes medically necessary services to the extent they are described in the State plan, and provide that the MCO or PIHP furnish the services in accordance with that provision. We believe that it is important for enrollees and providers to know that the contract includes specific information on all services available under the contract and how the State applies its medical necessity criteria. We also required that the contract be clear on coverage of services related to (1) the prevention, diagnosis, and treatment of health impairments; (2) the ability to achieve age appropriate growth; and (3) the ability to attain, maintain, or regain functional capacity.

In § 438.210(b) we required that MCOs and PIHPs, and their subcontractors, have in place and follow written policies and procedures for initial and continuing authorization of services. We also required that MCOs and PIHPs consistently apply review criteria when authorizing services; consult with the requesting provider, when appropriate; and that decisions to deny requests for authorizations, or authorize a service in an amount, duration, or scope that is less than was requested, must be made by a health care professional who has the appropriate clinical expertise in treating the enrollee's condition or disease.

In paragraph (c), we proposed that MCO and PIHP contracts provide that written notice of decisions to deny a service authorization request or to authorize the request in an amount, duration, or scope that is less than what was requested be provided to the enrollee and the provider. The notice to the enrollee must be in writing.

In paragraph (d), we proposed timeframes for decisions to authorize services. For standard authorization decisions, the notice must be provided as expeditiously as the enrollee's health condition requires and within State-established timeframes that do not exceed 14 calendar days following the request for service. A 14 calendar-day extension would apply at the enrollee's or provider's request or if the MCO or PIHP justifies a need for additional information and how the extension is in the enrollee's interest. We believe that an extension would be in the enrollee's interest when more information is needed for the MCO or PIHP to authorize the service and failure to extend the timeframe would result in a denial of the authorization.

For expedited authorization decisions, we proposed that the MCO or PIHP have a maximum of 3 working days after receipt of the request to make a decision. This period could be extended for 14 days under the same circumstances as apply for standard decisions.

In proposed § 438.210(e), we required that each MCO and PIHP contract must provide, consistent with § 438.6(g) and § 438.210(a)(2), that compensation to

individuals and entities that conduct utilization management activities not be structured so as to provide incentives to deny, limit, or discontinue medically necessary services to enrollees.

Comment: One commenter expressed the opinion that § 438.210 should apply to dental plans.

Response: We agree with the commenter. We decided to extend the provisions of § 438.210 to include PAHPs as well as MCOs and PIHPs because we believe that enrollees of PAHPs need the protections provided under this section. This includes dental plans as well as other PAHPs. We note that the services included in the plans are limited to those provided for under the contract and that the provisions are not always applicable to certain PAHPs, for example, transportation PAHPs.

Comment: Several commenters recommended a Federal definition of medical necessity be included in the regulation that includes access to habilitative services. One commenter said that habilitative services are important for children and adults with severe mental impairments.

Response: We do not agree that the regulation should include a Federal definition of medical necessity. There currently exists no widely accepted national definition and at present States are allowed, under § 440.230(d), to ''place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures,'' and have great flexibility in defining those criteria. Therefore, we do not believe it is appropriate to promulgate a national definition. However, we believe it is necessary to provide some specific guidance regarding what State contracts must include. In particular, we believe that whatever a State's fee-for-service Medicaid program uses as medical necessity criteria should not be further restricted by Medicaid MCOs, PIHPs, and PAHPs. Making this clear to all parties should decrease the potential for dispute. If the State's fee-for-service medical necessity criteria address whether a service is needed ''to attain, maintain or regain functional capacity,'' the regulation requires the contract with the MCO, PIHP, or PAHP to address this as well. We believe this would address the extent to which habilitative services are considered medically necessary. While we are not mandating that specific services must be covered to meet these goals, the contract must clearly address the extent of each MCO's, PIHP's, and PAHP's responsibility to provide such services.

Comment: One commenter asked that the words ''enrollee's ability to attain, maintain, or regain maximum function * * * could be jeopardized'' should be deleted from the definition of medical necessity, as this definition is so broad that it could be applied to nearly all medical necessity determinations.

Response: These words are not part of a definition of medical necessity. Rather, they make clear that State policies related to medical necessity under fee-for-service address any of the items listed in § 438.210(a)(4)(ii), then the State's contract with an MCO, PIHP or PAHP must also address these items. We believe this greater clarity will decrease the potential for disputes, among beneficiaries, the State and MCOs, PIHPs, and PAHPs.

Comment: One commenter expressed concern that the proposed rule allows MCOs and PIHPs to limit services on the basis of the medical necessity definition and utilization controls. This commenter noted that the EPSDT provision of the Medicaid statute ensures children the full range of needed health care services and recommended specific language in the regulation to ensure this end.

Response: Under § 440.230(d) States already have the authority to ''place limits on a service based on such criteria as medical necessity or on utilization control procedures'' and have great flexibility in defining those criteria. This provision also applies to services provided through the EPSDT program.

This managed care regulation does not affect any of the pre-existing EPSDT regulations. Furthermore, some States may choose to provide EPSDT services outside of the managed care contract. We believe it is redundant and unnecessary to repeat all existing requirements in this regulation, which focuses on managed care programs.

Comment: One commenter expressed concern that an MCO should not be ''placed in the middle of a decision'' by a provider to deny a service based on ''field experience and clinical documentation''. The commenter said that their State has consumer safeguards in place, both in the coverage and authorization process and grievance and appeal process, to protect enrollees.

Response: Section 1932(b)(4) of the Act requires that MCOs have internal grievance procedures for enrollees. Therefore, we must provide for such a process in the regulation and the MCO or PIHP must approve or disapprove a provider's decision.

Comment: Several commenters asked that the notice of action and right to appeal be removed in the case of a physician who denies a request for service, as this is not a realistic requirement and would trigger service continuation requirements. The commenter stated that there is no practical way for an MCO to know that a physician counseled against a medical service. Also, the requirement is unduly burdensome, particularly as it relates to modified requests for service authorizations that are agreed to by the requesting provider. One commenter said that this requirement is inconsistent with industry and Medicaid practice.

Response: We acknowledge that it is difficult for an MCO or PIHP to know when a physician counseled against a service and that it would be burdensome to require physicians to provide notice of denial to enrollees or to inform the MCO or PIHP that a requested service was not provided. To address this issue, in the final rule, at § 438.404(b)(1), we have revised the regulation to specify that the enrollee has the right to appeal a denial by the MCO or PIHP. The physician's decision to provide a service does not trigger an appeal right. This will require the enrollee who wishes to receive a service that the physician will not provide to contact the MCO or PIHP to request approval of the service. A denial of the service at that point by the MCO or PIHP will constitute an action that may be appealed by the enrollee. In response to the comment related to service continuation, we note that services must be continued only if they have been approved in advance by the MCO or PIHP, or by a provider acting on behalf of the MCO or PIHP.

Comment: One commenter asked for clarification that § 438.210 applies to provider requests for authorization and not when a beneficiary requests a service that the provider does not find to be medically necessary.

Response: As explained in the previous response, we specify in the final rule that the appeal right is triggered when an action is taken by the MCO or PIHP to deny a requested service or authorize it in an amount, duration, or scope that is less than was requested by the enrollee.

Comment: One commenter asked if the regulation intends to require that a ''clinical peer'' within the MCO be used to deny a service authorization. If so, the commenter stated that this would impose an additional requirement beyond what is required in State law (which permits any licensed physician to deny an authorization). This would require a significant change in operation for MCOs in that State.

Response: We do not use the term ''clinical peer'' to describe the qualifications of the health care

professional who must make a service authorization decision. Rather we say that the health care professional must have ''appropriate clinical expertise in treating the enrollee's condition or disease''. We believe that this criterion provides States latitude to specify what clinical experience will be required for individuals making authorization decisions. We also do not specify that the health care professional must be employed by the MCO or PIHP. This permits MCOs and PIHPs to contract for the services of health care professionals if they choose and the State approves.

Comment: One commenter believes that the standard set by the regulation, that prior authorization decisions be made by a health care professional who has appropriate clinical expertise, is unclear and may lead to unnecessary litigation. The commenter also noted that this standard is not imposed in FFS, nor is this expertise required at a State fair hearing.

Response: We believe that it is important that individuals who make authorization decisions for MCOs and PIHPs have appropriate medical knowledge and clinical experience when making these decisions. This supports the credibility of decisions and may be a factor in the enrollee's decision to appeal. In FFS and State fair hearings the situation is different, but in both cases, professional clinical judgments are available. In FFS, the beneficiary has an option to seek out another provider should a physician not agree to provide requested services. For State fair hearings, beneficiaries may present medical evidence in support of their claims.

Comment: One commenter suggested changing ''treating'' to ''assessing'' or ''evaluating'' in regard to the health care professional who must deny or limit a service authorization request. This would allow clinicians some latitude to determine if their level of expertise is appropriate for the review. The State in which the commenter resides holds licensed physician professionals accountable for consulting with appropriate specialists for each decision to deny care.

Response: We continue to believe that the requirement should be that health care professionals have clinical experience in treating the condition or disease under review. As noted above, we believe that the requirement provides some latitude for States to determine what experience is appropriate. We do not think it appropriate for a health care professional without clinical treatment experience to make judgments regarding treatment.

Comment: One commenter said that the lack of a definition of ''appropriate'' in § 438.210(b)(3) is problematic. This relates to health care professionals with the expertise to deny a service authorization request.

Response: We believe that the word ''appropriate'' conveys a responsibility to the State to specify further criteria to meet the intent of this provision. We do not believe that Federal regulations should provide greater detail as we are not able to address all medical situations or local conditions. We believe this responsibility should rest with the States.

Comment: One commenter suggested that the health care professional denying a request for services should be required to see the patient.

Response: We do not agree that a health care professional denying a request should be required to see the patient. We include a requirement under § 438.210(b)(2)(ii) that the MCO or PIHP policies and procedures include consultation with the requesting provider, when appropriate. We believe that this requirement will ensure that the MCO or PIHP has the information needed to make an informed decision.

Comment: One commenter suggested that we add ''or who has considered advice from a health care professional with clinical expertise in treating the enrollee's condition or disease'' at the end of § 438.210(b)(3).

Response: We do not agree that it is sufficient for the decision maker to rely on information gained through consultation with a clinical expert. We believe that the decision maker must be capable of rendering a decision based on his or her own expertise. Therefore, we have not revised the regulation as requested by the commenter.

Comment: Several commenters asked how we define ''standard decisions,'' as no definition is provided in the regulation.

Response: A standard decision is one that does not meet the criteria for an expedited decision. These criteria are specified in § 438.210(d)(2) and again at § 438.410(a).

Comment: Many commenters urged that expedited authorizations be required to be made within 72 hours rather than in 3 working days. A 72-hour standard would ensure that decisions are made in a timeframe consistent with the urgent medical needs of the case. This would also apply to Medicaid enrollees the same protections that apply to other private and public health programs and are consistent with the provision of the patient's bill of rights.

Response: In § 438.210(d)(2), we have retained the maximum timeframe for expedited decisions at 3 working days because this provides a State flexibility to set a timeframe that it believes appropriate while protecting beneficiaries by stipulating a maximum timeframe. The regulation also requires that the decision be made ''as expeditiously as the enrollee's health care condition requires.'' This provides beneficiaries further protection when a quicker decision is necessary because the timeframes set by the State would seriously jeopardize the enrollee's life or health.

Comment: Many commenters disagreed with the provision that would allow MCOs and PIHPs to extend the timeframe for expedited authorization decisions by 14 days when the extension is in the interest of the enrollee. The commenters believe that this provision undermines the strength of the shorter timeframe for expedited decisions and lessens the likelihood that the expedited timeframe will be met in practice. They also note that the provision is inconsistent with the Employee Retirement Income Security Act (ERISA) rules governing employer-sponsored groups and the patients' rights legislation supported by the Administration.

Response: We retain the provision that allows the MCO or PIHP to extend the decision period by up to 14 days when the extension is in the best interest of the enrollee. We believe this protects the enrollee in situations in which sufficient information is not available to authorize a service at the end of the 3-day period. Without this provision, the enrollee would be denied the service and would need to appeal the denial to pursue the request. With this provision, the MCO or PIHP can continue to pursue the outstanding information and, ultimately, approve the request, if appropriate.

Comment: One commenter suggested that the timeframe for authorization should begin when all information necessary to make a decision is received by the MCO and not when the enrollee's request is first denied.

Response: We have not accepted this comment because this would require a separate decision that all information needed to make a decision has been received. The authorization decision is generally made when information sufficient to make a decision is reviewed by the deciding health care professional. We believe that it is an important protection for the enrollee that the timeframe begin when the request for service is denied. It also provides an incentive for the MCO or

PIHP to promptly gather information needed for a decision.

Comment: One commenter said that the 14-day extension should not apply when MCOs and PIHPs make late requests for additional information.

Response: It would be difficult to assess when a request for information is late, as the deciding health care professional may find a need for additional information when reviewing the information associated with the request. Therefore, we do not believe that this is an appropriate standard to use.

Comment: One commenter asked that the regulation not provide a national timeframe for authorization decisions. Rather, States should be required to set standards based on community norms.

Response: We note that the timeframe provided in the regulation is a maximum timeframe; States may set shorter timeframes if they choose. We continue to believe that it is appropriate to set a maximum national timeframe as an important protection to Medicaid managed care enrollees.

Comment: Several commenters asked for a provision to prohibit requests for authorizations from having unnecessary or unduly burdensome information requirements for enrollees or providers. The commenters believe that such a provision is necessary to prohibit MCOs and PIHPs from increasing the ''hassle factor'' on physicians as a means of cutting costs.

Response: It is not possible or reasonable to regulate against unnecessary or burdensome information requirements. States have other tools to ensure that MCOs and PIHPs with which they contract are not deliberately making it difficult for enrollees to access services. These include monitoring grievances and appeals by enrollees; requirements for adequate provider networks, as providers are unlikely to contract with MCOs or PIHPs that make it difficult for them to provide services; and other monitoring by the State.

Comment: Many commenters asked that the regulation include a provision to require that MCO and PIHP policies and procedures for decisions on coverage and authorization of services reflect current standards of medical practice. One commenter believes that omission of such a provision suggests that providers would be permitted to have policies and procedures that do not reflect current medical practice standards.

Response: We believe that such a provision is unnecessary as the requirement related to medical necessity will ensure that coverage and authorization decisions reflect current standards of medical practice. The omission of this as a requirement in no way implies that States or CMS sanction or permit practitioners to have policies and procedures contrary to current standards of medical practice. On the contrary, the provision on practice guidelines at § 438.236 requires that MCOs, PIHPs, and PAHPs (where appropriate) adopt and disseminate practice guidelines to their contracting providers to ensure that enrollees' care is consistent with the latest and most effective clinical practices.

8. Provider Selection (Proposed § 438.214)

Proposed § 438.214 required State Medicaid agencies to ensure that contracted MCOs and PIHPs have written policies and procedures for the selection and retention of providers and a documented process for the initial credentialing and recredentialing of providers. It also required that MCOs and PIHPs not discriminate against providers who serve high-risk populations or specialize in conditions that require costly treatment. Finally, it prohibited MCOs and PIHPs from contracting with providers excluded from participation in Medicare and State health care programs.

Comment: One commenter asked that language be added under § 438.214(b) to say ''state-licensed providers'' and add ''of primary care, including at a minimum, physicians, psychologists, physician assistants, midwives, and nurse practitioners''.

Response: The definition of provider, at § 400.203, as amended by this regulation, requires that the individual or entity be legally authorized by the State to deliver health care services. Therefore, it is not necessary to say ''state-licensed providers.'' In addition, it is not necessary to specifically list types of providers, as the definition of provider is broad enough to encompass these types of individuals or entities.

Comment: Many commenters recommended that we apply the Medicare+Choice credentialing rules to Medicaid MCOs, PIHPs, and PAHPs.

Response: We have decided not to apply the Medicare+Choice credentialing rules. Since each State Medicaid managed care program is unique, we do not believe that it would be appropriate to create detailed national standards. The regulation was written to promote State flexibility to manage their programs. However, we agree that there should be a uniform State standard for credentialing and recredentialing and have revised § 438.214(b) to require the State to set this standard policy. These policies and procedures must, at a minimum, include a documented process for credentialing and recredentialing, not discriminate against providers that serve high-risk populations or specialize in conditions that require costly treatment, and may not employ or contract with providers excluded from participation in Federal health care programs. We also revised § 438.214 to apply it to PAHPs, based on general comments requesting that all the provision of subpart D apply to PAHPs.

Comment: One commenter expressed approval of not including specific requirements in the regulation but asked that CMS require States to use a process consistent with the credentialing guidelines of the National Committee on Quality Assurance (NCQA).

Response: We have decided not to require States to use a process consistent with NCQA's credentialing guidelines. It is up to each State to decide if they want to use these guidelines. Our regulation only requires MCOs, PIHPs, and PAHPs to implement written policies for the selection and retention of providers. However, we do require that each State set a uniform credentialing policy for all of its MCOs, PIHPs, and PAHPs.

Comment: One commenter seeks clarification that MCOs not be required to credential non-physician providers of licensed health facilities under contract to the plan if the facility itself credentials its providers.

Response: We do not address this level of specificity in the final rule. This provision speaks to the credentialing of providers and does not make a distinction between non-physician and physician providers or who does the credentialing. At a minimum, each MCO, PIHP, and PAHP must follow a documented process for credentialing and recredentialing providers who have signed contracts or participation agreements with the MCO, PIHP, or PAHP. Further, a provider in Medicaid managed care is defined as any individual or entity who is engaged in the delivery of health care services and is legally authorized to do so by the State in which he or she delivers the services.

Comment: One commenter stated that in the absence of a credentialing regulation, in many States, providers would set their own standards.

Response: This final rule does not allow individual providers to establish their own credentialing standards. Section 438.214(b) requires States to set uniform credentialing policies and each MCO, PIHP, and PAHP must follow this policy for credentialing providers.

Comment: One commenter expressed the opinion that a lack of specific credentialing requirements is an open door for States to lower standards for doctors who see Medicaid beneficiaries.

Response: We do not believe that States will establish lower standards for doctors who serve Medicaid beneficiaries. We allow States the flexibility to determine the credentialing policy that best fits their State's needs. The providers being credentialed must be legally authorized to deliver services in the State. Further, States must ensure that each MCO, PIHP, and PAHP maintains a network of providers that is appropriate to meet the needs of its enrolled population.

9. Enrollee Information (Proposed § 438.218)

This section provided that the information requirements under § 438.10 are part of a State's quality strategy. We received no comments on this section and have retained it as in the proposed rule.

10. Confidentiality (Proposed § 438.224)

This section of the proposed rule required that States must ensure that MCOs and PIHPs meet the privacy requirements of subpart F of part 431 of this chapter and 45 CFR parts 160 and 164.

Comment: Many commenters suggested that we strengthen the regulation to make clear that monitoring and oversight do not end with inclusion of contract language. The commenters suggested the addition of the following language ''The State must ensure, through its contracts *and by monitoring compliance with those contracts,* that etc.''

Response: We agree that monitoring and oversight require more than the inclusion of contract language. However, we provide for monitoring and oversight within the regulation. Under § 438.204(b)(3), the State quality strategy must include procedures to regularly monitor and evaluate MCO and PIHP compliance with the contract standards.

Comment: One commenter asked if State confidentiality laws that are stricter than Federal privacy laws will continue to apply.

Response: The Federal privacy laws do not pre-empt State confidentiality laws, to the extent that State laws are stricter.

Comment: One commenter noted that the privacy regulation cross referenced in this rule does not take effect until April 14, 2003. Assuming this regulation takes effect prior to that date, the commenter asked whether the privacy rules take effect earlier for Medicaid managed care MCOs and PIHPs.

Response: The privacy rule became effective on April 14, 2001. Most health plans and providers that are covered by the new rule must comply with the new requirements by April 14, 2003. Enforcement of the privacy rule will not occur until April, 2003. This final rule does not alter these dates, nor does it impose privacy requirements in addition to those of the privacy final rule that became effective on April 14, 2001 (65 FR 82462).

Comment: Several commenters requested that the regulation make clear that the confidentiality provisions extend to minors who seek health services through Medicaid.

Response: Section 438.224, as a whole, was intended to ensure that MCOs and PIHPs have procedures to protect the confidentiality of all enrollees. We intend the term ''enrollee'' to encompass all enrollees, regardless of age. Further, the privacy rule provides all individuals with certain rights with respect to their personal health information, including the right to obtain access to, and request amendment of, health information about themselves. The privacy rule also has specific requirements regarding a minor and the minor's personal representative and their control over the minor's health care information (See 45 CFR 164.502(g)).

11. Enrollment and Disenrollment (Proposed § 438.226)

This section of the proposed rule provided that each MCO and PIHP contact must comply with the enrollment and disenrollment requirements and limitations set forth in § 438.56. We received no comments on this section and have retained it as proposed.

12. Grievance Systems (Proposed § 438.228)

Proposed § 438.228(a) required that the State ensure through its contracts with MCOs and PIHPs that they have grievance systems that met the requirements of subpart F. Paragraph (b) required States that delegate to the MCO or PIHP responsibility for notifying enrollees of an adverse action to conduct random reviews of the MCO, PIHP, and their providers to ensure that notices are provided in a timely manner.

Comment: Many commenters urged that the provisions of subpart F on grievances and appeals be applied to PAHPs. They believe that enrollees of these plans should have equal rights to grieve and appeal and that States should have access to data on grievances and appeals to monitor PAHPs for quality. Another commenter said that enrollees of PAHPs should have access to grievances and appeals because managed care, by its nature, includes conflicts of interest between the plans and their enrollees.

Response: We do not agree that the grievance system required under Federal regulation should apply to PAHPs. The services provided by PAHPs are generally of a much more limited scope than those provided by MCOs and PIHPs. We note that States may extend the grievance system requirements to PAHPs, or may require another grievance and appeals process.

Comment: Many commenters suggested that the State should be required to review quality of care grievances at the request of the enrollee. Without a provision for quality of care grievances no external record exists of MCOs and PIHPs that consistently fail to adhere to basic quality standards. Another commenter stated his opposition to inclusion of a category of grievance for quality of care.

Response: The final regulation does not include a category of grievance for those related to quality of care. Rather, grievances related to quality of care fall into the general grievance category. We agree that data on grievances and appeals provide States with important information about the quality of care delivered by MCOs and PIHPs. For this reason, in § 438.416, we require that States must require MCOs and PIHPs to maintain records of grievances and appeals and review that information as part of the State quality strategy. While we do not require that States review quality of care grievances, we believe that States are responsive to issues raised by enrollees related to quality and will generally review these grievances when requested.

13. Subcontractual Relationships and Delegation (Proposed § 438.230)

Proposed § 438.230(a) set forth requirements specifying that an MCO or PIHP that contracts with the State retains full accountability for any activities under its contract that it delegates to a subcontractor. Paragraph (b) required that before an MCO or PIHP delegates responsibility to a subcontractor it must (1) evaluate the prospective contractor's ability to perform the functions to be delegated, and (2) have a written agreement that specifies the activities and report responsibilities of the subcontractor and provides for revoking the delegation or imposing sanctions if the subcontractor's performance is

inadequate. Paragraph (c) required that the MCO or PIHP monitor the performance of the subcontractor and conduct periodic formal reviews on a schedule established by the State.

We received no comments on this section and we have retained § 438.230 as proposed.

14. Practice Guidelines (Proposed § 438.236)

Proposed § 438.236 required that States ensure that each MCO and PIHP adopt practice guidelines that (1) are based on valid and reliable clinical evidence or a consensus of health care professionals in the particular field, (2) consider the needs of the MCO's or PIHP's enrollees, (3) are adopted in consultation with contracting health care professionals, and (4) are reviewed and updated periodically as appropriate. We also proposed that MCOs and PIHPs disseminate the guidelines to all affected providers and, upon request, to enrollees and potential enrollees. Finally, we specified that decisions with respect to utilization management, enrollee education, coverage of services, and other areas to which the guidelines apply must be consistent with the guidelines.

Comment: One commenter said that § 438.236 should apply to dental plans.

Response: We agree with the commenter. This section should apply to PAHPs, including dental plans, as well as to MCOs and PIHPs, and we have revised § 438.236 accordingly. We note that the scope of services in the PAHP contract will determine the areas in which practice guidelines are appropriate. For example, dental guidelines would only be appropriate for plans that are responsible for providing dental services. Likewise, a clinical practice guideline is incompatible with transportation services, making this section inapplicable to transportation PAHPs.

Comment: One commenter recommended that the regulation require MCOs and PIHPs to use practice guidelines developed and/or endorsed by the American Academy of Pediatrics.

Response: We are not specifying what guidelines MCOs and PIHPs must adopt but rather are establishing criteria to be used by MCOs and PIHPs in adopting guidelines.

Comment: Several commenters objected to the requirement that MCOs and PIHPs adopt practice guidelines. One commenter said that guideline adoption should not be required because nationally accepted standards are not available for all clinical areas, for example, for rehabilitative mental health services. Another commenter objected to this provision because he believes that to require use of clinical practice guidelines substitutes the judgment of CMS, the States, and MCOs and PIHPs for the judgment of health care professionals. Other commenters supported the provision but suggested that reference be made to HIV/AIDS guidelines or that the provision also require the use of clinical review criteria that are directed specifically to meeting the needs of at-risk populations.

Response: We continue to believe that States should require MCOs, PIHPs, and PAHPs (where appropriate) to adopt clinical practice guidelines in order to ensure the highest quality of care to enrollees. We are aware that clinical practice guidelines are not available for all areas of clinical practice. However, we believe that it is important to promote the use of guidelines based on clinical evidence. Guidelines are being developed by a variety of organizations in a variety of areas and will increasingly become available for use. This is why we have set criteria for MCOs, PIHPs, and PAHPs to use when adopting guidelines rather than specifying particular guidelines to be used. We do not agree that requiring the use of practice guidelines substitutes the judgement of CMS, States, or health plans for the judgement of health care professionals. Rather, guidelines assist health care professionals to apply the best evidenced-based practice to clinical care. Guidelines are developed to assist the health care professional, not to dictate a specific course of action. We require that MCOs, PIHPs, and PAHPs consult with their contracting health care professionals when adopting practice guidelines to ensure that the health care professionals have input into these decisions.

Comment: One commenter stated that the regulation should require MCOs to consult with organizations that develop practice guidelines.

Response: We do not agree that it is necessary or practical to require MCOs, PIHPs, and PAHPs to consult with organizations that develop practice guidelines. What we believe is important is that the guidelines are valid and reliable, are relevant to the enrollee population, are adopted in consultation with the contracting health care providers, and are reviewed and updated periodically to ensure that they continue to reflect the most recent evidence. Therefore, these are the criteria we specify in the regulation for MCOs, PIHPs, and PAHPs to use when adopting practice guidelines.

15. Quality Assessment and Performance Improvement Program (Proposed § 438.240)

This section sets forth the State's responsibility to ensure that each MCO and PIHP with which it contracts have in place a quality assessment and performance improvement program for the services it furnishes to Medicaid enrollees. In the NPRM we proposed that States must require that each MCO and PIHP include the following basic elements in its quality assessment and performance improvement program: (1) Conduct performance improvement projects, (2) have in effect mechanisms to detect both underutilization and overutilization of services, and (3) have in effect mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs.

In our proposed rule we specified that CMS, in consultation with States, and other stakeholders, may specify standardized quality measures and topics for performance improvement projects to be required by States in their contracts with MCOs and PIHPs. We proposed that MCOs and PIHPs measure performance using standardized measures annually, and implement performance improvement projects that address clinical and non-clinical areas. We also proposed that States review, at least annually, the impact and effectiveness of their quality assessment and performance improvement programs.

Comment: Several commenters supported the quality assessment and performance improvement provisions.

Response: We retain the provisions in § 438.240 in the final rule with certain revisions, discussed below.

Comment: One commenter supported the provision that CMS will consult with States and other stakeholders if we decide to exercise our authority to specify quality measures or topics for performance improvement projects that we would require States to include in their contracts with MCOs.

Response: We believe it is important to include all stakeholders in any discussions that would lead to specifying performance measures or topics for performance improvement projects that we would require States to include in their contracts with MCOs and PIHPs.

Comment: Several commenters were concerned that measures identified and developed by CMS, in consultation with States and other stakeholders, would be measures that are not routinely collected nor applicable to the unique circumstances of States and MCOs/

PIHPs and that the standardized performance measures would impose additional burden. The commenters suggested this requirement be removed. One commenter agreed that some standardization of performance measures is appropriate but believes the specifications for the measures should be determined by the MCO or PIHP.

Response: We hope that by including all stakeholders in discussions about performance measures that we will reach agreement about measures that are important to a wide range of stakeholders and to CMS. We recognize that each State and MCO and PIHP will have unique program circumstances and that the national measures chosen will not meet all these needs. However, the requirement to use standard measures does not preclude States, MCOs, and PIHPs from also using performance measures that they find useful. We believe we should have the ability to specify standard measures and topics for performance improvement projects to provide comparability across States for some measures and to establish national priority areas for performance improvement projects. Therefore, we retain this provision in the final rule.

Comment: Several commenters requested that we permit exceptions or deviations from the standard measures required by us.

Response: As we stated in the preamble to the proposed rule, we believe we should have the ability to specify standard measures and that we will be working in consultation with States and other stakeholders to agree upon standard measures. Policy regarding the implementation of the measures, including whether any exceptions should apply, will also be determined in consultation with stakeholders.

Comment: Several commenters disagreed with our proposal to allow CMS to specify topics for performance improvement projects. One commenter stated that States are in the best position to identify State health priorities and how to allocate their resources and suggested that this provision be removed. Several commenters encouraged us to defer to States in determining the number and type of studies to be performed. One commenter agreed that the identification of standard performance improvement project topics is appropriate but believes that the intervention and measurement specifications should be left up to the MCOs/PIHPs.

Response: As stated in the preamble of the August 2001 proposed rule, we believe that as the art of quality improvement and measurement advances, we should have the ability to specify standard measures and topics for performance improvement projects. We retain this provision in the final rule. As in the proposed rule, in the final rule, we do not specify the number or types of quality improvement projects nor do we specify improvement interventions that MCOs and PIHPs must implement.

Comment: Several commenters expressed concern that requiring performance improvement projects to achieve demonstrable and sustained improvement is not always feasible. Commenters said that this requirement could have a negative impact on quality improvement activities because it may impact the willingness of MCOs and PIHPs to take on difficult projects. One commenter suggested that the language in this section be changed to reflect that these projects have the goal of achieving demonstrable and sustained improvement as opposed to requiring the projects to achieve this improvement. Another commenter suggested deeming MCOs/PIHPs as having satisfied the quality assurance requirements found in this subpart if the MCO or PIHP is accredited by a private accreditation organization.

Response: We agree with the commenters that achieving demonstrable improvement is not always feasible. We have revised § 438.240(b)(1) to require that performance improvement projects be designed to achieve significant improvement sustained over time. This language is consistent with Medicare requirements that define demonstrable improvement as ''significant improvement sustained over time.'' We plan to address deeming of MCO and PIHP quality initiatives in the EQR final rule.

Comment: One commenter suggested that we allow States discretion to require demonstrable improvement or not.

Response: As indicated in the response to the previous comment, we are no longer requiring that performance improvement projects achieve demonstrable improvement. We are requiring that these projects be designed to achieve significant improvement sustained over time. States will have the discretion to define what is to be considered significant improvement.

Comment: Many commenters argued that MCOs and PIHPs should be required to meet minimum performance levels established by the States as part of their quality assessment and performance improvement program. The commenters recommended that this requirement be added under § 438.240(b). One commenter supported that we did not propose to require MCOs and PIHPs to meet minimum performance standards. The commenter argued that it is difficult to identify reasonable performance levels when taking into consideration the variation of local conditions, beneficiaries, and unique program characteristics. This commenter recommended that the provision for standard quality measures be modified to allow States to recommend modification to the standards on a regional or State basis.

Response: We do not agree that we should require States to establish minimum performance levels that MCOs and PIHPs must meet as an element of the quality assessment and improvement program. States have the option to establish such levels, whether they are State standards or regional standards. We agree that performance measures should be included as an element of the quality assessment and performance improvement program. This was our original intent. We have changed § 438.240(b)(2) to add calculation of performance measures as a basic element of quality assessment and performance improvement programs.

Comment: One commenter suggested that States require that the information obtained from assessments of underutilization and overutilization and of the quality and appropriateness of care to enrollees with special health care needs be reported by age, race, and ethnicity of Medicaid enrollees.

Response: We do not agree that this regulation should specify that information obtained on underutilization and overutilization of services or the quality and appropriateness of care furnished to enrollees with special health care needs should be reported according to age, race, and ethnicity. We believe that each State should specify how the information should be reported based upon individual State needs.

Comment: One commenter agreed with the requirement that MCOs and PIHPs annually measure performance using standard measures required by the State and report this information to the State. The commenter believes that this provision maintains MCO and PIHP accountability while providing critical flexibility in the manner in which the requirements are carried out.

Response: We agree with the commenter and we have retained the provision in § 438.240(c) of the final rule. We also take this opportunity to clarify that the State performance measures described in § 438.240(c) must

reflect any national performance measures that may be prescribed by the Secretary, consistent with § 438.204(c) and § 438.240(a)(2).

We also have taken the opportunity to recognize an additional approach to producing performance measures that maintains MCO and PIHP accountability while providing flexibility in the manner in which provisions at § 438.240(c) pertaining to performance measurement are met. Specifically, we have been reminded of a practice used by a growing number of States in which State agencies calculate measures of the performance of their MCOs or PIHPs using encounter and claims data transmitted by the MCO or PIHP to the State. We believe this is an acceptable practice that can reduce burden on MCOs and PIHPs, especially when MCOs or PIHPs are already transmitting encounter data to the State. Therefore, we have revised § 438.240(c) to indicate that there are three acceptable ways for States to obtain performance measures for each MCO and PIHP: (1) The MCO or PIHP could calculate the measures according to the States' specifications; (2) the State could calculate the measures using encounter or similar data submitted to the State by the MCO or PIHP; and (3) a State could obtain performance measures using a combination of these two approaches. We authorize States to determine the best approach or approaches to be used in its State, recognizing that a State may decide to use different approaches for individual MCOs or PIHPs.

Comment: Several commenters agreed with the limited detail included in this regulation related to performance improvement projects. The commenters argued that the regulation sufficiently describes Federal standards while allowing States and MCOs and PIHPs the flexibility to develop processes that work best to fit their programs. One commenter requested that we work with MCOs and PIHPs and other stakeholders to develop guidance related to the final regulation that will further explain our expectations for implementing performance improvement projects (for example, challenges inherent in efforts to positively affect quality of care and outcomes given eligibility status, changes of enrollees, small populations, etc.).

Response: We retain § 438.240(d) in our final rule. We have developed guidance for States on implementing performance improvement projects. As part of the development of the EQR regulation, we were statutorily mandated to contract with a national accreditation organization to develop protocols to be used in EQR. We awarded a contract to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to develop these protocols. The JCAHO, as part of this effort, convened an expert panel composed of State agencies, MCOs, experts on quality improvement activities, and other stakeholders to provide us feedback on the development of the protocols. Two protocols address performance improvement projects. One protocol provides guidance on how to conduct performance improvement projects and one provides guidance on how to validate performance improvement projects. These protocols can be found on our web site at *http://www.hcfa.gov/medicaid/mceqrhmp.htm.*

Comment: Several commenters asked us to clarify under § 438.240(d)(2) what is meant by the ''new information on quality of care every year'' that we are requiring be reported by the MCO or PIHP on each project upon request by the State.

Response: The MCO or PIHP should provide to the State new information from performance improvement projects underway or information on projects that had been initiated since the previous annual report. For example, a project recently initiated by the MCO or PIHP may only be able to describe the topic selected and methodology to be used at the time of the first report. In year two, the intervention may have been implemented, but there may not yet be data to report. In year three, base line data may be collected, and in year four, there may be a repeat measurement. As projects progress, different information will be available to report.

Comment: Many commenters argued that our final rule should include more specific requirements related to performance improvement projects that include more specificity such as (1) that the MCOs/PIHPs include objective, clearly and unambiguously defined measures based on current clinical knowledge or health services research (2) that the measures measure outcomes such as change in health status, functional status, enrollees satisfaction, or proxies of these outcomes, and (3) that over time, MCOs/PIHPs vary projects to focus on a full spectrum of services rather than repeatedly monitoring areas that are easy to measure and improve. One commenter was concerned that the lack of specificity in the NPRM will result in MCOs and PIHPs developing quality measures that may be irrelevant to patient care and projects that may not protect patients. Another commenter was concerned that the lack of specificity relieves States and MCOs from developing and monitoring performance measures for specific conditions such as mental illness and other severe disabilities.

Response: We do not agree that this regulation should provide more detail on performance improvement projects or on the indicators used to measure performance. We believe the final regulation creates a balance between an appropriate amount of detail needed to ensure that States implement interventions to improve quality, while at the same time, provides States with the flexibility to determine the measures and levels they want to require of their contracting MCOs and PIHPs. We believe that States and MCOs and PIHPs will use performance measures and performance improvement projects that reflect important areas. These activities are costly and time-consuming and we believe that States and MCOs/PIHPs will target the investments in financial and staffing resources required for these activities to topics that will benefit from program improvement.

Section 438.240 requires, as a basic element of a quality assessment and performance improvement program, that MCOs and PIHPs have in effect mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs. This includes beneficiaries with conditions such as mental illness and other severe disabilities.

Comment: Many commenters argued that MCOs and PHPs should be required to conduct performance improvement projects on topics specified by the State and that MCOs and PIHPs should be required to participate in at least one statewide project. The commenters recommended that we incorporate these requirements in our final rule.

Response: We do not agree that this rule should require that States have their MCOs and PIHPs participate in statewide projects. We reserve the right to set performance improvement project topics in the future as specified in § 438.240(a)(2). A State, at its discretion, however, may choose to specify topics for MCOs or PIHPs improvement projects or to mandate participation in statewide projects.

Comment: One commenter encouraged us to recognize the long-term nature of quality initiatives, that improvement in quality is incremental. The commenter was concerned that the short-term commitment to initiatives that is usually the perspective of States does not provide a paradigm for studying and understanding what works in managed care. The commenter argued

that quality initiatives should not change capriciously from year to year.

Response: We agree with the commenter and acknowledge that quality improvement initiatives need a sufficient amount of time to be implemented and for findings to be determined. We do not prescribe the duration in which performance improvement projects must be completed. We only require that a project be completed in a reasonable time period and that information be provided on the project's progress annually.

Comment: Several commenters asked for clarification on how the program review by States will be coordinated with the EQR regulations. Several commenters suggested that we coordinate these efforts to avoid duplication of efforts. For example, one commenter suggested that we permit MCOs and PIHPs that are certified by an accreditation agency or who are reviewed by another State agency to be exempt from Medicaid reviews and EQR. One commenter suggested that we provide a cross reference to the EQR regulation and that we provide States sufficient discretion to define and modify their external review activities. Another commenter suggested that we amend the regulation to allow a State to use the EQR to meet the program review by the State requirements under § 438.240(e).

Response: States at their option may use EQR findings to meet the program review requirements under § 438.240(e)(1). The final EQR rule addresses the circumstances under which an MCO or PIHP may be exempt from quality initiatives and what types of quality initiatives we consider to be EQR activities. We are not providing a cross reference to the EQR provisions or amending this rule to stipulate that EQR can be used to meet this requirement. We are providing States with the flexibility to decide if they want to use EQR or some other activity to meet these requirements.

Comment: One commenter agreed with the requirement that States review the MCO's and PIHP's performance on standard measures on which MCOs and PIHPs are required to report.

Response: In the final rule, we retain § 438.240(e)(1) as proposed.

16. Health Information Systems (Proposed § 438.242)

Section 1932(c)(1)(iii) of the Act requires States that contract with MCOs to develop a quality assessment and improvement strategy that includes procedures for monitoring and evaluating the quality and appropriateness of care and services to enrollees. It also provides that MCOs provide quality assurance data to the State using the data and information set specified by the Secretary for the Medicare+Choice program or other data specified by the Secretary in consultation with States. Section 438.242 proposed that States require that MCOs and PIHPs have health information systems sufficient to provide data to States and CMS.

Paragraph (a) required that States must ensure that MCOs and PIHPs maintain data systems that collect, analyze, integrate, and report data to achieve the objectives of subpart D. It required that the system must provide information on utilization, grievances, and disenrollments (other than those that result from ineligibility for Medicaid). Paragraph (b) provided that the State must require MCOs and PIHPs to collect data on enrollee and provider characteristics and on services furnished to enrollees, and to ensure the accuracy and completeness of data received from providers by (1) verifying its accuracy and completeness; (2) screening the data for completeness, logic, and consistency; and (3) collecting service information in standard formats to the extent feasible and appropriate.

Paragraph(c) required MCOs and PIHPs to make all data available, as required in this subpart, to the State and, on request, to CMS.

Comment: One commenter urged CMS to establish national data collection standards for collection of encounter data, EPSDT information, and network information by States, using standards established under the Health Insurance Portability and Accountability Act (HIPAA) where possible.

Response: We do not agree that CMS should establish national data collection standards as part of this regulation. Under HIPAA, the Secretary is establishing standards for the electronic transfer of health data, including encounter data. The HIPAA regulations also specify the entities to which the standards apply. Medicaid MCOs and PIHPs, as well as State Medicaid agencies, will need to comply with the HIPAA regulations to the extent they apply.

Comment: One commenter noted that MCO and PIHPs can only supply data to States to the extent they are provided data by providers. This commenter suggested that this regulation require that providers give data to health plans.

Response: This regulation is directed to States and, by placing requirements on States for their contracts with MCOs, PIHPs, PAHPs, and PCCMs, on these other entities. The regulation does not address the relationships of MCOs and PIHPs and their providers. Therefore, we are not including a provision to require data reporting by providers.

Comment: One commenter noted that it is important for States to negotiate price discounts with hardware and software vendors that can be passed on to providers and to develop guidance materials for practices preparing to install hardware and software.

Response: States are in the best position to identify means to assist providers with the electronic submission of data. We do not believe that this issue should be addressed in Federal regulations. We revised § 438.242(a) by adding the words ''and appeals'' after ''grievances''. This change was made to be consistent with § 438.416, which requires States to review information collected by MCOs and PIHPs as part of the State quality strategy.

E. Grievance System (Subpart F)

Proposed subpart F is based on section 1902(a)(3) of the Act, (which requires a State plan to provide an opportunity for a fair hearing to any person whose request for assistance is denied or not acted upon promptly), section 1902(a)(4) of the Act, (which authorizes the Secretary to specify methods of administration that are ''necessary'' for ''proper and efficient administration''), and section 1932(b)(4) of the Act, (which requires that MCOs have an internal grievance procedure under which a Medicaid enrollee, or a provider on behalf of an enrollee, may challenge the denial of coverage of, or payment by, the MCO).

In this subpart, we proposed regulations that lay out the elements of the grievance system required under section 1932(b)(4) of the Act, and how it interfaces with the State fair hearing requirements in section 1902(a)(3). We defined terms, described what constitutes a notice of action, and addressed how grievances and appeals must be handled, including timeframes for taking action. We included a process for expedited resolution of appeals in specific circumstances; addressed the requirement for continuation of benefits; and laid out the requirements relating to record keeping, monitoring and effectuation of reversed appeal resolutions.

We proposed conforming amendments to part 431 to reflect changes in terminology and other new provisions enacted in the BBA. We also made conforming changes to the fair hearing regulations in subpart E of part

431, to reflect the MCO grievance and appeals process in subpart F of part 438. We note that we revised § 431.244(f)(3) to require State approval for direct access to an expedited State fair hearing for MCO and PIHP enrollees. Due to the close relationship of the subject matter with subpart F, comments and responses regarding part 431 are addressed in this subpart.

1. Statutory Basis and Definitions (Proposed § 438.400)

Definitions of terms used in proposed subpart F are found in proposed § 438.400 and have the following meanings:

Action means, in the case of an MCO or PIHP or any of its providers,

- The denial or limited authorization of a requested service, including the type or level of service;
- The reduction, suspension, or termination of a previously authorized service;
- The denial, in whole or in part, of payment for a service; or
- For a resident of a rural area with only one MCO or PIHP, the denial of a Medicaid enrollee's request to exercise his or her right to obtain services outside the network.

Appeal means a request for review of an action, as ''action'' is defined in this subpart.

Grievance is defined as an expression of dissatisfaction about any matter other than an action. This term can also be used to refer to the overall system that includes grievances and appeals handled at the MCO or PIHP level and access to the State fair hearing Process. Possible subjects for grievances include, but are not limited to, the quality of care or services provided, aspects of interpersonal relationships such as rudeness of a provider or employee, or failure to respect the enrollee's rights.

Proposed § 438.400 contained the definition of a ''governing body.'' We, however, had not proposed regulatory requirements for a governing body. Therefore, we are removing the definition of a governing body in the final rule.

We received the following comments on these definitions.

Comment: One commenter felt that having several potentially conflicting Federal statutes and State laws related to a health care plan's grievance system is troubling for the plans. They asked that, if a Patients' Bill of Rights is enacted, CMS review the provisions of this regulation to make it consistent with the mandate under that legislation, as well as ERISA rules.

Response: We agree with the commenter. If a Patients' Bill of Rights is enacted, we of course would be required to conform to the new statute if it applied to Medicaid, but even if it did not, we would review the provisions and consider making changes if it is appropriate for the Medicaid program.

Comment: Many commenters believe that the definition of ''action'' must include the failure to furnish services in a timely manner, the failure to resolve an appeal in a timely manner, or the denial of an enrollee's request to disenroll. They argued that if a plan delays furnishing services or adjudicating a claim in a timely manner, no ''action'' is triggered. Therefore, the enrollee would be denied his or her right under section 1902(a)(3) to a fair hearing if a claim medical assistance is ''not acted upon with reasonable promptness.''

Response: We agree that section 1902(a)(3) of the Act requires access to a State fair hearing for those requests not acted upon in a timely manner, and therefore, in § 438.400(b) we have modified the definition of ''action'' to include unreasonable delays in services, or appeals not acted upon within the timeframes provided in § 438.408(b). However, we disagree that a denial of a request to disenroll constitutes an ''action,'' as it addresses an issue separate from those specific denials, limitations, reductions, or suspensions of services that trigger fair hearing requirements.

Comment: Some commenters believe that the grievance and appeals provisions should apply to PAHPs as well as to MCOs and PIHPs.

Response: We agree that PAHP enrollees should have the right to appeal denials, but believe that direct access to the existing fee-for-service fair hearing process is the more appropriate vehicle for this in the case of PAHPs. Therefore, in response to this comment, we have revised the fair hearing regulations in subpart E of part 431 to expressly reference PAHP enrollees as having a right to a fair hearing under those provisions in the case of an ''action.'' In general, we believe that the State should decide how best to address grievances involving PAHPs that do not involve an action, since they are often individual physicians or small group practices and cannot be expected to have the administrative structure to support a grievance process.

Comment: Several commenters disagreed that the independent professional judgment of providers should automatically trigger an action in the same manner as a denial from an MCO or PIHP. They believed that it is sometimes impossible for the MCO or PIHP to know when a provider has denied a service, or offered an alternative form of treatment that may or may not be a denial. They requested that providers be removed from the ''action'' definition.

Response: We agree with the commenters. Since a provider is making independent professional judgments as to the care and treatment of enrollees, his or her denial of a particular request, or the suggestion of an alternative should not automatically trigger a formal notice of appeal rights from the MCO or PIHP. We have removed ''or any of its providers'' from the definition of an ''action.'' However, anytime an enrollee challenges the decision of a provider to the MCO or PIHP, an action is triggered if the MCO or PIHP affirms the provider's decision, triggering a notice from the MCO or PIHP.

Comment: Many commenters wanted the regulations to provide expressly for a ''quality of care'' grievance in cases in which the enrollee believed that any aspect of his or her care was substandard, or could have caused them harm. These commenters recommended that the State be required to review any such ''quality'' grievance that was not disposed of to the enrollee's satisfaction. Some commenters wanted these grievances to be reviewable by a State fair hearing.

Response: We believe that those enrollee complaints not meeting the standard of an appeal should be treated uniformly under Federal statute. The definition of ''grievance'' includes ''quality of care'' and it should be up to the State to decide whether or not a review, or a mechanism allowing State review, is necessary. We also believe that an enrollee only has the right to a State fair hearing under section 1902(a)(3) in cases that involve an ''action,'' since section 1902(a)(3) refers to a denial of medical assistance, or a case in which a claim for assistance is ''not acted upon,'' and not a case in which there are concerns about the quality of the assistance. We believe that the quality assurance requirements in subpart D of part 438 address the commenter's concerns.

Comment: One commenter felt that appeal rights should be extended to providers in managed care systems. They argued that this is notable considering the appeal rights extended to MCOs in the right to pre-termination hearings.

Response: The grievance and appeal rights in this subpart implement statutory provisions that grant rights to Medicaid beneficiaries, not providers. The right to a fair hearing in section 1902(a)(3) applies to an ''individual'' whose claim for medical assistance is

denied or not acted upon. The statutory requirement in section 1932(b)(4) that MCOs have grievance procedures similarly applies to ''an enrollee* * *or a provider *on behalf of an enrollee.* * * *'' (Emphasis added.) While it is true that the statute provides for the right to a hearing before an MCO contract is terminated, there is no statutory provision for an appeal right for providers subcontracting with managed care plans. While States are free to provide such rights, and information must be provided about such rights where they exist (see section A. above), there are no such rights under Federal statute. We defer to congressional intent on this issue, and have not provided for any subcontracting provider appeal rights in this final rule.

2. General Requirements (Proposed § 438.402)

Proposed § 438.402 required each MCO and PIHP to have a grievance system in place for enrollees that includes a grievance process, an appeal process, and access to the State's fair hearing system.

Proposed § 438.402(b)(1) specified that an enrollee may file a grievance or an MCO or PIHP level appeal, and may request a State fair hearing. In addition, as provided in section 1932(b)(4), the proposed rule provides that a provider, acting on behalf of an enrollee (with the enrollee's written consent) may file an appeal of a ''denial of coverage of or payment for'' assistance, or an ''action.'' However, under proposed § 438.402(b)(1)(ii), the provider could not file a grievance or request a State fair hearing on behalf of the enrollee.

Under § 438.402(b)(2), we proposed timeframes within which the enrollee or provider (on the enrollee's behalf) may file an appeal. Our intent was to mirror the filing timeframes for a State fair hearing, that is, a reasonable amount of time up to 90 days. In addition, we incorporated the longstanding policy at section 2901.3 of the State Medicaid Manual that beneficiaries be given a minimum of 20 days to file an appeal. We believe that this policy gives beneficiaries a reasonable amount of time to file an appeal. Therefore, the proposed regulation required that the State specifies a timeframe for filing an appeal that is no less than 20 days or more than 90 days from the date of the MCO's or PIHP's notice of action. Within this timeframe, the enrollee (or the provider on his or her behalf) may file an appeal, and in a State that does not require exhaustion of the MCO and PIHP level appeals, the enrollee may request a State fair hearing.

In proposed § 438.402(b)(3), we specified the manner in which enrollees may file grievances, and enrollees (or a provider on the enrollee's behalf) may file an appeal. For grievances, the enrollee may file either orally or in writing, either with the State or the MCO or PIHP, as determined by the State. The enrollee (or the provider on the enrollee's behalf) was permitted to file an appeal either orally or in writing, and unless he or she requests expedited resolution, was required to follow an oral filing with a written, signed, appeal. While enrollees were permitted to start the appeal clock with an oral request, under the proposed rule, they were required under the proposed rule to follow it with a written request, as we determined that a written appeal best documents the issue being appealed. In expedited situations, the proposed rule provided that the enrollee was not required to put the appeal in writing.

Comment: A few commenters believed that permitting States to require the exhaustion of internal MCO or PIHP appeals procedures was unwarranted, and favored appeal rights administered by a state agency using the Federal fair hearing regulations. Other commenters believed that since MCOs are responsible for coordinating care and making coverage decisions, enrollees should be required to utilize their internal appeals process first before filing for a State fair hearing.

Response: We disagree with both sets of commenters. With respect to the commenters opposing an internal grievance procedure, section 1932(b)(4) actually requires that such a procedure be available, and that enrollees be permitted to ''challenge'' a ''denial of coverage of, or payment for'' services under such procedures. Thus, using exclusively a State administered fair hearing mechanism was not even an option under the law. Furthermore, providing for an MCO/PIHP level of review is consistent with the appeals rules under the Medicare+Choice program, and most versions of Patients Bill of Rights legislation. We believe that as long as the timeframes and notice requirements conform with what is allowed under direct access, an internal system is a proper and efficient way to adjudicate appeals. However, we also believe that the State should have full discretion when it comes to whether to require the utilization of the required internal appeals process, or permit direct access to State fair hearing.

Comment: Some commenters found that the word ''grievance,'' referring to the overall system as well as a particular avenue of adjudication, is inherently confusing. They recommended changing ''grievance system'' to something such as the ''dispute resolution process'' or ''complaint process.'' Others felt that the definition was too broad, triggering rights where a different avenue for resolution would make more sense.

Response: While we refer to the overall process as the ''grievance system,'' States are free to call it by any name they prefer. We chose ''grievance system'' over terms such as ''dispute resolution process'' or ''complaint process'' because this is the term used in section 1932(b)(4), and the other terms suggested by the commenters were too informal. To some people, ''complaint'' conjures up ideas of more trivial matters, while ''dispute resolution'' is sometimes associated with arbitration, which connotes a less strict standard than we wanted to convey. While we based our reference to the overall system on the reference to ''an internal grievance procedure'' in section 1932(b)(4), our use of the term ''grievance'' to refer to disputes not resulting from an ''action'' tracks the approach in the Medicare+Choice regulations, and is based on the broad connotations of the word grievance to capture a variety of types of complaints. We believe that the timeframes and other administrative requirements in this final rule provide sufficient State flexibility to not be a burden on the grievance system.

Comment: Many commenters recommended additional general requirements for the grievance system. These recommendations included specific terms in the regulations requiring: (1) That all processes, policies, and procedures meet the conditions set forth in this subpart; (2) a State's written approval of an MCO's or PHP's policies and procedures before implementation; (3) a governing body responsible for effective operation of the system including disposing of grievances and resolving appeals; (4) assurance that punitive action is neither threatened nor taken against a provider who requests or supports a grievance or appeal; (5) acceptance of grievances and appeals from the enrollee or his or her representative; (6) the provision of information required under this subpart, (7) the referral to the State of quality of care grievances in which the enrollee is dissatisfied; and (8) that providers be required to give notice in accordance with § 438.404(d).

Response: We believe that many of the above suggested requirements are already addressed in this final rule, either directly or implicitly. For example, we believe that while it would be clear without any explicit statement that grievance processes, policies and

procedures must be consistent with the regulatory requirements in part F, § 438.228 already expressly requires States to ensure, through its contracts, that MCOs and PIHPs have grievance systems that satisfy the requirements of this subpart. This includes the requirement on States to conduct random reviews of MCOs and PIHPs to ensure that they are notifying enrollees in a timely manner. The acceptance of appeals and grievances from the enrollee or a representative is similarly already provided for, as is the requirement, in § 438.10, for provision of information on appeals. We have addressed in section A of this preamble the commenters' suggestion for an assurance of no punitive action for requesting an appeal. Most of the other suggestions above would in our view most appropriately be addressed by the States without further Federal regulation.

Comment: Many commenters believed that a State should not be permitted to establish a deadline for appealing an adverse action that is less than 30 days, even though shorter periods are now permissible in the fee-for-service Medicaid program.

Response: As stated in the introduction, our intent was to mirror the filing timeframes for the State fair hearing; that is, a reasonable amount of time up to 90 days. In addition, we incorporated the longstanding policy at § 2901.3 of the State Medicaid Manual that beneficiaries be given a minimum of 20 days to file an appeal. We believe that this policy gives beneficiaries a reasonable amount of time to file an appeal, while providing States with the flexibility to tailor those timeframes to their particular internal and State procedures. Therefore, we will retain the requirement that the State specify a timeframe for filing an appeal that is no less than 20 days and does not exceed 90 days from the date of the MCO's or PIHP's notice of action.

Comment: One commenter objected to the fact that the proposed rule would allow providers, with written consent, to file an appeal on behalf of the enrollee, but prohibit providers from acting as an authorized representative for grievances or State fair hearings.

Response: As noted in section E. 1. above, we have limited the right to request a fair hearing, and the right to appeal a denial of coverage, to enrollees, and to providers on behalf of enrollees, in deference to our interpretation of congressional intent. In the case of grievances, since these are likely to involve a provider, we have limited the right to file a grievance to an enrollee. The commenter, however, correctly notes that we have not just denied a provider the *right* to file a grievance or fair hearing request on behalf of an enrollee, but have affirmatively *prohibited* providers from doing so, through the second sentence in proposed § 438.402(b)(1)(ii). In considering this comment, we have determined that we do not wish to prohibit providers from acting as authorized representatives for grievances, appeals and state fair hearings, if the State wishes to provide them with this right. Since the current prohibition would pre-empt a State law to the contrary, we are, in response to this comment, changing the second sentence in proposed § 438.402(b)(1)(ii) to read, ''A provider may file a grievance or fair hearing request on behalf of an enrollee if the State permits the provider to act as the enrollee's authorized representative in doing so.''

3. Notice of Action (Proposed § 438.404)

Under the proposed rule, the notice MCOs and PIHPs are required to provide to enrollees under proposed § 438.404 would be the first step in the grievance system. It would serve as the enrollee's first formal indication that the MCO or PIHP will or has taken action, such as denying payment or denying, limiting, reducing, suspending or terminating a service through a service authorization decision. We proposed in § 438.404(a) that the notice meet the language and format requirements of proposed § 438.10(c) and (d) of this chapter to ensure ease of understanding. The notice must include the elements that are listed in proposed § 438.404(b), as follows:

- The action the MCO or PIHP or its contractor has taken or intends to take.
- The reasons for the action.
- The enrollee's or the provider's right to file an MCO or PIHP appeal.
- If the State does not require the enrollee to exhaust the MCO or PIHP level appeal procedures, the enrollee's right to request a State fair hearing.
- The procedures for exercising the rights specified in this section.
- The circumstances under which expedited resolution of an appeal is available, and how to request it.
- The enrollee's right to have benefits continue pending resolution of the appeal, how to request that benefits be continued, and the circumstances under which the enrollee may be required to pay the costs of these services.

In proposed § 438.404(c), we specified the timeframes in which the MCO and PIHP must mail the notices. Under proposed § 438.404(c)(1), timeframes for notices for the reduction, suspension, or termination of previously authorized services are governed by the State fair hearing regulations found in 42 CFR part 431, subpart E. While some MCOs and PIHPs may find the advance notice requirement inappropriate, there are exceptions to advance notice that allow notice to be given on the date of the action (see § 431.213). These exceptions would cover the situation in which a provider believes an immediate change in care is appropriate for the health condition of the enrollee. For denial of payment, we required in proposed § 438.404(c)(2) that notice be given at the time of any action affecting the claim. Proposed § 438.404(c)(3) and (c)(4) required that for standard service authorization decisions that deny or limit services, notice must be given within the timeframes specified in § 438.210(d). Further, if the MCO or PIHP were to extend the timeframe in accordance with proposed § 438.210(d), it would have to give the enrollee written notice of the reason for the decision to extend the timeframe, inform the enrollee of the right to file a grievance if he or she disagrees with that decision, and issue and carry out its determination as expeditiously as the enrollee's health conditions requires and no later than the date the extension expires. In situations in which the service authorization decision is not reached within specified timeframes, and the failure to authorize a decision constitutes an adverse decision, we proposed at § 438.404(c)(5) that notice be mailed on the date that the timeframe for authorizing services expires without an authorization decision being made. Finally, for expedited service authorization decisions, under the proposed rule notice had to be given within the timeframes specified in proposed § 438.210(e) (recodified in this final rule at § 438.210(d)).

Comment: Several commenters believed that a strict application of the proposed notice requirement would be burdensome, especially if applied to decisions of primary care physicians (PCPs) made without involvement of the MCO or PHP. Commenters also asked that CMS distinguish between claims that involve liability where the enrollee is actually billed, versus where there is no actual payment liability. Some commenters contended that MCOs and PIHPs do not always know when their providers deny services, making it difficult for them to comply with the notice requirements. Another commenter was concerned with § 438.404(b)(1) requiring a notice to explain the action the MCO or PIHP or its contractor has taken or intends to take. They felt that ''contractor'' could

be read as being a provider. They requested clarification.

Response: We agree with the commenters that a provider, using his or her professional judgement in making a determination of medical necessity, should not trigger a notice by reason of recommending against or preferring an alternative to a particular treatment. As discussed above, in response to comments received (including this comment), we have removed the word ''provider'' from the definition of ''action'' triggering notice obligations and appeal rights. As used in § 438.404(b)(1), a ''contractor'' would not include a provider, but rather any entity in which an MCO or PIHP delegated this particular authority/responsibility. However, an enrollee retains the right to request that the MCO or PIHP provide a particular service against the advice of a provider, triggering the requirement of a notice from that MCO or PIHP if the request results in a denial, reduction, or suspension. We disagree that notice rights are triggered only when a beneficiary is actually held liable for a particular claim. An action that may include a claim arising from a third party (such as, a hospital) because an MCO or PIHP refused to pay the claim. Even though the hospital may choose not to bill the beneficiary, a denial for payment of a service has occurred, triggering a notice to the beneficiary that the claim was denied. This ensures that a beneficiary is made aware of his or her appeal rights in case they are billed by a third party.

Comment: Several commenters noted that they do not believe that the expiration of an approved number of visits should be considered a termination. They noted that the enrollee is free to request that the service be continued, but that this request should be treated as a new request for a service. Other commenters expressed the opposite view; they believe that re-authorization of a service at a lower level than previously received, or a denial of re-authorization, is a termination or reduction of the service and should require notice and the continuation of benefits pending appeal.

Response: We agree with the first set of commenters that the expiration of an approved number of visits does not constitute a termination for purposes of notice and continuation of benefits. Likewise, when a prescription (including refills) runs out and the enrollee requests another prescription, this is a new request not a termination of benefits. In these circumstances, the MCO or PIHP would not need to send a notice or continue benefits pending the outcome of an appeal or State fair hearing. If the enrollee requests a re-authorization that the MCO or PIHP denies, the MCO or PIHP must treat this request as a new request for service authorization and provide notice of the denial or limitation. We disagree with the second commenters that a denial of authorization for additional days is a ''termination,'' since the enrollee had no expectation of coverage on those days, and this was thus simply a denial of a new request, not a termination of services the enrollee had a right to expect to continue.

We believe that the proposed rule already clearly reflected the above interpretation. In the definition of ''Action,'' the reference to a ''reduction, suspension, or termination'' in the proposed rule was qualified by the phrase, ''of a previously authorized service.'' Thus, the cessation of services because the authorization expired would not be an ''action,'' because services after the date when the authorization expired would not be ''previously authorized.'' In proposed § 438.404(c)(1), the reference to timeframes for a notice of a ''termination, suspension, or reduction'' was similarly qualified by ''of previously authorized Medicaid-covered services.'' In proposed § 438.420(b), specifically governing the continuation of services, the right to continued benefits is expressly conditioned on the ''[t]he appeal involv[ing] the termination, suspension, or reduction of a previously authorized course of treatment.'' Again, we believe it is clear that if additional days were not authorized, ending treatment as provided in the original authorization would not constitute a termination triggering the right to continued benefits. We have made one change in this rule in response to this comment, however. In a case in which services which *were* ''previously authorized'' are continued or reinstated at the request of the enrollee pending appeal, and during this continuation period, the period of authorization expires, services may be terminated as provided in the original authorization. We have added a new § 438.420(c)(4) to make this clear.

Comment: One commenter believed that CMS underestimated the true burden associated with MCO and PIHP notices, suggesting that it is closer to 20 minutes than 30 seconds per notice.

Response: We address this issue under the Collection of Information Requirements section of this preamble.

Comment: We received many comments regarding the elements of a notice. Several commenters suggested that the written notice requirements of proposed § 434.404 be modified to mirror the existing State fair hearing regulations. Other commenters did not believe that there were sufficient protections in place to ensure that enrollees not only have rights, but have effective notice of those rights. These other commenters recommended additional requirements addressing the right to request a State fair hearing, the right to present evidence, how to contact the MCO or PHP for assistance, how to obtain copies of enrollee records, the right of an enrollee to represent himself or herself or use counsel, and the right to be free from any negative impact from having filed an appeal. Several commenters were concerned that while oral requests for standard appeals must be followed up in writing, there was no requirement that enrollees be told this in the notice. They wanted to see this added.

Response: We agree that information given by MCOs and PIHPs should generally contain the information required by the State fair hearing notices. However, the provision of most of this information is required under the information requirements in § 438.10(g)(1) and the content requirements for a notice in § 438.404. These requirements will ensure that enrollees are informed, for example, that an oral request for a standard appeal will not be pursued unless it is followed up in writing, of the enrollee's right to a hearing, the method for having a hearing, and circumstances surrounding continuation of benefits, if applicable. We have previously addressed the comment on language concerning negative actions by an MCO or PIHP.

Comment: One commenter noted that § 438.404(c)(6) included an incorrect reference. The reference to § 438.210(e) should read ''§ 438.210(d).''

Response: We agree with the commenter. We have made the appropriate change in § 438.404(c)(6) by correcting the cross reference to read § 438.210(d).

4. Handling of Grievances and Appeals (Proposed § 438.406)

Section 438.406 proposed to set forth how grievances and appeals must be handled. The general requirement for handling grievances and appeals would require MCOs and PIHPs to do the following:

- Give enrollees any reasonable assistance in completing forms and taking other procedural steps.
- Acknowledge receipt of each grievance and appeal.
- Ensure that individuals who make decisions on grievances and appeals are

individuals who were not involved in any previous level of review or decision making and who, if deciding an appeal of a denial that is based on lack of medical necessity, a grievance regarding denial of expedited resolution of an appeal, or a grievance or appeal that involves clinical issues, are health care professionals who have the appropriate clinical expertise in treating the enrollee's condition or disease.

We would require the MCO and PIHP, at proposed § 438.406(a)(1), that the ''reasonable assistance'' provided to enrollees include interpreter services and toll free numbers that have adequate TTY/TTD and interpreter capability. By including these as examples of types of assistance required to meet certain needs, we did not intend that other reasonable assistance need not be given. We believe, for example, that MCOs and PIHPs are required by this provision to provide reasonable assistance to meet other needs of enrollees, and assisting enrollees who have low-literacy abilities.

Proposed § 438.406(b) specified the following requirements that the appeals process would have to meet:

- Provide that oral inquiries seeking to appeal an action are treated as appeals and must be confirmed in writing, unless the enrollee or the provider requests expedited resolution. This is required in order to establish the earliest possible filing date for the appeal.
- Provide the enrollee a reasonable opportunity to present evidence, and allegations of fact or law, in person as well as in writing.
- Provide the enroll and his or her representative the opportunity, before and during the appeals process, to examine the enrollee's case file, including medical records, and any other documents and records considered during the appeals process.
- Include, as parties to the appeal, the enrollee and his or her representative or the legal representative of a deceased enrollee's estate.

Comment: One commenter was unclear whether the proposed rule permitted conducting State fair hearings using a video-conferencing system. The commenter noted that many states now use this technology, with videoconference facilities in numerous locations. Multiple sites can be linked to make it more convenient for all parties to participate in the hearing, reducing travel costs, and conserving time.

Response: Nothing in the statute or regulation prevents MCOs, PIHPs, or States from using videoconferencing equipment as long as they adhere to the evidentiary rules described in parts 431 and 438.

Comment: Several commenters recommended that CMS establish more general standards regarding the qualifications of hearings officers. Commenters were concerned with the burden of finding providers with clinical expertise for a voluminous number of cases. They requested that it be permissible to either use physicians or other types of providers with appropriate clinical expertise. Other commenters recommended being more specific in linking certain cases to a particular area of expertise. For example, one commenter wanted language ensuring that all grievances and appeals involving care to a child be reviewed by pediatricians and pediatric specialists.

Response: We believe that it is important for adjudicators to have clinical training appropriate for the case in which they are presiding. However, we are leaving the definition of ''appropriate clinical expertise'' to be defined by the States. This allows States to decide what clinical expertise level is necessary to fit its particular appeals process and volume of cases.

Comment: Several commenters suggested adding ''but not limited to'' to § 438.406(a)(1) where it includes examples of enrollee assistance with grievance and appeals procedures. They believed that this addition would make the language of the regulation comport with the expressed intent of CMS.

Response: We agree with the commenters, and in response to this comment, we have added ''but is not limited to'' in § 438.406(a)(1).

Comment: Several commenters urged CMS to require MCOs and PHPs to have an adequately staffed office designated as the central point for enrollee issues, including grievances and appeals. This would ensure that the processing is someone's job, and not viewed as a chore that is handled on an ad hoc basis.

Response: We disagree with the commenters. As long as States can ensure that those requirements in § 438.406 are met, we believe that it should be their decision as to how best an MCO or PIHP can fulfill those requirements.

Comment: Several commenters questioned the impartiality of an internal appeals system, and felt that CMS should add language to the regulation preventing any employees of the MCO or PHP from being final decision makers on coverage decisions.

Response: In both the Medicare and Medicaid programs, the Congress has provided for an initial level of review of enrollee appeals at the managed care organization level. We believe that the use of the words ''internal grievance procedure'' in section 1932(b)(4) indicates that the Congress contemplated that review be performed by MCO employees. Within this context, this final rule requires that the decision-makers not be individuals involved in any previous level of review, and either be physicians or have the clinical expertise needed to make a decision involving the enrollee's particular condition or disease. We believe that these requirements help insure that internal decisions will be as objective as possible. With respect to the ''final decision'' on a coverage question, all MCO or PIHP coverage decisions are subject to review by non-MCO employees at the State fair hearing level. We believe that those safeguards are reasonable and necessary at the internal appeals level.

Comment: Several commenters believed that we should require MCOs and PHPs to explicitly state that enrollees may obtain copies of their records.

Response: Section 438.406(b)(3) requires that MCOs and PIHPs provide the enrollee and his or her representative with the opportunity to examine the enrollee's case file, including medical records, and any other documents and records considered during the appeals process. However, we believe that the State is in the best position to decide in what way enrollees must be notified about this right.

5. Resolution and Notification: Grievances and Appeals (Proposed § 438.408)

In proposed § 438.408(a), we required that the MCO or PIHP dispose of each grievance and resolve each appeal, and provide notice, as expeditiously as the enrollee's health condition requires. In addition, this section required that the State establish timeframes for disposition of grievances and resolution of appeals, not to exceed the specific timeframes proposed in this section.

While we proposed timeframes to resolve appeals, we realize that the Congress, as part of proposals for a patient's bill of rights, is considering several other timeframes for internal MCO appeals. Some of these proposals would apply the timeframes to the Medicaid program. If these proposals were enacted, such statutory timeframes would supersede those set forth in this final rule.

Under proposed § 438.408(b), we established the specific maximum timeframes for disposition of grievances

and resolution of appeals. For the standard disposition of a grievance and notice to affected parties, the State may establish a timeframe for disposition that may not exceed 90 days from the day the MCO or PIHP receives the grievance. For standard resolution of an appeal and notice to affected parties, proposed § 438.408(b)(2) required that the State establish a timeframe no longer than 45 days from the day the MCO or PIHP receives the appeal. However, this proposed timeframe could be extended under proposed § 438.408(c), which specified that the MCO or PIHP may extend the timeframe by up to 14 calendar days if the enrollee requests the extension, or the MCO or PIHP shows (to the satisfaction of the State agency, upon its request) that there is need for additional information and how the delay is in the enrollee's interest.

Proposed § 438.408(b)(3) provided a maximum timeframe for expedited resolution of appeals and notice to affected parties. We required that the State establish a timeframe no longer than 3 working days after the MCO or PIHP receives the appeal. We believe that expedited resolution is necessary to ensure that appeals of situations that potentially place an enrollee's heath in jeopardy are not delayed. Although States have historically instituted different processes to protect beneficiaries, we believe that a standardized expedited appeal process is needed to protect beneficiaries in a capitated health care delivery system. Further, this is an important beneficiary protection and is necessary to ensure that the overall timeframe of 90 days for a decision at the State fair hearing (excluding the time the beneficiary takes to file for a State fair hearing) can be met in all cases. However, similar to standard resolution of appeals, we proposed that this expedited timeframe can also be extended by 14 calendar days if the enrollee requests extension or the MCO or PIHP shows (to the satisfaction of the State agency, upon its request) that there is need for additional information and how the delay is in the enrollee's interest.

We proposed certain parameters for the extension process. Under proposed § 438.408(c)(2), if the MCO or PIHP grants itself an extension, it is required to notify the enrollee in writing of the reason for the delay. In § 438.408(d), we required the State to establish the method MCOs and PIHPs will use to notify an enrollee of the disposition of a grievance. Under proposed § 438.408(e), we specified that written notice of the appeal resolution must include the following:

- The results of the resolution process and the date it was completed.
- For appeals not resolved in favor of the enrollee, the enrollee's right to request a State fair hearing and how to do so, the right to request to receive continuation of benefits, and that the enrollee may be held liable for the cost of those continued benefits if the State fair hearing decision upholds the MCO's or PIHP's action.

Finally, at proposed § 438.408(f) (this paragraph was erroneously codified as a second paragraph (c), an error that has been corrected in this final rule), we outlined the requirements for State fair hearings. We required the State to permit the enrollee to request a State fair hearing within a reasonable time period specified by the State, but not less than 20 days or in excess of 90 days from the date of the MCO's or PIHP's notice of resolution (if the State requires exhaustion of the MCO or PIHP level appeal procedures) or from the date on the MCO's or PIHP's notice of action (if the State does not require exhaustion and the enrollee appeals directly to the State for a fair hearing). We also felt it was important to outline at proposed § 438.408(f)(2) that the parties to the State fair hearing include the MCO or PIHP as well as the enrollee and his or her representative, or the representative of a deceased enrollee's estate.

Comment: Several commenters felt that proposed § 438.408(a) should be revised to require that all notices of dispositions of grievances be provided in writing. These commenters argued that MCOs and PIHPs often confuse cases which should be treated as a grievance with those that should be handled as an appeal. Written dispositions of grievances would in the views of these commenters provide a mechanism for addressing this issue by revealing whether or not an MCO or PIHP is resolving a dispute pursuant to the appropriate mechanism.

Response: We believe that § 438.408 makes the difference between a grievance and an appeal very clear. An appeal is triggered through an action, while a grievance involves any dissatisfaction other than an action. If a State chooses to monitor its MCOs and PIHPs by requiring written notices, it may do so. However, we see no reason to require a written notice at the Federal level for all grievances, when many may not be of a nature for which such a notice is appropriate, and there is no Federal right to review by the State of such matters.

Comment: Comments on timeframes widely differed. Many commenters questioned the fact that the timeframes for appeals in the proposed rule were longer than those in place under Medicaid fee-for-service, Medicare+Choice, and versions of Patients Bill of Rights legislation. The commenters apparently believed that departing from these standards failed to adequately protect beneficiaries, and raised constitutional due process questions. These commenters wanted standard internal appeals to be resolved within 30 days. However, several other commenters found the 45-day timeframe more reasonable. Still other commenters were confused about the timeframes in general, and wanted an explanation of how they worked.

Response: We realize that the proposed timeframes were confusing as proposed, and potentially would not give the State a reasonable amount of time—or under some scenarios, any time, to conduct a fair hearing. We believe that after an MCO or PIHP takes up to 45 days, plus a possible 14-day extension, to make a decision, the 90-day clock for a fair hearing decision should stop during the time the enrollee takes to file for a State fair hearing (which could be as long as 90 days itself). Therefore, in response to the above comments, we have clarified in § 431.244(f) that the State is required to resolve the State fair hearing within 90 days of the day the MCO or PIHP received the appeal, not including the number of days the enrollee took to subsequently file for a State fair hearing. We believe that this is a reasonable timeframe because it holds the State accountable within a 90-day timeframe as long as the enrollee takes prompt action to follow up any denial at the internal appeal level. This will guarantee a high level of commitment on both sides. We also believe that 45 days is a reasonable standard timeframe for an MCO or PIHPs, because an enrollee may request an expedited appeal if he or she feels that a standard timeframe could jeopardize his or her health. With respect to the comments raising constitutional due process issues, we believe that applying this timeframe in this situation is fully consistent with due process requirements.

Comment: Some commenters noted that most States already have a complex grievance system in place, with specified timeframes and other rules, and changing these requirements may be confusing for beneficiaries and may not provide any additional protections to enrollees. These commenters asked us to permit ''deeming'' of compliance with Medicaid rules when the State's system met certain standards.

Response: The grievance and appeals requirements in § 438.408 set forth

minimum standards that MCOs, PIHPs, and States must follow. As long as those standards are met, a State is free to tailor those to the system it operates. We believe that these timeframes, notice requirements, and other standards grant States flexibility (*e.g.,* the State is granted the discretion to establish timeframes, within ranges), and constitute the minimum necessary to ensure reasonable beneficiary protections. We strongly believe that the established timeframes give States, MCOs and PIHPs adequate time to make an informed decision for enrollees at both the internal and State fair hearing levels.

Comment: Several commenters believed that the mandatory timeframes for the grievance and appeals process in § 438.408 might be difficult to meet if enrollees fail to submit timely information, or are not available for an in-person presentation to the MCO or PIHP. These commenters asked that a limit be placed on the number of days MCOs and PIHPs are responsible for providing continued services pending a final determination in the case of an appeal from a termination of benefits. Some commenters wanted the timeframes to begin when all documentation is received from providers, rather than the date of notice of the action being appealed, for fear that the timeframes would be impossible to meet in certain cases.

Response: We believe that the timeframes in § 438.408 will result in timely decisions based on all necessary evidence in the vast majority of cases. Enrollees have a strong incentive to cooperate fully with officials in an internal appeals process to facilitate timely coverage decisions. However, if some enrollees do not provide enough information to support their appeal, the MCO or PIHP is responsible for deciding the appeal on the basis of available information within the timeframes set out. Since continuation of benefits for authorized services being terminated may, at the beneficiary's request, continue throughout the appeals process until the final decision is made at the MCO, PIHP, or State level, we believe that it is reasonable to require MCOs and PIHPs to make decisions within the specified timeframes so they are not responsible for covering benefits due to another party's delay.

Comment: One commenter felt that the timeliness for grievance and fair hearing completions may be difficult to meet in the case of mental health enrollees. The commenter inquired as to whether decisions on an action could be made retroactively, still comply with the requirements.

Response: The timeframe for filing an appeal in a State will be between 20 and 90 days, as determined by that State. We believe that this should be sufficient time for all enrollees to request a hearing. MCO, PIHPs, and States are then responsible for assisting enrollees with any procedural barriers they may encounter. Once the appeal is filed, the MCO, PIHP, or State is responsible for ensuring that a fair decision is made within the mandated timeframes.

Comment: A few commenters noted that in proposed § 438.408, the paragraph titled ''Requirements for a State fair hearing,'' which was identified in the preamble as paragraph (f), was inadvertently labeled paragraph (c) in the regulations text. The commenter assumed this was a typographical error.

Response: We agree with the commenter, and as noted above, we have made the appropriate change in § 438.408.

6. Expedited Resolution of Appeals (Proposed § 438.410)

In proposed § 438.410 we required each MCO and PIHP to establish and maintain an expedited review process for appeals when the MCO or PIHP determines or the provider indicates that taking the time for a standard resolution could seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function. Further, the MCO or PIHP was required under proposed § 438.410(b) to ensure that no punitive action is threatened or taken against a provider who requests an expedited resolution, or supports an enrollee's request for an expedited appeal.

If the MCO or PIHP denies a request for expedited resolution of an appeal, it would be required under proposed § 438.410(c) to transfer the appeal to the standard resolution timeframe in accordance with proposed § 438.408(b)(2), and give the enrollee prompt oral notice of the denial following within two calendar days with a written notice.

Comment: One commenter contended that the definition of ''expedited authorization decisions'' can be applied to nearly any medical necessity determination. This commenter recommend removing language related to the ''enrollee's ability to attain, maintain, or regain maximum function * * * could be jeopardized.''

Response: We disagree with the commenter. If a standard appeals process is long enough to place an enrollee's health in jeopardy based on the definition above, we believe that an expedited appeal is warranted. Furthermore, the provider, MCO, PIHP, or State has the final decision on whether or not that threshold has been met. Therefore, we believe that it does not add any unwarranted administrative burden to MCOs, PIHPs, or States during the process.

Comment: Comments on the timeframes in proposed § 438.410 again differed widely. Many commenters (again citing due process concerns and comparing the timeframes to other situations) wanted expedited internal appeals to be resolved within 72 hours, mirroring Medicare+Choice and State fair hearing timeframes.

However, several commenters found the timeframes unreasonable, unrealistic, subjective, and too prescriptive, and asked for more State flexibility to set timeframes. Some wanted the expedited process to be longer, such as a minimum of five working days, arguing that the present timeframe was unworkable. One commenter noted that most States already have timeframes, and suggested that changing these requirements may be confusing for beneficiaries while not providing any additional meaningful protections to enrollees.

Response: We continue to believe that the regulation should establish timeframes for steps in the internal appeal process, and that an expedited timeframe is necessary when the use of standard timeframes may jeopardize the enrollee's health. An expedited timeframe is an important beneficiary protection and ensures that those enrollees who need a quick decision will receive one. However, we believe that three working days for an expedited internal appeal makes the most sense. It provides for a very timely decision for those enrollees whose health may be in jeopardy, yet facilitates MCOs and PIHPs with the difficulty of operating during weekends and holidays. If an enrollee's health is jeopardized by an emergency medical condition, as defined in § 438.114(a), then he or she would go to the nearest emergency room. In § 438.408(a) we provide for States to establish timeframes that may not exceed the timeframes specified in this final rule. Thus, States may establish shorter timeframes. Again, with respect to the commenter's due process concerns, we are unaware of any legal basis for the suggestion that these regulations would violate due process.

Comment: Several commenters suggested that the regulations expressly allow the beneficiary to obtain an expedited review based on their primary care provider's opinion that the standard for expedited review has been met. They believed that MCOs and

PIHPs should not be given complete control over the situation, because their financial arrangements may provide an incentive to deny services.

Response: Under § 438.410(a), an MCO or PIHP must provide expedited review if it determines the standard for such review has been met, in the case of a request by an enrollee or if ''the provider'' makes such a determination. The preamble to the proposed rule did not specify whether ''the provider'' included the enrollee's primary care provider, or only the provider who would be furnishing the service requested in connection with the appeal. In response to this comment, we are clarifying that ''the provider,'' as used in § 438.410(a), refers to the provider of the services requested, since this provider is in the best position to evaluate the enrollee's need for those services. In some cases, this may be the primary care provider, in which case the current regulations would provide for the result the commenter seeks. In other cases, however, the primary care provider's opinion would not be dispositive of whether expedited review would be granted. We assume that the primary care provider's views would be taken into account by the MCO or PIHP in making their determination, or by ''the provider'' of the services sought, in deciding whether to request review or support the enrollee's request as provided in § 438.410(a). If an enrollee disagrees with the MCO's or PIHP's decision, and the provider who would be furnishing the services does not support the enrollee's request, nothing prevents him or her from contacting the State and asking for its involvement or assistance. Furthermore, States have the option to make a primary care provider's decision binding in all cases as part of their contract requirements, or State law, if they choose.

Comment: Several commenters were concerned about the MCO's and PIHP's ability to extend the 3-day expedited timeframe for 14 more days in cases in which this extension was not requested by the enrollee, and with the fact that the enrollee does not have the right to appeal such an extension. These commenters argued that the State has no mechanism for knowing that an MCO or PIHP has given itself such an extension, making the expedited provision arguably an empty mechanism. Furthermore, it appears to these commenters that the MCO or PIHP could give itself extensions indefinitely because there is no requirement to resolve the appeal after the first extension. They recommended only allowing an extension in these cases if the enrollee requests it.

Response: We partially disagree with the commenters' interpretation of the regulation. We state in § 438.408(b)(3) that an MCO or PIHP may extend the timeframe of 3 working days up to an additional 14 calendar days. This is intended to be the outer time limit before a decision is made or the enrollee is eligible to file for a State fair hearing. Thus, an MCO or PIHP could not continue ''indefinitely'' to grant additional 14 day extensions. With respect to cases in which an enrollee does not request the extension, the extension still must be in the enrollee's interests, and an enrollee is free to argue to the State that this standard has not been met. The State then may decide if it should intervene. Moreover, we note that States have the option in contracts or in State law of permitting extensions only when requested by the enrollee.

Comment: One commenter expressed concern regarding the logistics of requiring MCOs and PHPs to give prompt oral notice to an enrollee of any denial of an expedited request. They noted that some Medicaid enrollees may not be accessible by telephone.

Response: We are aware that some Medicaid enrollees may not have telephones, and that it therefore may be difficult in some cases to provide oral notice. Therefore, in response to this comment, we have revised § 438.410(c)(2) by requiring MCOs and PIHPs to make reasonable efforts to notify enrollees orally of decisions not to expedite an appeal, and to follow up with a written notice within two calendar days. MCOs and PIHPs should request information from enrollees about how and where they can be contacted.

Comment: Several commenters recommended that the State Medicaid agency be permitted 3 working days to hear expedited appeals that they receive, rather than 72 hours.

Response: We agree with the commenters. In response to this comment, the final rule, at § 431.244(f)(2) and (3), now requires the State to conduct a fair hearing and make its decision within 3 working days for service authorization denials that meet the criteria for expeditious handling. We have chosen to use the same 3-working-days standard that applies to MCO or PIHP review in expedited cases so that the State would not be required to complete review of all expedited cases during weekends or holidays.

Comment: Many commenters advocated a requirement that expedited internal appeals not decided wholly in the enrollee's favor be automatically forwarded to the State fair hearing process. These commenters felt that timing during an expedited process was essential, and that automatic forwarding would provide necessary speed to the process.

Response: We disagree with the commenters. We believe that the burden on MCOs, PIHPs and States, of automatic forwarding of appeal materials even in cases in which the enrollee may not wish to pursue a further appeal outweighs any benefits that might be achieved by such a policy. As in the case of when a beneficiary files an appeal during the 90 standard timeframe, it is reasonable to expect any enrollee who is seeking a particular service or benefit to promptly file for a State fair hearing if he or she is not wholly successful at the internal appeals level. We do not believe this would significantly add to the time it takes to handle the appeal. We note that the MCO or PIHP must give enrollees reasonable assistance in completing forms and taking other procedural steps.

Comment: One commenter noted that the proposed rule did not grant enrollees a right to a State fair hearing for an enrollee whose request for an expedited resolution is denied. Specifically, the commenter noted that this was not listed among the bases for a State fair hearing. The commenter wanted clarification on this point.

Response: The omission of a denial of a request for an expedited hearing from the ground for a fair hearing was intentional. As noted above, if a request for an expedited resolution is denied, the case is automatically treated as a standard appeal. However, if that internal appeal is not resolved wholly in favor of the enrollee, then the enrollee has a right to a State fair hearing.

Comment: One commenter objected to the fact that the proposed rule did not include a requirement for an expedited review process for grievances. They argued that this would be dangerous for enrollees with severe health problems who could not wait for the time frame of the standard review process.

Response: A grievance involves any dispute other than an ''action.'' Only an action should involve the possibility of a delay putting an enrollee with severe health problems at risk. We have an expedited provision for those type of disputes. Therefore, we do not believe that an expedited grievance process is a necessary mandate at the Federal level.

Comment: One commenter noted that proposed § 438.410(a) should have a period at the end rather than a semi-colon.

Response: We agree with the commenter, and we made the appropriate change in § 438.410(a) the final regulation.

7. Information About the Grievance System to Providers and Subcontractors (Proposed § 438.414)

Proposed § 438.414 required that the MCO or PIHP must provide the information specified at § 438.10(g)(1) about the grievance system to all providers and subcontractors at the time they enter into a contract.

Comment: One commenter requested that CMS require that information about the grievance system be provided to subcontractors as well as to contracting providers.

Response: Proposed § 438.414, which is unchanged in this final rule, already provided that this information must be provided to providers ''and subcontractors.''

8. Recordkeeping and Reporting Requirements (Proposed § 438.416)

Proposed § 438.416 required the State to require MCOs and PIHPs to maintain records of grievances and appeals and review the information as part of the State quality strategy.

Comment: Commenters urged that the regulation require States to provide members of the public, upon request, with MCO and PHP summaries of grievance and appeal logs.

Response: States have the authority to require that MCOs and PIHPs make available to the State, or at the State's option, to members of the public, grievance and appeal logs or other MCO and PIHP grievance system documents. We do not agree that we should mandate this, however. In some cases, raw appeals data may be confusing to the public, or potentially misleading. We believe States are in the best position to decide how such information should be presented to the public. In designing their quality strategies, States should consider what information they and the public will need to support those strategies.

9. Continuation of Benefits When an MCO or PIHP Appeal of a Termination, Suspension, or Reduction, and State Fair Hearing on Such an Action, are Pending (Proposed § 438.420)

Proposed § 438.420 required that when the dispute involves the termination, suspension, or reduction of a previously authorized course of treatment, the MCO or PIHP must continue the enrollee's benefits until issuance of the final appeal decision or State fair hearing decision, if all of the following occur:

- The enrollee or the provider files the appeal timely.
- The services were ordered by an authorized provider.
- The period covered by the authorization has not expired.
- The enrollee requests such an extension of benefits.

We specified that timely filing means filing on or before the later of either the expiration of the timeframe specified by the State (in accordance with § 438.404(c)(2)) and communicated in the notice of action or the intended effective date of the MCO's or PIHP's proposed action.

This provision would apply only when the MCO or PIHP physician initially authorized the services (that is, it would not apply to pre-service authorization requests that were denied) and when the beneficiary requests the services be continued (that is, the mere action of filing for an appeal or State fair hearing in a timely manner is not sufficient for benefits to be continued). The continuation of benefits provision would not require a further statement of authorization from the MCO or PIHP physician or affect benefits not originally authorized.

If the MCO or PIHP continues or reinstates the enrollee's benefits while the appeal is pending, under proposed § 438.420(c), the benefits must be continued until one of the following occurs:

- The enrollee withdraws the appeal.
- The MCO or PIHP resolves the appeal against the enrollee, unless the enrollee has requested a State fair hearing with continuation of benefits until a State fair hearing decision is reached.
- A State fair hearing officer issues a hearing decision adverse to the enrollee.

Beneficiaries who have received continuation of benefits while they appeal to the MCO or PIHP are not obligated to pursue their appeal further, through the State fair hearing process, if the MCO or PIHP denies their appeal. It remains the beneficiaries' choice. It is important to note, however, that enrollees who lose their appeal at either the MCO, PIHP or State fair hearing levels will be liable for the costs of all appealed services from the later of the effective date of the notice of intended action or the date of the timely-filed appeal, through the date of the denial of the appeal. As a result, in § 438.420(d), we proposed that if the final resolution of the appeal is adverse to the enrollee (that is, it upholds the MCO's or PIHP's action) the MCO or PIHP may recover the cost of the services furnished to the enrollee while the appeal was pending, to the extent that they were furnished solely because of the requirements of this section, and in accordance with § 431.230(b).

Comment: Many commenters pointed out that the proposed rule does not specify all the same circumstances set forth in §§ 431.230 and 430.231 as situations in which benefits must be continued or reinstated. These commenters specifically cited advanced notice requirements, and argued that this rewards MCOs and PIHPs that do not provide advanced notice.

Response: We disagree with the commenters. MCOs, PIHPs, and States have a strong incentive to notify enrollees timely of any reduction, limitation, or suspension of existing services. While enrollees have to actively request continuation of benefits while filing an appeal, they must be given the opportunity to do so before the benefits are reduced, limited, or suspended. And since enrollees have this right until an adverse State fair hearing decision (assuming of course that he or she follows the applicable rules), a delay in notice only gives enrollees benefits for a longer period of time. However, in response to this comment, we now state in the regulation text that the enrollee has 10 days after the MCO or PIHP mails the notice of action to request continuation of benefits. Therefore, even if the effective date of action has passed, an MCO or PIHP may not discontinue those benefits until 10 days after the notice is mailed. We believe that this sufficiently addresses the commenters' concern.

Comment: We received many comments regarding enrollees' rights to continuation of benefits during the MCO and PIHP appeal process. Several commenters thought that the regulations mandate that MCOs and PIHPs continue benefits in all cases in which the appeal involves services that are being terminated or reduced. Several commenters felt that continuation of benefits pending resolution of an appeal or State fair hearing, without financial risk, is one of the most important protections needed for managed care enrollees.

In contrast, several other commenters were opposed to extending continuation of benefits requirements to the MCO and PIHP appeal process. One commenter contended that this requirement would have significant cost implications for MCOs and PIHPs. Another commenter felt that benefits should be continued only at the point when an enrollee requests a State fair hearing.

One commenter thought that requiring MCOs and PHPs to continue benefits would place them in an untenable position with their providers, compromising their ability to manage care and cost. This commenter expressed concern that this provision

may damage managed care programs, and believed it was unnecessary, given the requirement of expedited review of appeals in cases in which a delay could jeopardize health.

Response: Because we allow States to require exhaustion of the MCO and PIHP appeal before receiving a State fair hearing, we believe that, in order for the right to continued benefits during a State fair hearing to be meaningful, continuation of benefits must begin with the filing of an MCO or PIHP appeal, and continue until the State fair hearing decision. Given that, with few exceptions, the overall 90-day timeframe for a final fair hearing decision applies even when exhaustion is required, the amount of time benefits must be continued is the same under this final rule as under the longstanding fair hearing system. Continuation of benefits at the MCO and PIHP level thus is part of the same longstanding right to continuation of benefits that has existed for Medicaid beneficiaries when services are reduced or terminated.

As in fee-for-service, under managed care, the right to continuation of benefits is not exercised without financial risk to the beneficiary of payment for services provided should he or she lose the appeal. Otherwise, MCOs, PIHPs, or States would be unfairly liable for treatment in which they were correct in limiting, reducing, or suspending. It is because of this potential risk for enrollees that we require that the enrollee specifically request continuation of benefits. Under § 438.404(b)(7), the notice of adverse action must include an explanation of this choice.

While expedited appeals will decrease the amount of time MCOs and PIHPs are liable to continue benefits for enrollees with pending appeals, the expedited appeal process does not substitute for the protection provided to Medicaid beneficiaries of the right to continuation of previously authorized benefits pending the outcome of a State fair hearing decision.

If the benefit is a Medicaid covered service, but not an MCO or PIHP covered service, the State, not the MCO or PIHP is responsible for providing those services pending the outcome of the State fair hearing.

Comment: Several commenters requested that § 438.420 should clearly state that re-authorization of a service at a lower level than previously received, or a denial of re-authorization, is a termination or reduction of the service requiring the continuation of benefits pending appeal. Other commenters requested that we make clear in the regulation text that continuation of benefits does not include the expiration of an approved number of visits through an authorized course of treatment.

Response: As noted above, we agree that the expiration of an approved number of visits does not constitute a termination for purposes of notice and continuation of benefits. If an enrollee requests re-authorization for services and the MCO or PIHP denies the request or re-authorizes the services at a lower level than requested, the MCO or PIHP must treat this request as a new service authorization request and provide notice of the denial. We have explained above that the language in the proposed rule already limited the right to continued benefits to services that were authorized. In response to this comment, in order to make clear that the continuation of benefits itself is not what we mean by ''authorized,'' we have revised § 438.420(b)(4) by adding the word ''original'' to make clear that benefits are only continued to the extent they were originally authorized. As noted above, we also have added a new § 438.420(c)(4) in this final rule to make clear that when benefits are continued under § 438.420(b), they may be discontinued when the original authorization expires.

Comment: One commenter was concerned about the status of enrollees who received authorization for a course of treatment from a non-network physician but then had those benefits limited by a new MCO once the course of treatment had begun. They believe that these enrollees need protection for their benefits.

Response: An enrollee who has his or her existing benefits reduced, limited, or suspended by an MCO, PIHP, or State has the right to request a continuation of benefits regardless of the source as long as it originated from a Medicaid participating provider. It is the State's decision as to what entity is liable for those benefits during the appeals process.

Comment: One commenter argued that discontinuing services being provided by an MCO without a State fair hearing was unconstitutional.

Response: We do not believe that we need reach constitutional issues (such as, regarding whether a property interest or State action exist) because Medicaid beneficiary rights are directly addressed in section 1902(a)(3) and 1932(b)(4), and it is these statutory rights that are implemented in this final rule. As noted above, we believe that if services are discontinued on the date the authorization expires, this is not a ''termination'' of services that the enrollee had any right to expect to receive, and thus is not a termination within the meaning of section 1902(a)(3) and the implementing regulations. In the case of a termination of authorized services prior to the expiration date of the authorization, we agree with the commenter that a beneficiary should have the right to have these benefits continue pending a hearing on the termination. We provide the enrollee with 10 days to request to have benefits continue under these circumstances, pending an appeal and State fair hearing. We believe that this process is fully consistent with the Medicaid statute and constitutional requirements, to the extent applicable.

Comment: Several commenters requested that we delete the requirement that the beneficiary must request continued benefits. They contended that this requirement was constitutionally defective in that they believed continued benefits, without pre-requisites to obtaining them, to be required under due process.

The commenters noted that while the existing regulation at § 431.230(b) provides for the possibility of recoupment, benefits are continued when an appeal is filed timely. The commenters found no reason to change this long-standing rule for beneficiaries who are receiving services through an MCO or PIHP. Also, several commenters believed that proposed § 438.420(c)(2) made it impossible for benefits to continue through a State fair hearing, because a beneficiary would have had to file for a State fair hearing before the MCO or PIHP had even made its internal appeal decision in order for benefits to continue.

Response: Again, we do not believe we need reach constitutional issues here, but that the final rule as proposed is fully consistent with any applicable constitutional requirements. It is not true that benefits continue under fee-for-service Medicaid ''without pre-requisites to obtaining them.'' Benefits only continue under fee-for-service if the beneficiary timely files an appeal. We do not see the difference between requiring the filing of an appeal for benefits to continue and requiring that as part of such an appeal, the beneficiary request that benefits continue. Indeed, given the possibility of beneficiary liability in both cases, we believe that the approach in this final rule is more protective of beneficiary rights. Under this rule, after an action, the beneficiary will be notified both of this right to continuation of benefits and the possible liability for services if the final decision is not in his or her favor. Thus, we believe the general concern about continued benefits not being automatic with an appeal is unfounded.

However, we agree with the concerns expressed by several commenters' that proposed § 438.420(c)(2) could make it impossible for benefits to continue through a State fair hearing as proposed. Therefore, in response to these comments, we have revised § 438.420(c)(2) by requiring beneficiaries to re-request continuation of benefits within 10 days after the mailing of the internal appeal decision against the enrollee, in order to preserve continuation of benefits during a State fair hearing.

10. Effectuation of Reversed Appeal Resolutions (Proposed § 438.424)

Proposed § 438.424 required that if the MCO, PIHP, or the State fair hearing officer reverses a decision to deny, limit, or delay services that were not furnished while the appeal was pending, the MCO or PIHP must authorize or provide the disputed services promptly, and as expeditiously as the enrollee's health condition requires. Furthermore, if the MCO, PIHP, or the State fair hearing officer reverses a decision to deny authorization of services, and the enrollee received the disputed services while the appeal was pending, the MCO, PIHP, or the State would be required to pay for those services, in accordance with State policy and regulations.

Comment: Many commenters supported a time frame of no more than 10 days for an MCO or PIHP to provide or pay for services subsequent to a State fair hearing because enrollees with successful appeals should not have to adjudicate over the word ''promptly.''

Response: We disagree that MCOs and PIHPs should be held to a Federal timeframe to provide or pay for services, because such a timeframe may not be reasonable in the case of the circumstances of all States. Consistent with the State fair hearing policy in § 431.246, we are requiring that the services are provided promptly, or as expeditiously as the enrollee's health condition requires. We believe that the States are in the best position to decide whether to require specific time limits if they choose.

F. Certifications and Program Integrity (Subpart H)

Fraud and abuse can negatively affect both the quality of health care services rendered to Medicaid beneficiaries, and an MCO's, PIHP's, PAHP's, or PCCM's financial viability. Promoting program integrity within Medicaid managed care programs can protect against misspent Medicaid program funds, and promote quality health care services. Proposed subpart H of part 438 contains safeguards against fraud and abuse and requires that organizations with Medicaid contracts make a commitment to a formal and effective fraud and abuse program.

In proposed § 438.600 we stated that the statutory basis for this subpart is under sections 1902(a)(4) and 1902(a)(19) of the Act. These sections require that methods be provided in the State plan for the proper and efficient operation of the plan and that safeguards are provided consistent with the best interests of the recipients.

In proposed § 438.602 we provided that the certification and program integrity requirements contained in subpart H apply to MCOs and PIHPs as a condition for contracting and for receiving payment under the Medicaid managed care program.

In proposed § 438.604 we provided that data, including enrollment and encounter data, must be certified and submitted to the State, if State payments are based on the data. We also specified that other information required by the State and information included in contracts, proposals, and other related documents must be certified. We also required in § 438.604(b) that the MCO or PIHP certify that they are in substantial compliance with the terms of the contract.

In proposed § 438.606 we required that certifications be provided concurrently with the data they relate to, and required that certifications be signed by the MCO's or PIHP's Chief Executive Officer, Chief Financial Officer, or an individual delegated authority to sign for one of these individuals. We proposed that the certifications must include attestations to the truthfulness, accuracy, and completeness of the data based on best knowledge, information, and belief.

In proposed § 438.608 we required that each MCO or PIHP have administrative and management arrangements or procedures, including a mandatory compliance plan, designed to guard against fraud and abuse. This section also outlined the required elements to be included in the arrangements and procedures.

In this final rule we are making a technical correction to add two additional sources of authority. First, we are adding a citation to section 1903(m), which establishes conditions for payments to the State with respect to contracts with MCOs. Second, we are adding a new § 438.610 to incorporate the requirements of section 1932(d)(1) of the Act. That provision of the statute is self-implementing, and therefore we did not include it in the proposed regulation. However, we are including the substance of the requirement in this final regulation to make it easier for the public to find all the relevant provisions in one place. Under the authority of section 1902(a)(4) of the Act, we are also applying these provisions to PIHPs and PAHPs.

We believe it is in the best interests of State Agencies, MCOs, PCCMs, PIHPs, PAHPs, and CMS to significantly aid in the fight against fraud and abuse and the requirements of this subpart work to achieve that goal.

Comment: One commenter proposed that we develop a standard form for certifications since we are requiring certifications by the Chief Executive Officer or the Chief Financial Officer or other person who is delegated the authority of the MCO or PIHP to certify data submitted.

Response: We disagree with the commenter as we wish to maintain State flexibility in this area. In §§ 438.604 and 438.606 respectively, we provide that data certifications are required if data are being used to set payments. We have described the source, content, and timing required for certifications. We do not, however, wish to be overly prescriptive and therefore, we are not prescribing the format of the certifications. If the commenter is requesting a sample format that could be used as a model certification form, one can be found on the CMS website at *http://www.hcfa.gov/medicaid/letters/smd80700.htm* in the document entitled, ''Guidelines for Addressing Fraud and Abuse in Medicaid Managed Care'' at appendix 2.

Comment: One commenter suggested that it is unclear as to when certifications are required and if the certifications of data to set payments is meant to reference payments under the current contract year or for proposed contract years. The commenter also believes that the requirements for certifications for substantial compliance with the terms of the contract are unclear.

Response: In § 438.604(a) we require that MCOs and PIHPs provide certification of data requested by the State if payments to the MCOs and PIHPs are based on the data submitted, and in § 438.606(c) we require that MCOs and PIHPs submit the certification concurrently with the data. This applies regardless of whether the data are used for setting payments for current contract years, or for other contract years. If data are not being used to set payments, then certifications would not be required.

We agree with the commenter that clarification is necessary regarding

certification for substantial compliance with the terms of the contract. We previously proposed, in §§ 438.604(b), that an MCO or PIHP must certify that it is in substantial compliance with the terms of its contract.

We understand the commenter's confusion regarding this requirement since the statute and regulations already require States to monitor compliance with contracts executed under this rule and provides sanctions to be used where certain requirements are not met. Further we would expect to require corrective action plans in situations in which a State is found to be out of compliance with these rules. Consequently, we believe that the requirements on States, MCOs, PIHPs, PAHPs, and PCCMs contained in § 438.6 and elsewhere in this rule and the mechanisms for monitoring and enforcement are sufficiently clear that the requirements for ''substantial compliance'' in §§ 438.604 and 438.606 are unnecessary and we have deleted them from this subpart. Hence renumbering has taken place in these sections.

Comment: Several commenters believe that subcontractor certifications are necessary since MCOs could delegate functions to subcontractors including physicians, hospitals, and clinics as well as to administrative service organizations that collect data from network providers and report the data to the MCO and the State. The commenters argued that without accurate and complete data, States may not have the information necessary to set actuarially sound capitation rates. Commenters expressed opposing views on this issue with one commenter believing that this requirement would be burdensome to plans and providers because of the complexities involved in obtaining provider certifications. Other commenters stated that subcontractor certifications are necessary to protect CMS and others against being defrauded or paying an MCO more than the amount to which it should be entitled. We received further suggestions that not having subcontractor requirements could undermine federal enforcement of the False Claims Act.

Response: We have considered the commenters' suggestions and we agree that subcontractors play an important role in an MCO's network. We require MCOs and PIHPs to certify *all* data they submit, which would include any data produced by subcontractors. We believe that MCOs and PIHPs should be held accountable for their subcontractors and their subcontractors' data. We believe that States must be able to rely on the MCOs' and PIHPs' certifications if they are to combat potential fraud and abuse, and continue to set capitation payments to MCOs and PIHPs appropriately. Therefore, we are only requiring in this subpart that data certifications be required of MCOs and PIHPs and not of their subcontractors. It is up to the State or the MCO or PIHP to determine whether subcontractor data is accurate. If data is not used to set payments, certifications by MCOs and PIHPs are not necessary.

Comment: We received opposing views about whether PAHPs should be exempt from the program integrity protections outlined in this subpart. One commenter suggested that PAHPs should be required to have fraud and abuse plans and data certifications to justify State payments, since fraud can be significant in ambulatory plans also. In contrast, another commenter believes we should require that fraud and abuse plans be implemented only by entities with 10,000 enrollees or more.

Response: We clearly intend that PAHPs should work to combat against fraud and abuse. However, we are recognizing that it may not be appropriate to require those organizations to implement formal fraud and abuse plans, given that they generally have relatively few enrollees and provide a relatively narrow range of services. We believe that the benefits of requiring PAHPs to comply with the formal measures of subpart H in order to protect against fraud and abuse is outweighed by the level of burden placed on these organizations, which could place some plans at financial risk.

Consequently, we are only requiring that §§ 438.600 through 438.610 apply to MCOs, to PIHPs, and only to PAHPs and PCCMs where specifically noted. Typically, MCOs and PIHPs, which include at least some inpatient hospital or institutional care services, are larger, more complex organizations, and will in most cases, have higher enrollment levels.

We believe the more comprehensive plans (such as, MCOs and PIHPs) are likely to need to provide for more sophisticated methods for combating fraud and abuse and may also need to provide for compliance officers as part of their staff. This is because they are more complex organizations, and need to contract with a large number, and greater variety of providers. These plans typically serve more enrollees and provide more services. Furthermore, more complex organizations are likelier to include administrative staff that collect and report data, and that need more in-depth monitoring. We disagree with the commenter that the applicability of these requirements should depend on the PAHP's enrollment level, because enrollment can fluctuate, and we believe that approach would lead to arbitrary results.

Comment: A commenter suggested that we should not mandate the use of a compliance plan developed by a federal enforcement agency, that is, the OIG, that was intended for M+C plans.

Response: We agree with the commenter that to require the use of guidelines developed for a national program (such as, M+C) by a Federal enforcement agency would be overly prescriptive and could impede State flexibility in combating fraud and abuse. In § 438.608 we require MCOs and PIHPs to have administrative and management procedures, including a mandatory compliance plan, designed to guard against fraud and abuse; however, we have not mandated the use of the compliance plan developed by the OIG. The commenter is correct that the compliance plan developed by the OIG is intended for M+C plans and not for Medicaid managed care plans. Further, we agree that it is important for States to have flexibility in combating fraud and abuse in the Medicaid program and we believe States can maintain that flexibility by developing their own compliance plans.

G. Sanctions (Subpart I)

Section 1932(e)(1) of the Act requires, as a condition for entering into or renewing contracts under section 1903(m) of the Act, that State agencies establish intermediate sanctions that the State agency may impose on an MCO that commits one of six specified offenses: (1) Failing substantially to provide medically necessary items and services that are required by law, or are required under the MCO's contract with the State; (2) imposing premiums or charges in excess of those permitted under title XIX; (3) discriminating among enrollees based on health status or requirements for health care services; (4) misrepresenting or falsifying information; and (5) failing to comply with statutory requirements that apply to physician incentive plans. Under section 1932(e)(1)(A) a State may also impose sanctions against MCOs and PCCMs for distributing, directly or through an agent or contractor, marketing materials that contain false or materially misleading information. Proposed § 438.700 contained the above provisions from section 1932(e)(1) of the Act.

In section 1932(e)(2) of the Act, Congress described the types of sanction authority that would satisfy the State's obligation to have intermediate

sanctions. For the most part, the State has discretion to choose which of these sanctions to use. However, the State is required to have authority to appoint temporary management under section 1932(e)(2)(B), and to permit individuals to terminate without cause under section 1932(e)(2)(C). This is because section 1932(e)(3) requires the State to impose at least those two sanctions if an MCO repeatedly fails to meet the requirements of sections 1903(m) or 1932. The other provisions that would clearly satisfy the State's obligation to have intermediate sanction authority include authority to impose civil money penalties for specified violations, up to specified maximum amounts, and to suspend enrollment or payment for new enrollees. These provisions were reflected in proposed § 438.702(a).

Under section 1932(e)(2)(B), one of the sanctions that would satisfy section 1932(e)(1) is for the State to oversee the operation of the MCO ''upon a finding by the State that there is continued egregious behavior by the organization or there is a substantial risk to the health of enrollees * * * or to assure the health of the organization's enrollees.'' Given the extraordinary nature of the sanction of taking over management of an MCO, we proposed in § 438.706 that this sanction be imposed only when those egregious circumstances exist.

The requirement in section 1932(e)(1), that the State have intermediate sanction authority as a condition of contracting, only applies to contracts with MCOs. It does not place a similar requirement on States with respect to PCCMs. However, subsections (e)(1)(A) and (e)(2)(D) and (E) refer to ''managed care entities,'' and thus envision that the State would choose to apply those sanctions to PCCMs as well.

Section 1932(e)(4) of the Act authorizes State agencies to terminate the contract of any MCO or PCCM that fails to meet the requirements in sections 1932, 1903(m), or 1905(t) of the Act. This provision was included in proposed § 438.708. However, if the State chooses that remedy, under section 1932(e)(4)(B) the State is required to provide a hearing before terminating a contract. Proposed § 438.710 set forth requirements that apply to the notice to the MCO or PCCM, and to the pre-termination hearing. Under section 1932(e)(4)(C), enrollees may be notified of their right to disenroll immediately without cause in the case of any entity subject to a termination hearing. Proposed § 438.722 described the provisions for disenrollment during the termination hearing process. Finally, in § 438.724, we proposed that States be required to notify CMS whenever it imposes or lifts a sanction.

Under section 1903(m)(5) of the Act, CMS has its own direct authority to impose sanctions when Medicaid-contracting MCOs commit offenses that are essentially the same as those identified in section 1932(e)(1) of the Act. Section 1903(m)(5) is currently implemented by regulations codified at 42 CFR § 434.67. We proposed to move those regulations to proposed § 438.730. However, we inadvertently made substantive changes, including omission of parts of the original regulation text dealing with denial of payment, and expanding the State plan requirement previously found in § 434.67(i). The final rule conforms the text of §§ 438.726 and 438.730 to the text of § 434.67. We proposed in § 438.726 to broaden the State plan requirements to include a plan to monitor for violations that involve the actions and failures to act that are specified in part 438 and to implement the provisions of part 438. We received no comments on this change and will maintain as it was proposed in this final rule. It also incorporates into § 438.726 the text of the existing § 434.22, which was cross-referenced by § 434.67(e), and which was inadvertently eliminated in the proposed changes to the regulation. Finally, there were certain ambiguities in the original regulation text which we are clarifying. In particular, § 434.67(c) was not clear with respect to who would forward the notice of sanction to the OIG at the same time it was sent to the MCO. We have clarified that it is sent by CMS.

Comment: One commenter requested clarification as to which sanctions were mandatory and which were discretionary.

Response: Section 1932(e)(1) of the Act requires, as a condition for entering into or renewing contracts under section 1903(m) of the Act, that State agencies must establish intermediate sanctions that the agency may impose on an MCO that commits one of the specified offenses in § 438.700(b). The type of sanction and the discretion to apply sanctions is generally up to the State agency. However, if it finds that an MCO has repeatedly failed to meet substantive requirements in section 1903(m) or section 1932 of the Act, or this Part, then the State must impose temporary management, must permit beneficiaries to disenroll without cause, and must notify them of the right to disenroll. See section 1932(e)(3) of the Act, and proposed §§ 438.706(b) and 438.702(a)(3).

Comment: Many commenters suggested that PIHPs and PAHPs be subject to the same sanctioning as MCOs.

Response: We disagree with the suggestion. The PIHP and PAHP regulations are based on the authority under section 1902(a)(4) of the Act to provide for methods of administration that are ''found by the Secretary to be necessary for * * * proper and efficient administration.'' While we believe this provides the authority to establish requirements that apply to PIHPs and PAHPs, we do not believe it provides the authority to promulgate regulations that would authorize a State to impose civil money penalties, or other sanctions that are provided for by the Congress only in the case of MCOs. However, States may cover PIHPs and PAHPs under their own State sanction laws, and we encourage States to do so whenever they believe it necessary.

Comment: A commenter requested clarification of whether the requirement for a pre-termination hearing in proposed § 438.710(b) applies if the State is terminating an MCO or PCCM contract under State authority and not the authority in § 438.708.

Response: A State that is not relying on the authority in § 438.708 to terminate an MCO or PCCM contract should follow only the State procedures related to the authority they are exercising to terminate the MCO or PCCM contract. To the extent the State is relying on the authority under § 438.708, the State must meet the requirements for a pre-termination hearing. The State may exercise the disenrollment options provided in § 438.722 regardless of the underlying authority on which they are basing termination.

Comment: One commenter was unclear about whether the notice to CMS under proposed § 438.724(a) was required only for sanctions specified in § 438.702(a) or if it also applied to State operated penalty systems such as a progressive penalty point accumulation system.

Response: Under § 438.724, notice to CMS is only required when a State imposes an intermediate sanction for one of the violations in § 438.700(b). To the extent the State has sanctions that it imposes for additional violations, notice to CMS is not required, but encouraged. We have added clarifying language to the regulation text.

Comment: Many commenters suggested notification to CMS was appropriate but that beneficiaries have the right to know when a plan has been sanctioned and that publication of the notice should be required in the

regulations. These commenters recommended that the State publish a notice describing the intermediate sanction imposed, explaining the reasons for the sanction and specifying the amount of any civil money penalty. Further, this notice should be published no later than 30 days after the State imposes the sanction, and the notice should be published in the newspaper of widest circulation in each city within the MCO's service area that has a population of 50,000 or more or in the newspaper of widest circulation in the MCO's service area, if there is no city with a population of 50,000 or more in that area. Several other commenters supported limiting the notification requirements to notifying CMS noting that publication is an unnecessary expense and inconsistent with current insurance practices.

Response: We agree that widespread publication would be an unnecessary expense. We also believe requiring public publication could discourage a State from imposing sanctions and could unnecessarily alarm enrollees. In addition, a State is not prohibited from publishing sanction information.

Comment: One commenter requested that we clarify in proposed § 438.726 that States can delegate certain functions to other entities as an acceptable way of accomplishing the goal of enrollee protection.

Response: The State agency is ultimately responsible for implementation of the provisions of this subpart but may delegate appropriate functions to other entities as part of their process.

Comment: One commenter indicated that it is crucial that the State's ability to delegate certain functions to other entities be explicitly recognized as an acceptable method for accomplishing the goal of enrollee protection through the use of sanctions and temporary management.

Response: We believe that the regulation, as written, maintains the State's ability to delegate functions. We recognize that with the imposition of temporary management, the State may need to delegate activities to another department within the State. We have maintained flexibility for States to determine what best fits their needs.

H. Conditions for Federal Financial Participation (Subpart J)

Subpart J of the proposed rule contains rules regarding the availability of Federal financial participation (FFP) in MCO contracts. In addition to setting forth recodified versions of existing regulations governing eligibility for FFP currently set forth in part 434, subpart F, the regulations in proposed subpart J reflected new provisions in the BBA affecting FFP (such as., the new restrictions on FFP in enrollment broker contracts), and set forth a proposed new limitation on FFP related to the actuarial soundness requirements in proposed § 438.6(c).

1. Basic Requirements (Proposed § 438.802)

Proposed § 438.802 was based largely on the existing § 434.70, and provided that FFP is only available in expenditures under MCO contracts for periods for which (1) the contract is in effect and meets specified requirements, and (2) the MCO, its subcontractors, and the State, are in substantial compliance with specified contract requirements and the requirements in part 438.

Comment: One commenter requested that we clarify what we meant by the requirement in § 438.802 that the MCO and its subcontractors be in ''substantial compliance'' with physician incentive plan requirements and that the MCO and the State be in ''substantial compliance'' with the contract and these regulations, in order to qualify for FFP.

Response: Proposed § 438.802 was based on the existing § 434.70, which, in paragraph (b), specifically provided that FFP may be withheld for any period the MCO fails to comply with the physician incentive requirements, or the MCO or the State fail to comply with the terms of the contract between them or the provisions of this regulation. We understand the commenter's confusion regarding this requirement since this rule already requires states to monitor compliance with this rule and contracts executed under this rule and provides sanctions to be used where certain requirements are not met. Further we would expect to initiate penalties such as corrective action plans in these situations where a state is found to be out of compliance with these rules. Finally, in considering the commenter's question, we realize the difficulty in issuing useful guidance as to what constitutes ''substantial compliance'' for purposes of putting FFP at risk. Because we believe that the requirements on States and MCOs contained in § 438.6 and elsewhere in this rule, and the mechanisms for monitoring and enforcement are sufficiently clear, the requirement for ''substantial compliance'' in § 438.802 is potentially confusing and unnecessary, we have deleted it from this section.

2. Prior Approval (Proposed § 438.806)

Proposed § 438.806 was based on § 434.71 (as affected by new threshold amounts for prior approval enacted in section 4708(a) of the BBA), and provided that FFP was not available in expenditures under contracts involving over a specified financial amount ($1,000,000 for 1998, adjusted by the consumer price index for future years) unless the contracts were ''prior approved'' by CMS.

Comment: One commenter inquired whether § 438.806 precludes the availability of FFP for a period that a risk contract was under review by CMS, and whether the prior approval requirement applied to all MCOs or just new MCOs. If applicable to all MCOs, the commenter asked whether the FFP limitation applied to the entire amount paid or just the marginal difference from the previously approved contract amount?

Response: The requirement for prior approval of a new contract or new contract amendment applies to all comprehensive risk contracts, whether with a new or currently contracting MCO. FFP is not available for contracts that CMS has not approved. However, once we approve a contract, FFP is available for any period during which an approvable contract was under review. The limitation on FFP in this provision must be applied to the entire contract. FFP is not available for any portions of the contract unless it is approved.

Comment: One commenter questioned whether the requirement in § 438.806(a)(2) meant that a State would lose FFP should it not reach its quality strategy goals.

Response: Section 438.806(a)(2) requires that the written contract with the MCO meets the requirements specified as a condition for FFP. The contract would not be approved if it did not meet all the requirements of the law and regulations, including establishing the quality assessment and performance improvement program required by § 438.240. However, this is different from the issue of the MCO's or State's performance in implementing this contractually required program. A failure on the part of an MCO or State to meet a particular quality goal would not apply to the conditions in § 438.806(a)(2).

Comment: Several commenters pointed out that the reference in § 438.806(a)(1) to entities described in § 438.6 (a)(2) through (a)(5) should instead refer to § 438.6(b)(2) through (b)(5).

Response: We appreciate the commenters' assistance and have made the appropriate changes.

3. Exclusion of Entities (Proposed § 438.808)

Proposed § 438.808 reflects the limitation on FFP in section 1902(p)(2) of the Act, under which FFP in payments to an MCO is conditioned on the State excluding from participation as an MCO any entity that could be excluded from Medicare and Medicaid under section 1128(b)(8) of the Act, that—

- Has substantial contractual relationship with an entity described in section 1128(b)(8)(B) of the Act.
- Employs or contracts with individuals excluded from Medicaid.

We received no comments on this section.

4. Expenditures for Enrollment Broker Services (Proposed § 438.810)

Proposed § 438.810 reflects the conditions on FFP for enrollment broker services set forth in section 1903(b)(4) of the Act, which was added by section 4707(b) of the BBA. This section permits FFP in State expenditures for the use of enrollment brokers only if the following conditions are met:

- The broker is independent of any managed care entity or health care provider that furnishes services in the State in which the broker provides enrollment services (regardless of whether the entity or provider participates in Medicaid).
- No person who is the owner, employee, or consultant of the broker or has any contract with the broker:
- Has any direct or indirect financial interest in any managed care entity or health care provider that furnishes services in the State in which the broker provides enrollment services.
- Has been excluded from participation under title XVIII or XIX of the Act.
- Has been debarred by any Federal agency.
- Has been, or is now, subject to civil monetary penalties under the Act.

In addition to reflecting the above statutory requirements from section 1903(b)(4), proposed § 438.812 included the following proposed requirement:

- The initial contract or memorandum of agreement (MOA) or memorandum of understanding (MOU) for services performed by the broker must be reviewed and approved by CMS before the effective date of the contract or MOA.

Comment: One commenter felt that the proposed regulations were too broad for application in many States, and that States thus were required to create standards to ensure protective measures to support independent operations of enrollment brokers.

Response: We disagree with the commenter that the regulations are too broad. We believe that the language in section 1903(b)(4) of the Act, reflected in § 438.810, is very specific about limitations as to who can serve as an enrollment broker. A broker either is independent of ''any'' MCO, PIHP, or PCCM and of ''any health care providers'' that provide services in the State, or it is not. Similarly, a broker either does or does not have an owner, employee, consultant or contract with a person who (1) has a direct or indirect interest in an MCO, PIHP, PCCM or provider, or (2) has been excluded, debarred or subject to civil money penalties. While these standards are ''broad'' in their reach, this was a decision made by Congress. We do not believe that significant additional clarification is required. Moreover, § 438.810 does contain some additional clarification, in that paragraph (a) contains definitions of ''choice counseling,'' ''enrollment activities,'' ''enrollment broker,'' and ''enrollment services.'' It is not clear what additional clarification the commenter thinks would be needed. We also note that States may set rules more stringent than the Federal rules if they wish.

Comment: One commenter questioned whether there was a conflict between § 438.208(c), which provides for health screening assessments by an enrollment broker, and § 438.810(b)(1), which requires that enrollment brokers be independent.

Response: There is no conflict between these two sections. The independence of enrollment brokers from MCOs, PIHPs, PCCMs and providers of services is a separate issue from the activities of the enrollment broker in assessing and screening special needs individuals. The latter activities are performed by the broker for the State, as part of its activities as an enrollment broker, and not as the agents of an MCO, PIHP, PCCM or provider.

Comment: A commenter asked whether it was CMS' intent to exclude all potential enrollment brokers who have any relationship with a health care provider, whether or not that health care provider serves the Medicaid population.

Response: CMS is bound by the statutory provision on enrollment brokers, and section 1903(b)(4)(A) of the Act specifically prohibits the availability of FFP for enrollment brokers who are not independent of any health care providers, ''whether or not any such provider participates in the State plan under this title.'' Congress presumably believed that such independence was necessary to ensure that the Medicaid enrollment process was free from even potential bias.

Comment: Several commenters noted that the independence requirement could prevent employees of a county from serving as enrollment brokers that operates an MCO, PIHP, or PCCM, or provides services or is affiliated with providers, from serving as enrollment brokers, and contended that this result would be detrimental to the enrollment process. Commenters also felt that MCOs should be able to assist in enrollments. One commenter believed that it was not feasible for States to rely only upon community-based or non-profit organizations to process enrollments.

Response: First, with respect to the comments on MCO involvement in enrollment, States may permit MCOs to process enrollments in their own plans. This provision only involves a State contract with an enrollment ''broker'' which processes enrollments in multiple plans. With respect to the issue of employees of counties that operate managed care entities or provide health care services, we believe that such an employee would not meet the statutory standard of being ''independent'' of such providers, and that Congress has prohibited them from serving as enrollment brokers. An enrollment broker might be a public or quasi-public entity with a contract or MOA/MOU with the State or county, as long as the entity does not furnish health care services in the State. For example, a State may not claim FFP for a contract with, or have an MOU with, a county health department to do managed care enrollment or choice counseling because the health department provides health services. A community organization that provides health services in the State, for example, an organization providing health care to homeless individuals, may contract or subcontract to perform outreach and education, but not enrollment and choice counseling functions covered by the enrollment broker provisions in section 1903(b)(4).

Neither the statute nor these rules specifically address the use of non-profit or community-based organizations to fulfill the enrollment broker function, but these entities would be subject to the same requirements for independence and prohibitions on conflict of interest as any other prospective brokers. We note that the regulations also would permit for-profit enrollment brokers if they met the conditions in § 438.810.

5. Costs Under Risk and Nonrisk Contracts (Proposed § 438.812)

Proposed § 438.812 was transferred in its entirety from previous §§ 434.74 and 434.75. It provides that States receive Federal matching for all costs covered under a risk contract at the medical assistance rate, while under a non-risk contract, only the costs of medical services are matched as medical assistance, while all other costs are matched at the administrative rate. We received no comments on this provision.

6. Limit on Payments in Excess of Capitation Rates (Proposed § 438.814)

Section 438.814 proposed limitations on the availability of FFP in contracts, which contain incentive arrangement or ''risk corridors.'' As described in proposed § 438.6(c)(5) on rate setting for risk contracts, under this proposal, FFP was only available in contract payments to the extent they did not exceed 105 percent of the payment rate determined to be ''actuarially sound.'' The theory for this limitation was that rates too far in excess of those established to be actuarially sound were not actuarially sound, and therefore did not meet the condition for FFP in section 1903(m)(2)(A)(iii).

Comment: Many commenters disagreed with the proposal to limit Federal matching at 105 percent of approved capitation rates in contracts with risk corridors. Some commenters questioned the rationale for setting the limit at 105 percent, while others questioned how it was determined that this limit would be appropriate for every contracting situation, State and contractor. Most commenters felt that the limit on risk corridors was inappropriate and arbitrary; would discourage States from using this mechanism, which the commenters felt could be an effective tool in setting rates for populations with little or no managed care experience, including the chronically ill and disabled; would prevent the State and Federal governments from sharing in profits and being protected from overpayments; and would discourage MCOs from taking the risk to cover these populations.

Other commenters pointed out that risk corridors are an important mechanism to address unforeseen costs to MCOs during contract periods from these factors as changes in case mix, enrollment patterns, utilization patterns, or provider networks, or coverage of populations with little or no managed care history. A 105 percent cap on these arrangements constrains States' flexibility to effectively address these issues without administratively cumbersome mid-year rate adjustments and could, in the commenters' view, result in over-projection of capitation rates in order to remain under the ceiling. Commenters suggested CMS either: (1) Accept an actuarial certification that the amount paid to an MCO after settlement is actuarially sound, and permit FFP for that entire amount; (2) permit a ''good cause'' exception to the 105 percent limit; or (3) or raise the limit to 110 percent. One commenter supported CMS' acknowledgment of risk sharing and risk corridors as acceptable payment mechanisms up to 105 percent of capitation rates.

Response: We understand the commenters concerns and upon consideration of these comments, agree that the 105 percent limit on FFP on contracts, or portions of contracts with risk corridors, is too restrictive to permit the continued use of this important risk sharing mechanism. We agree that is inappropriate to place a specific percentage limitation on FFP where risk corridors are used in a contract. The purpose of this mechanism is to share both the risk and the profits between the contractor and the State (and the Federal government by virtue of its matching of State expenditures.) One potential risk that can be addressed in risk corridors is the risk of fluctuations in utilization based on the changing demographics of a population (such as, the high costs of an increased percentage of disabled enrollees.) A fixed percentage limit does not take such risks into account. In considering the commenters' concerns, we have determined that a more appropriate outer limit on the actuarial soundness of payments under a risk corridor methodology would be a limitation based on what Medicaid would spend for the specific services utilized, plus an amount to cover the managed care plan's reasonable administrative costs. Such a limit would be similar to the ''non-risk upper payment limit'' in § 447.362, except for the recognition of administrative costs. The reason we did not simply adopt the rule in § 447.362 is because the amount allocable to administrative costs under that section of the regulations is not based on a managed care entity's reasonable administrative costs, but rather on the amount the Medicaid agency ''saves'' in its administrative costs by not having to pay fee-for-service claims for the beneficiaries enrolled in the managed care plan. We believe this amount is likely to be much lower than even the administrative costs of a well run managed care organization.

Thus, we are revising the requirement in proposed § 438.814 to impose an upper limit on payments under risk corridors that is based on ''what Medicaid would have paid on a fee for service basis for the services actually furnished to recipients'' plus an allowance for the managed care plan's reasonable actual administrative costs. This limit reflects the fact that a risk corridor extended to its ultimate extreme would become a nonrisk contract, and that the rule governing FFP in nonrisk contracts (with the modification noted) is the most logical limit to apply. We are also moving this requirement to § 438.6(c)(5) in order to have all of the payment provisions in one subpart of this rule.

Comment: Some commenters also believe the 105 percent limit was arbitrary and inappropriate for incentive arrangements, and could discourage programs intended to achieve quality-related goals (such as increases in EPSDT services and meeting quality improvement targets).

Response: We do not agree with commenters that the 105 percent limit is inappropriate and arbitrary for, and would discourage the use of, incentive arrangements. Under the new payment rules in § 438.6(c), capitation rates are to be established to reflect the level of State plan services to be delivered under the contract. Further, States are free to combine financial withholds and incentives for such things as quality improvement targets. Thus, we do not believe it is necessary to establish financial incentives above a level at which FFP would be available under this provision. As with the provision on risk corridors, we are moving this provision to § 438.6(c)(5).

Comment: One commenter asked that CMS define the term ''risk corridors'' as used in this section and in § 438.6(c).

Response: A risk corridor is 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.

Comment: Several commenters asked whether this provision places a limit on any and all payments and payment mechanisms that are in excess of the capitation rate, or whether there are any

payment mechanisms which would be excepted from the cap?

Response: Section 438.6(c) sets forth the requirements for payments under all risk contracts, and requires that these payments be identified and computed on an actuarially sound basis. This requirement applies to reinsurance, stop-loss limits, or other risk sharing mechanisms. We believe that amounts payable under these other arrangements (except for incentives and risk corridors) will be offset by actuarially determined amounts in determining the capitation rate to be paid. Thus, the limit in any of these arrangements will be predetermined based on the amount of the offset or deduction from the capitation rate. Since the potential payments under these risk-sharing mechanisms are determined in this manner, the limits in this provision do not apply. Section 438.6(c) does not authorize any other payment in excess of the capitation rates.

Comment: Several commenters asked that CMS define what is included in the term ''aggregate amount of approved capitation payments'' as used in this section. Specifically, the commenters wanted to know whether this includes administration, profit and other expenditures. One commenter asked whether this provision applies when a State withholds a percentage of approved capitation rates and later distributes the pool of withheld funds based on some type of risk arrangement, and whether the amount of funds withheld would be considered part of the approved capitation amount, or would be capped under this provision.

Response: The term ''aggregate amount of approved capitation payments'' as used in this section refers to the total amount of the capitation rates approved under the contract that are attributable to the individuals and services covered by the incentive arrangement. This would include portions of the rate intended for administration, profit or any other purposes and would be determined prior to any withhold amount being deducted. Further, the 105 percent limit applies only to those portions of a contract, which apply to the individuals or services, governed by the incentive arrangement. For example, if the contract includes provisions to withhold a portion of the capitation payments for not meeting targets for initial screenings for enrollees, neither the payments nor any withheld amounts for these services would be part of the calculation for determining any incentive payments due the plan under a separate contract provision for meeting targets for childhood immunizations. To further clarify this distinction, we have eliminated the provision in § 438.6(c)(5)(iii)(C) that required contracts with incentive arrangements to have withhold penalties for targets not met (proposed paragraphs (D), (E) and (F) have been redesignated as paragraphs (C)).

Comment: One commenter questioned whether the 105 percent limit is to be applied in the aggregate, or is it applicable to each individual rating cell.

Response: This would be determined by the specific arrangement under the contract. In most contracts, we would expect a target established for specific populations who may comprise their own rate cells under the contract. In this case, the limit would have to be applied to each individual or groups of cells covered by the arrangement. If the incentive applies to the entire population covered under the contract, the limit would be applied in the aggregate.

I. Revisions to Parts 435, 440, and 447; Miscellaneous Comments

In addition to the provisions set forth in the new part 438 and the fair hearing provisions in part 431 discussed in section II. E. of this preamble, the proposed rule contained amendments to parts 435, 440, and 447 that we discuss below. These provisions included amendments to §§ 435.212 and 435.326 to reflect the new terminology adopted by the BBA. We also proposed a new § 440.168 in part 440 to include a description of primary care case management services. Amendments to part 447 not already addressed above include a new § 447.46(f) implementing the timely claims payment requirements in section 1932(f), and a new § 447.60 regulating MCO cost-sharing, which was made permissible under BBA amendments to section 1916 of the Act. In this section, we discuss the comments we received on the above regulations. We received no comments on the revisions to § 447.60. In this section, we also address miscellaneous comments that did not relate to a specific section of the proposed regulations.

1. Guaranteed Eligibility (Proposed § 435.212)

Section 435.212 was revised in the proposed rule to implement section 1902(e)(2) of the Social Security Act. This change will permit State agencies, at their option, to provide for a minimum enrollment period of up to 6 months for individuals enrolled in a PCCM or any MCO. Previously, this option was only available to enrollees of Federally qualified HMOs.

Comment: One commenter expressed support for this provision.

Response: We thank the commenter for the support.

2. Definition of PCCM Services (Proposed § 440.168)

Section 4702 of the BBA added PCCM services to the list of optional Medicaid services in section 1905(a) of the Act. The BBA also added section 1905(t) to the Act. This subsection defines PCCM services, identifies who may provide them, and sets forth requirements for contracts between PCCMs and the State agency. This means that in addition to contracting with PCCMs under a section 1915(b) waiver program or section 1115 demonstration project, or under the new authority in section 1932(a)(1) to mandate managed care enrollment, States may add PCCMs as an optional State plan service. Regardless of the vehicle used, proposed § 438.6(k) set forth the minimum contract requirements States must have with their primary care case managers.

Proposed § 440.168(a), implementing section 1905(t)(1) of the Act, defined ''primary care case management services'' as case management related services that include locating, coordinating and monitoring health care services, and that are provided under a contract between the State and a primary care case manager. A PCCM was defined as including either (1) an individual physician (or, at State option, a physician assistant, nurse practitioner, or certified nurse-midwife), or (2) a group practice or entity that employs or arranges with physicians to furnish services. Proposed § 440.168(b) provided that PCCM services may be offered as a voluntary option under the State plan, or on a mandatory basis under section 1932(a)(1) or under a section 1115 or section 1915(b) waiver.

Comment: One commenter disagreed with the language designating it a ''State's Option'' to qualify nurse practitioners as PCCM providers. The commenter believes nurse practitioners should be recognized as PCCM providers by the Medicaid program. It is critical that CMS ensure that Medicaid beneficiaries have the option to choose a nurse practitioner as their PCCM provider.

Response: The definition of a primary care case manager in § 438.2 of this part mirrors the statutory language in section 1905(t)(2) of the Act. The statute is clear that there are two categories of PCCMs. The first category is PCCMs that are physicians or physician groups, or that employ or arrange for the provision of physician services. The definition of a physician does not include a nurse

practitioner. (See sections 1905(a)(5)(A) and 1861(r)(1) of the Act.) The second category is non-physicians who are included as PCCMs ''at State option.'' The statute expressly provides for nurse practitioners to be PCCMs ''at State option.''

3. Timely Claims Payment by MCOs (Proposed § 447.46)

Section 1932(f) of the Act specifies that contracts with MCOs under section 1903(m) must provide that, unless an alternative arrangement is agreed to, payment to health care providers for items and services covered under the contract must be made on a timely basis, consistent with the claims payment procedures described under section 1902(a)(37)(A) of the Act. Section 1902(a)(37)(A) of the Act requires that 90 percent of claims for payment (for which no further written information or substantiation is required in order to make payment) made for covered services provided by health care providers are paid within 30 days of receipt, and that 99 percent of the claims are paid within 90 days of receipt. These requirements were included in proposed § 447.46. We received no comments on this section.

4. Miscellaneous Preamble Comments

a. Effective Date of the Final Rule

Comment: Numerous commenters offered suggestions for the effective date and timeframe for implementation of the final rule. The commenters urged CMS to provide an adequate opportunity for MCOs and States to come into compliance with the regulation following its effective date as implementation will require both States and MCOs to make substantial changes to contracts, waivers, and other State procedures. One commenter recommended that the effective date be 180 days after the State's MCO contract renewal date following publication of the final rule. A few commenters recommended that States be given 2 years to come into compliance with the final rule. Several other commenters recommended that a full year be given for all contracts, regardless of their renewal date, to come into compliance with the final rule.

Response: We agree with the commenters that adequate time needs to be given for implementation of this final rule. Therefore, we have established that the final regulation will become effective 60 days post publication, and must be fully implemented by 1 year from the effective date of the regulation. This would allow new provisions to be implemented without forcing States to amend contracts in mid-term, although States would have the option to implement portions of the regulation in the interim period.

b. Violation of APA

Comment: A few commenters contended that the August 20, 2001 proposed rule did not comply with the Administrative Procedure Act (APA) as interpreted by the Supreme Court in *Motor Vehicle Manufacturers Assoc.* v. *State Farm Mutual Automobile Ins. Co.*, 463 U.S. 29 (1983). Specifically, the commenters suggested that we did not comply with the requirement in that case that agencies supply reasoned analysis in support of a change in policy. The commenters also quoted the U.S. Court of Appeals for the District of Columbia's decision in *National Black Media Coalition* v. *FCC*, 775 F.2d 342, 356 n. 17 (D.C. Cir. 1985) for the proposition that ''an agency may not repudiate precedent simply to conform with shifting political mood,'' and that ''the agency must demonstrate that its new policy is consistent with the mandate with which the Congress has charged it.'' In citing these cases, these commenters were comparing the regulations in the August 20, 2001 proposed rule, to those in the January 19, 2001 final rule that never took effect. The commenters believe that we were required in the proposed rule to explain any differences between the rules proposed in the August 2001 proposed rule and those published on January 19, 2001 and find support in ''the rulemaking record'' for any such differences.

Response: The cases cited by the commenters concern changes made to existing regulations. In those cases, regulations had been published and taken effect, and the agencies were making changes to existing regulations. In this case, as noted in the previous comment, the effective date of the January 19, 2001 final rule was delayed, and those regulations had never taken effect. Thus, there are no ''existing regulations'' in part 438 that this proposed rule would ''change.'' Rather, the existing regulations governing Medicaid managed care are the regulations in part 434 which predate the earlier rulemaking that led to the January 19, 2001 final rule. We believe that the preamble to the proposed rule clearly articulates our reasons for proposing changes to these existing part 434 regulations. Most of the major changes in the proposed rule implement, or are based on, Medicaid managed care provisions in the Balanced Budget Act of 1997 (BBA), which was enacted after the existing part 434 regulations were promulgated. When we proposed changes in policy not directly based on BBA provisions, the preamble explains the basis for the policy choice made, including discussion of inadequacies in the part 434 regulations, when appropriate.

We note that, while not required to do so by the cases cited by the commenters, we did explain in the preamble our rationale for the departures in this proposed rule from the approach taken in the January 19, 2001 regulations. We indicated that in developing this proposed rule, we were ''guided by several considerations'' set forth in detail in the preamble. (See 66 FR 43616.) For example, we indicated that the proposed rule was designed to recognize that Medicaid is a ''Federal-State partnership'' under which ''States are assigned the responsibility of designing their State programs'' and need the flexibility to ''employ different approaches to achieving the same goal within their varying State marketplaces and health care delivery systems.'' We also noted ''new advances and findings in health care, health quality assessment and improvement'' that ''unfold on an almost daily basis,'' and noted that regulations containing too rigid a structure are not able to adapt to these changes. The extent to which some aspects of the proposed rule differed from those in the January 19, 2001 rule is attributable to our reassessment, described above.

c. Applicability of BBA Provisions and Other Parts of This Final Rule To Waiver Programs

Section 4710(c) of the BBA specifies that the requirements in sections 4701 through 4710 do not affect the terms and conditions of any demonstration projects or waiver programs approved by the Secretary under the authority of sections 1115 or 1915(b) of the Act. We have consistently interpreted this to be a ''grandfather'' provision that applies only to waivers or demonstration projects that were in effect, or already approved, as of August 5, 1997, the date of enactment of the BBA. Thus, when the waiver or demonstration project expires, the grandfather provision in section 4710(c) no longer applies.

Under section 4710(c), the grandfather provision applies to the ''terms and conditions'' of a waiver. Any provisions of a State's section 1115 demonstration project or section 1915(b) waiver program that were 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, are

considered to be the ''terms and conditions'' of the waiver. To the extent the terms and conditions of the State's approved waiver program covered the same subject matter as any of the BBA requirements, that portion of the State's program would not have to comply with the BBA until the waiver expired. For example, if the State's waiver program included enrollment and disenrollment rules, the enrollment and disenrollment rules in section 1932 of the Act would not apply while the waiver was still in effect. For any part of the State's Medicaid managed care program that was not within the scope of the waiver, the BBA provisions applied immediately, with certain exceptions specified below, dealing with 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 that was approved or in effect as of August 5, 1997 expired. Because none of those waivers exceeded two years, all of them expired no later than 1999. After the waiver expired, the State was required to comply with all BBA requirements. Similarly, in the case of section 1115 demonstration projects, the ''grandfather'' provision in 4710(c) only applies until the demonstration expires, as established by the expiration date that appears in the waiver documents that were approved or in effect on August 5, 1997. However, section 1115(e) of the Act provides a State with a statutory right to extend any waiver previously approved under 1115(a), on the same ''terms and conditions,'' unless the Secretary specifically disapproves the extension. This extension can be for up to three years. As long as the State applies for an extension under section 1115(e) while its demonstration project is still subject to the ''grandfather'' provision described above, the statutory requirement that the waiver continue under the ''same terms and conditions'' means that those waiver provisions cannot be subject to the BBA requirements until the extension expires. 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) added section 1115(f) of the Act, to provide for additional extensions of section 1115 health care reform demonstrations. Unlike section 1115(e), section 1115(f) does not require that the demonstration project be extended under the same terms and conditions, providing, instead, for the negotiation of new terms and conditions. Therefore, unless the Secretary uses his discretionary authority to waive the requirements, as explained below, the BBA requirements apply to all demonstration projects approved under section 1115 except during the ''grandfather'' period and any subsequent extension under section 1115(e)(2).

For newly submitted or amended section 1115 waivers, the Secretary of DHHS retains the discretionary authority to exempt the State from specific BBA managed care provisions. Generally, exemptions are granted to allow States some flexibility in operating their Medicaid programs, while promoting the proper and efficient administration of a State's plan. However, particularly for those BBA provisions related to increased beneficiary protections and quality assurance standards, we anticipate that we would not approve an exemption unless a State can demonstrate that the waiver program has beneficiary protections or quality standards that would equal or exceed the BBA requirements.

In addition, the Secretary may use his discretionary authority (to the extent permitted by the specific waiver provision) to waive other requirements in this rule which do not implement provisions of the BBA, such as the new rate setting requirements, requirements that apply to PIHPs and PAHPs, and requirements that were redesignated from part 434 or other parts of 42 CFR.

Comment: Several commenters questioned the applicability of these rules to waiver programs. One commenter wanted CMS to confirm the belief that the proposed rule does not apply to States with current section 1115 demonstrations, while another wanted CMS to specify in the text of final rule that these regulations do not apply to waiver programs under section 1115 or 1915(b), to be consistent with section 4710(c) of the BBA. Another commenter supported CMS' decision to apply the final rule to both new and renewed section 1115 and 1915(b) waivers.

Response: As stated in the proposed rule and reiterated above, section 4710(c) of the BBA is time-limited, has expired for all section 1915(b) waiver programs, and only applies to section 1115 health care reform demonstrations during the period of approval that was in effect as of August 5, 1997 and any 3-year extension periods granted under the authority in section 1115(e)(2) of the Act. We disagree with the suggestion that the provisions of this part should never apply to programs conducted under these waivers.

Comment: One commenter asked that CMS grant States flexibility in applying these rules through 1915(b) waivers, but another commenter opposed the decision to consider granting any new waivers of these requirements.

Response: As indicated above, waiver authorities in section 1915(b) and 1115 remain in effect. If a State requests a waiver in order to implement an alternative approach for its Medicaid program that requires a waiver of provisions contained in this rule, while maintaining necessary beneficiary protections and meeting the specific requirements of the waiver authority requested, we may grant the waiver. We believe granting these waivers reflects the intent of the Congress which did not modify or limit the authority in either of these waiver provisions.

Comment: One commenter asked to what extent the provisions in this rule apply to section 1915(c) waiver programs.

Response: To the extent any provisions of these rules are relevant to the contract requirement, payment mechanisms, enrollment, or any other aspect of a program operating under a section 1915(c) waiver authority, the requirements apply. While we do not believe that most current 1915(c) programs would be subject to any of these requirements, any program operating under a combined 1915(b) and (c) authority which includes such things as an enrollment lock-in period, a capitated reimbursement methodology, or a provider that qualifies as a PAHP, would have to comply with the provision of this final rule as applicable.

See section II.E. of this preamble for further discussion regarding the applicability of the BBA requirements to States with waivers.

d. Education of MCOs, PIHPs, PAHPs, and PCCMs About Special Health Care Needs

Comment: Many commenters believe that there should be language stating that the ''State agency must have in effect procedures for educating MCOs, PIHPs, PAHPs, PCCMs, and any subcontracting providers about the clinical and other needs of enrollees with special health care needs.'' The commenters stated that this is an essential way for the State to ensure that health plans, that have not traditionally served Medicaid enrollees or enrollees with special health care needs, understand those needs. Another commenter stated that managed care must be sensitized to the needs of special needs beneficiaries, for whom

disruptions in service and impediments to access can be serious.

Response: While we understand the need for awareness of special health care needs, we want to give States the flexibility to decide at what level this should happen. Many States may not have the capability or feel that it is appropriate for the State to provide education to MCOs, PIHPs, PAHPs, PCCMs, and providers on what is often a clinical issue. Public health departments and local medical societies are often doing this type of work in the State.

e. Miscellaneous Comments

Comment: Numerous commenters applauded CMS for amending the Medicaid managed care regulations with the proposed rule published on August 20, 2001. Commenters appreciated that the proposed regulation removed much of the prescriptiveness of the requirements and acknowledged the expertise and work that continues at the State level. Most commenters were pleased to see a renewed emphasis on State flexibility. The proposed rule changed the focus from detailing how States and MCOs should operate to laying out the basic requirements for Medicaid managed care and allowing States the authority to implement them in a manner appropriate for each State. Further, commenters stated that the new rule simplified many of the provisions and eliminated redundancy so that requirements are stated only once. Commenters believe that the simplification of the regulation and removal of duplicative and redundant provisions will help States to accurately interpret, follow, and enforce this regulation.

Other commenters stated that the proposed rule will permit innovation and support program growth under standards that respond to the needs of the full spectrum of enrollees and implementation of the January 2001 rule would have seriously undermined the availability of the benefits of MCOs to Medicaid beneficiaries. Another commenter believes that removal of much of the highly detailed language contained in the January 2001 rule will enhance the ability of both the Federal and State governments to exercise responsibilities as purchasers and regulators effectively. Further, States have proven their ability to innovate in the quality arena and will continue to strive towards providing the highest quality care to Medicaid beneficiaries. Several other commenters noted that the proposed rule is a significant improvement over the rules published in January 2001, many provisions of which would have significantly raised health plan compliance costs without meaningfully improving patient care. One commenter urged immediate implementation of the proposed rule.

Response: We thank the commenters for their support. We will continue to work with States during the implementation period of the final rule.

Comment: Numerous commenters expressed their dissatisfaction with the proposed rule published on August 20, 2001. These commenters strongly support the immediate implementation of the January 19, 2001 final rule. Most of these commenters stated that the January rule reflected a true balance between providing States additional flexibility and providing Medicaid beneficiaries, including those with disabilities, the protections they need to ensure that Medicaid managed care meets their needs; that the revised proposed rule and the accompanying delays in implementation demonstrate that the Administration is more attuned to the desires of the States and managed care industry than to the needs of the people who are supposed to benefit from the Medicaid program; that the proposed rule pays too little attention to the special needs of children and adults with mental retardation and other disabilities. These commenters believe that the January rules establish important new protections for beneficiaries with respect to access to care, grievance and appeal procedures, and mandatory enrollment requirements.

Other commenters stated that more specific requirements are warranted related to transitioning children into and out of managed care, and the identification, screening and assessment of children with special health care needs. Some commenters urged CMS to strengthen the proposed rule to ensure safeguards for children with special health care needs, consistent with the waiver criteria for children with special health care needs. These commenters also called upon CMS to incorporate the recommendations of the Department's November 2000 Report to the Congress entitled ''*Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care*'' into the regulation.

Another commenter expressed concern that many provisions of the proposed rule do not provide adequate protections for consumers of mental health and substance abuse services enrolled in managed care plans through the Medicaid program. The commenter further suggested that the proposed rule unjustifiably undermines the consumer safeguards established in the January 2001 final rule. Another commenter specified that the proposed rule represents a profound failure to implement the statutory provisions of the BBA and does not provide even basic patient protections. These commenters urged CMS to reinstate many aspects of the January rule, which they believe better effectuate the BBA. Many other commenters believe that if the proposed rule is implemented it will be extremely harmful to Medicaid beneficiaries with special health care needs, including people living with HIV/AIDS.

Response: In development of the proposed and final rules we gave serious attention to all of the concerns raised to us. We believe the final rule reflects the path chosen by the Congress to strike an appropriate balance between State flexibility and beneficiary protections. We believe that this final rule reflects that balance and appropriately implements the beneficiary protections established by the BBA. We believe all commenters have expressed the same goal, namely: strong, viable, State Medicaid managed care programs that deliver high quality health care to Medicaid beneficiaries. We believe that the final rule will help States achieve this goal. The Congress drafted the statute in full recognition of the Medicaid program as a Federal-State partnership and we share that recognition. States are assigned the responsibility of designing their State programs. We drafted this regulation to recognize the responsibilities of the States and the need to employ different approaches to achieving the same goal within their State marketplaces and health care delivery systems. We heard from some key stakeholders in Medicaid managed care, including States, provider organizations, and advocates for beneficiaries. Some of these stakeholders expressed serious concerns about the regulation, including changes made to the January 2001 final rule that had not been included in the September 1998 proposed rule. Other stakeholders strongly supported the January 2001 final rule and urged us to continue with implementation. We decided that the best approach was to make some modifications to the January 19, 2001 final rule and republish it as a proposed rule in order to give everyone the opportunity to comment on all of the provisions.

We believe we have created a set of requirements that appropriately balances the necessary protections for all beneficiaries enrolled in Medicaid managed care plans, including individuals with special health care needs, and States' flexibility to manage

their managed care programs. We have not reduced the emphasis on requiring States to provide high quality care to beneficiaries, especially those with special needs. The rule requires States to identify managed care enrollees with special needs to make sure that they will receive appropriate access to quality care. States retain the flexibility to develop these mechanisms and define the special needs populations. This approach enables States to better target their Medicaid resources to those most in need. We believe this is a far more efficient approach than imposing regulatory burdens that may not have their intended effects.

Comment: One commenter expressed concern that the August 20, 2001 proposed rule did not contain important regulatory language that was included in the 1998 proposed rule supportive of protections for the mentally ill in Medicaid managed care. The commenter pointed out that a number of its recommendations were not included and the commenter requests an explanation for these negative decisions.

Response: The regulation, as now written, is intended to address the needs of, and protections for, all Medicaid beneficiaries in managed care, including persons with disabilities and those who suffer from mental illness. The regulation is written in a manner to establish a general framework for States to use when developing managed care programs to serve all of its enrolled populations. Therefore, we do not believe it is necessary to list specific medical conditions within the regulation text. As far as comments received on the September 28, 1998 proposed rule, responses to all of the comments and rationale for changes can be found in the January 19, 2001 final rule preamble.

Comment: A few commenters, while supportive of the fact that CMS delayed implementation of the January 2001 final rule and then made substantial revisions in the August proposed rule, were still concerned that the proposed rule will increase the cost and administrative burden associated with Medicaid managed care. The commenters believe that health plans serving members other than Medicaid beneficiaries will be placed at a disadvantage. The commenters also urged CMS to take steps to encourage commercial plans and providers to participate in Medicaid managed care programs and to regulate the program in a manner that allows States to continue moving forward with managed care. Another commenter expressed concern regarding the overall impact on access, quality of care and cost effectiveness of applying the regulations to specialty mental health programs. And to the extent CMS does not provide more flexibility to States in these regulations, it should seriously consider providing reasonable flexibility to States in the section 1915(b) waiver process. Another commenter stated that the speed with which these rules have been rewritten has lead to a proposed rule that shows a lack of clarity and careful consideration. The regulatory process did not provide for adequate participation by the States with the knowledge and experience to help draft effective and efficient rules for managed care. The commenter urged CMS to involve State representatives in a final rewrite of the rule. In addition, when considering the imposition of every new administrative requirement, CMS needs to be cognizant that each of those requirements costs the States' increasingly limited resources that could better be focused on provision of care. Further, every new requirement on MCOs and providers can affect their continued participation in managed care. Another commenter advised CMS to keep in mind that as regulations are designed with particular focus on enrollee protections, it is critical to keep in mind that overly prescriptive requirements that shift potentially unnecessary administrative costs and burdens to plans and providers may result in the unintended consequence of provider and/or plan withdrawal from the Medicaid program. This could then lead to impeded access to quality care for vulnerable populations.

Response: The regulation was developed to provide States with an appropriate level of flexibility that we believe to be consistent with necessary beneficiary protections.

State flexibility had to be balanced against the statutory requirements of the BBA. Further, the regulation has been designed to provide a framework that allows CMS and States to continue to incorporate further advances for oversight of managed care, particularly as they pertain to beneficiary protection and quality of care. We recognize that States are unique and have different needs for their enrolled populations. This final rule was designed to promote State flexibility as much as possible so that States can implement managed care programs that meet the needs of their beneficiaries. With respect to MCO and provider participation, we further believe that the new rate-setting provisions will allow States to set rates that more appropriately reflect the costs of health services for the variety of Medicaid populations served, especially those with special health care needs.

Comment: One commenter stated that changes should be made to the proposed rule to ensure that providers are compensated in a timely manner, so they can continue to provide needed services to low-income patients.

Response: Section 1932(f) of the Act specifies that contracts under 1903(m) must provide that, unless an alternative arrangement is agreed to, payment to health care providers for services covered under the contract be made on a timely basis, consistent with the claims payment procedures described under section 1902(a)(37)(A) of the Act. These procedures require that 90 percent of claims for payment (for which no further written information or substantiation is required in order to make payment) made for services covered under the contract and provided by health care providers are paid within 30 days of receipt, and that 99 percent of the claims are paid within 90 days of receipt. These requirements are included in § 447.46. We do not believe that additional changes need to be made.

Comment: One commenter noted that the proposed rule does not take into consideration the frontier nature of some States. Many of the provisions would be difficult to meet even for the non-Medicaid population.

Response: We believe this final rule affords States the flexibility to implement these requirements for Medicaid managed care in all areas of their State. Further, the final rule provides for an exception to the choice requirements (§ 438.52) for residents in rural areas.

Comment: One commenter stated that these rules continue to require monitoring and oversight on issues that would result in higher requirements for Medicaid enrollees than for fee-for-service Medicaid or the general population. The commenter noted that it remains a distressing tendency to enforce things for managed care that are not enforced for the fee-for-service population.

Response: While CMS agrees that beneficiary protections are also important for beneficiaries receiving care under fee-for-service arrangements, this rulemaking implements Chapter 1 of Subtitle H of the BBA, titled ''Managed Care.'' These statutory provisions do not apply to fee-for-service Medicaid, and cannot be extended to fee-for-service arrangements in this final rule. However, States do have the flexibility to develop beneficiary protections similar to those presented in this regulation for those still receiving care through fee-for-service. States may establish similar

standards that can be monitored on the same scale as those standards established for Medicaid managed care. We agree that it is important to recognize that beneficiaries are afforded additional assistance in managed care than may be afforded in fee-for-service.

Comment: One commenter noted that when establishing protections for Medicaid managed care beneficiaries, CMS should recognize that oral health is an inseparable part of an individual's overall health and the formation of an effective Medicaid dental delivery system is just as important as the creation of an adequate Medicaid medical delivery system. The commenter stated that all dental patients, whether they are in private plans, Medicaid fee-for-service or any Medicaid managed care arrangement, deserve equal access to health services and equal protections under the law.

Response: We recognize the importance of oral health and the importance of serving the dental needs of the Medicaid population. The final rule is designed to address access issues related to all Medicaid managed care services. For example, an MCO or PAHP that delivers dental services to Medicaid beneficiaries must comply with the access requirements in this regulation. The MCO or PAHP must ensure that it offers an appropriate range of services and that it maintains a network of providers that is sufficient to meet the needs of enrollees. Further, each State must ensure that all of the covered services are accessible for all beneficiaries enrolled. We are also optimistic that managed care will facilitate increased utilization in the area of dental services.

Comment: One commenter expressed concern regarding some of the regulatory provisions, as they may pose or have a different effect in the territories, particularly since Medicaid funds are capped.

Response: We recognize the commenter's concern, however territories are required to meet all Medicaid requirements except for provisions specified in Federal law and regulation.

Comment: Several commenters stated that none of the Medicaid managed care rules has included any discussion of the need for State Medicaid programs to develop incentives for physicians to participate in Medicaid managed care plans. The commenters specified that lack of sufficient physician participation may pose a significant barrier to high quality care for Medicaid beneficiaries. Development of incentives for physician participation should be a central issue for Federal and State governments as they design, implement and evaluate managed care programs. One commenter recommended that State agencies be required to consult with State medical societies early on in the process of designing Medicaid managed care programs and continue to seek input from the physician community throughout implementation. The commenter cited a recent report from the American Academy of Pediatrics that concluded ''in order to ensure that expanding insurance coverage for children translates into viable access to care, States must provide incentives for pediatricians to extend their resources to serve new Medicaid and SCHIP enrollees.''

Response: We realize that physician consultation is an important factor in the development of Medicaid managed care initiatives and encourage stakeholder input at all stages of managed care development. However, we are not specifically requiring stakeholder involvement since States, based on the uniqueness of their Medicaid managed care programs, are in the best position to determine how this involvement should be structured. Each State is required to have a Medical Care Advisory Committee (MCAC) established for the purpose of advising the Medicaid agency about health and medical services. This committee, by regulatory definition, is required to include physicians. We encourage States to continue to use the MCAC as a mechanism for obtaining input on managed care issues. Likewise, under § 438.202, we require public consultation in development of the State's quality strategy.

Comment: One commenter disagreed with the deletion of the requirement that no more than 75 percent of enrollees in risk contracts be eligible for Medicare or Medicaid.

Response: This change was made by the Congress in the BBA, and we thus had no discretion in this rulemaking to retain it. We note that this requirement was previously used as a rough ''proxy'' to ensure quality services by requiring that an MCO attract commercial consumers. This ''proxy'' has been replaced in the BBA with more direct quality requirements implemented in this final rule.

III. Summary of Changes to the Proposed Rule

For reasons discussed above in the preamble, we have made the following changes to the proposed rule:

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

Section 431.200

We have added language to include PAHP actions to suspend, terminate, or reduce services such as those that would result in access to the State fair hearing.

Section 431.220

We have included a new paragraph (a)(6) requiring that any PAHP enrollee who has an action must be granted the opportunity for a State fair hearing.

Section 431.244

We have added language in paragraph (f)(1)(i) to specify that the 90-day timeframe for resolution of the State fair hearing begins the date the enrollee filed an MCO or PIHP appeal, not including the number of days the enrollee took to subsequently file for a State fair hearing. In paragraph (f)(1)(ii) we clarify the regulation text to State that if permitted by the State, the date the enrollee filed for direct access to a State fair hearing.

In paragraphs (f)(2) and (f)(3) we have changed the limit for appeals of a denial of service by an MCO or PIHP 72 hours to three working days.

PART 438—MANAGED CARE PROVISIONS

Subpart A—General Provisions

Section 438.1

In paragraph (b), we have included PIHPs in the scope of contracted entities provided in part 438.

Section 438.2

We moved the definition of ''health care professional'' from § 438.102 to § 438.2, as it applies to all of part 438.

We have clarified the definition of ''health insuring organization'' to reflect language in section 1932(a)(3) of the act.

Section 438.6

In paragraph (c)(3)(ii), we have added language to clarify that we are referring to data factors such as medical trend inflation, incomplete data, and MCO, PIHP, or PAHP administration.

In paragraph (c)(4)(ii), we have added language to clarify that payment rates are based only upon services covered under the State plan, or costs directly related to providing these services (such as, MCO, PIHP, or PAHP administration.)

We removed proposed § 438.6(c)(5)(ii) that referred to limitations on payment for risk corridors and incentive arrangements in proposed § 438.814. We

added new paragraph c)(5)(ii), which contains revised limitations on payment for risk corridors.

We added a new paragraph c)(5)(iii) that contains the payment limitations for incentive arrangements that were originally in proposed § 438.814.

We have redesignated proposed paragraph (c)(5)(iii) as (c)(5)(iv).

We have removed proposed paragraph (c)(5)(iii)(C), which required that for all incentive arrangements, the contract must provide that the arrangement is designed to include withholds or other payment penalties if the contractor does not perform the specified activities or does not meet the specified targets.

We have included a new paragraph (c)(5)(v) to require that if a State makes payments to providers for graduate medical education costs under an approved State plan, the State must adjust the capitation rates to account for the aggregate amount of the graduate medical education payments to be made on behalf of enrollees covered under the contract.

We have included a new paragraph (i)(2) specifying that all PAHP contracts must also provide compliance with the advance directive requirements if the PAHP includes, in its network, any of those providers listed under requirements on advance directives in § 489.102(a).

Section 438.8

We have made revisions in paragraph (b)(1) to specify that PAHPs must meet the contract requirements of § 438.6, except for those that pertain to HIOs and the requirements for advance directives unless the PAHP includes any of the providers listed in § 489.102.

We have revised paragraph (b)(6) to require PAHPs to meet all designated portions of subpart D (Quality Assessment and Performance Improvement).

We have added a new paragraph (b)(7) to specify that PAHP enrollees have the right to a State fair hearing under subpart E of part 431 (State Organization and General Administration).

Section 438.10

We have added paragraph (b)(2) requiring that the State must have in place a mechanism to help enrollees and potential enrollees understand the State's managed care plan. We also added paragraph (b)(3) requiring each MCO and PIHP to have in place a mechanism to help enrollees and potential enrollees understand the requirements and benefits of the plan.

We have revised paragraph (c)(2) to require that the State must make available written information in each prevalent non-English language.

In paragraph (f) we rephrased the introductory language to require that information be furnished to MCO, PIHP, PAHP, and PCCM enrollees. In paragraph (f)(1) we have added language to clarify that for those States that choose to restrict disenrollment for periods of 90 days or more, notice of the enrollees disenrollment rights must be sent no less than 60 days before the start of each enrollment period. In paragraphs (f)(2) and (3) we now include references to paragraphs (g) and (h) of this section to specify the information certain enrollees have a right to request and obtain at least once a year.

We have included, in paragraph (f)(4) that the State, its contracted representative, or the MCO, PIHP, PAHP, or PCCM must give each enrollee written notice of any change that is deemed significant in the specified information in paragraphs (f)(6) of this section and paragraphs (g) and (h) of this section, if applicable.

In paragraph (f)(6) we have clarified that the information in this section must be provided by the State, its contracted representative, or the MCO, PIHP, PAHP, or PCCM. We have revised paragraph (f)(6)(i) to clarify that information on the names, locations, telephone numbers of, and non-English languages spoken by current contracting providers in the enrollees service area, including identification of providers that are not accepting new patients be provided to all enrollees. For MCOs, PIHPs, and PAHPs this includes, at a minimum, information on primary care physicians, specialists and hospitals. Further, in paragraph (f)(6)(iv) we add that for PAHP enrollees, the information specified in § 438.10(h) must be provided.

We have revised paragraph (g)(3) to provide that detailed information of physician incentive plans is available upon request.

We have added a new paragraph (h) that requires specific information that must be provided for PAHP enrollees. The State, its contracted representative, or the PAHP must provide information to their enrollees on the right to a State fair hearing, including the right to a hearing, the method for obtaining a hearing, and the rules that govern representation. In paragraph (h)(2), we have specified that information must be provided on advance directives, as set forth in § 438.6(i)(2) and in paragraph (h)(3) that, upon request, information must be provided on physician incentive plans as set forth in § 438.6(h). We have redesignated the previous paragraph (h) as paragraph (i) in the final rule.

We have clarified in paragraph (i)(2)(i) the timeframes for when information must be furnished to all enrollees of a State plan program under § 438.50. For these enrollees, the timeframe is annually and upon request and for potential enrollees within the timeframe specified in § 438.10(e)(1). In paragraph (i)(3), we have clarified that the information provided is only for each contracting MCO or PCCM in the potential enrollee and enrollee's service area. Finally, in paragraph (i)(3)(v), we have removed reference to disenrollment rates as defined by the States as information that must be included.

Subpart B—State Responsibilities

Section 438.60

We have included language allowing for payment exceptions when the State has adjusted the capitation rates paid under the contract, in accordance with § 438.6(c)(5)(v), to make payments for graduate medical education.

Subpart C—Enrollee Rights and Protections

Section 438.100

We have moved paragraph (b)(3)(iii) regarding requests for medical records to new paragraph (b)(2)(vi). We have revised paragraph (b)(3) to specify that an enrollee of an MCO, PIHP, or PAHP (consistent with the scope of the PAHP's contracted services) has the right to be furnished health care services in accordance with §§ 438.206 through 438.210. We have removed paragraph (b)(3)(ii), regarding the right to obtain a second opinion.

Section 438.102

We have moved the definition of health care professional to § 438.2.

Section 438.104

We have revised paragraph (b)(1)(iv) to clarify that the requirement regarding the sale of other insurance applies to ''private'' insurance.

In paragraphs (b)(2) and (c) we have corrected cross-references to paragraphs (e) and (f) of § 438.10.

Section 438.114

In paragraph (a) we have removed references to § 422.113(b) and (c) and included the full text of definitions of emergency medical condition, emergency services and post-stabilization care services. In paragraph (d)(1)(ii) we have revised language to specify that entities may not refuse to

cover emergency services based on the emergency room provider, hospital, or fiscal agent not notifying the enrollee's primary care provider, MCO, or applicable State entity of the enrollee's screening and treatment within 10 days of presentation for emergency services.

Subpart D—Quality Assessment and Performance Improvement

In subpart D, §§ 438.200, 438.206, 438.207, 438.208, 438.210, 438.214, 438.224, 438.230, and 438.236 have been amended by adding PAHPs to allow this network to have the same services.

Section 438.202

In paragraph (b) we replaced the words ''provide for'' with ''obtain'' and the words ''including making'' to ''and make.'' In paragraph (c) we replaced the word ''compliance'' with the words ''The MCOs, PIHPs, and PAHPs comply.''

Section 438.204

In paragraph (b)(1) we have removed the word ''including'' and clarified that procedures must assess the quality and appropriateness of care and services furnished to Medicaid enrollees under the MCO and PIHP contracts, and to all individuals with special health care needs. In paragraph (b)(3), we have clarified that the procedures must regularly monitor and evaluate the MCO and PIHP compliance with the standards. In paragraph (c) we have added, ''For MCOs and PIHPs, any national'' before ''performance'' and ''that may be'' before ''identified.'' In paragraph (e) we have added the phrase ''For MCOs,'' before ''appropriate.''

Section 438.206

In paragraph (a) we reversed the words ''services'' and ''covered,'' and added the words ''under the State plan'' after ''covered.''

In paragraph (b)(1)(ii) we revised the second clause to read ''taking into consideration the characteristics and health care needs of specific Medicaid populations represented in the particular MCO, PIHP, and PAHP.''

In paragraph (c)(1)(i) we added the word ''the'' between the words ''of'' and ''need.''

In paragraph (c)(1)(iv) we added at the end, the words ''by providers.''

In paragraph (c)(1)(v), we added the word ''providers'' after the word ''Monitor'' and replaced ''continuously'' with ''regularly'' to clarify that each MCO, PIHP, and PAHP must monitor regularly to determine compliance.

Section 438.207

In paragraph (a), we added the words ''and providers supporting documentation that demonstrates'' after the word ''State.''

In paragraph (b), we changed the title from ''Nature of assurances'' to ''Nature of supporting documentation'' and removed the words ''acceptable to CMS.''

In paragraph (c), we removed the words ''and specifically'' and replaced them with ''but no less frequently than.''

In paragraph (d) we replaced the word ''submission'' to ''certification'' in the title.

Section 438.208

Section 438.208 is revised. We have made significant changes to the organization of this section.

Section 438.210

In paragraph (a), we have reorganized and revised language for clarity.

Section 438.214

In paragraph (b) we have added a requirement that each State must establish a uniform credentialing and recredentialing policy that each MCO, PIHP, and PAHP must follow.

Section 438.240

In paragraph (a)(2) we have removed ''standardized quality measures'' and replaced it with ''performance measures.'' We have revised paragraph (b)(1) to require that performance improvement projects must be designed to achieve, through ongoing measurements and intervention, significant improvement, sustained over time, in clinical care and non-clinical care areas that are expected to have a favorable effect on health outcomes and enrollee satisfaction. We redesignated paragraph (b)(2) as (b)(3) and we redesignated paragraph (b)(3) as (b)(4). We added a new paragraph (b)(2) to specify that each MCO and PIHP must submit performance measurement data, as described in paragraph (c) of this section.

In paragraphs (c) and (d)(2) we have clarified that each MCO and PIHP must annually measure and report to the State its performance (including requirements under § 438.204(c) and § 438.240(a)(2)), submit to the State data to enable the State to calculate measures, or perform a combination of the above activities.

Section 438.242

In paragraph (a) we have added ''and appeals'' after ''grievances'' to clarify that a health information system must provide information on appeals.

Subpart E—[Reserved]

Subpart F—Grievance System

Section 438.400

We have removed ''or any of its providers'' from the definition of ''action.'' We have clarified the definition of ''action,'' to include unreasonable delays in services or appeals not acted upon within the necessary timeframes provided in § 438.408(b).

Section 438.402

In paragraph (b)(1)(ii) we clarified that a provider may file a grievance or request a State fair hearing on behalf of an enrollee, if the State permits the provider to act as the enrollee's authorized representative in doing so.

Section 438.404

In paragraph (c)(6) we have corrected the cross-reference to § 438.210(d)—timeframes for expedited service authorizations.

Section 438.406

We have revised paragraph (a)(1) to clarify that giving enrollees any reasonable assistance in completing forms and taking other procedural steps is not limited to providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability.

In paragraph (a)(3)(ii) we have clarified that the individuals who make decisions on grievances and appeals are individuals who are health care professionals who have the appropriate clinical expertise, as determined by the State, in treating the enrollee's condition or disease.

Section 438.408

In paragraph (d)(2)(ii) we have added language clarifying that the MCO or PIHP must also make reasonable efforts to provide oral notice.

Section 438.410

In paragraph (c)(2) we have added language clarifying the MCO or PIHP must make reasonable efforts to give the enrollee prompt oral notice of the denial.

Section 438.420

In paragraph (b)(4) we have included the word, ''original'' to describe the type of authorization.

In paragraph (c), we have added language to clarify the duration of continued or reinstated benefits. If, at the enrollee's request, the MCO or PIHP continues or reinstates the enrollee's benefits while the appeal is pending, the

benefits must be continued until one of the following occurs:

- The enrollee withdraws the appeal.
- Ten days have passed after the MCO or PIHP resolves the appeal against the enrollee, unless the enrollee, within the 10-day timeframe, has requested a State fair hearing with continuation of benefits until a State fair hearing decision is reached.

We have added a new paragraph (c)(4) to specify that benefits must be continued until the time period or service limits of a previously authorized service has been met.

Subpart G—[Reserved]

Subpart H—Certifications and Program Integrity

Section 438.600

We have added sections ''1903(m)'' and ''1932(d)(1)'' to the statutory basis to establish conditions for payments to the State with respect to contracts with MCOs and to incorporate the BBA provisions prohibiting affiliations with individuals debarred by Federal agencies.

Sections 438.604 and 438.606

We deleted the requirement for ''substantial compliance'' with the terms of the contract and for submitting certifications for ''substantial compliance'' respectively in order to prevent unnecessary lawsuits against MCOs and States. In addition, the statute and regulations already require States to monitor compliance with contracts executed under this rule.

Section 438.610

We added a new section to incorporate language from section 1932(d)(1) of the Act to the regulation to implement the BBA provisions prohibiting affiliations with individuals debarred by Federal agencies. This self-implementing provision has not been published previously, but was added in the final rule to include all of the relevant protections against fraud and abuse in one section.

We added application to PCCMs and to PAHPs to this section. (The BBA provided that section 1932(d)(1) of the Act be applied to MCEs; therefore we included application to PCCMs. We applied this section to PAHPs under the authority of section 1902(a)(4) of the Act.

Subpart I—Sanctions

Section 438.724

We have clarified that the notice that must be given to the CMS Regional Office whenever a State imposes or lifts a sanction is only applicable to those sanctions under § 438.700.

Section 438.726

We have added a new paragraph (b) which states that a contract with an MCO must provide that payments provided for under the contract will be denied for new enrollees when, and for so long as payment for those enrollees is denied by CMS.

Section 438.730

We have reorganized this section so that it conforms to removed § 434.67.

Subpart J—Conditions for Federal Financial Participation

Section 438.802

We have removed the requirement for substantial compliance with physician incentive plans, the MCO's contract, and the provisions of part 438 as a condition for FFP.

Section 438.806

We have made technical revisions to correct erroneous cross-references in paragraph (a)(1). We now correctly refer back to paragraphs (b)(2) through (b)(5) of § 438.6.

Section 438.814

We have revised and moved the provisions of this section to paragraphs (c)(5)(ii) and (c)(5)(iii) of § 438.6.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval.

In order to fairly evaluate whether OMB should approve an information collection, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comments on each of these issues for the information collection requirements discussed below.

The following information collection requirements and associated burdens are subject to the PRA. For purposes of this requirement, we incorporated pertinent managed care data from the 2000 Medicaid enrollment report. As of June, 2000, there were 339 managed care organizations (MCOs) (this includes three HIOs that must adhere to the MCO requirements of this regulation), 37 primary care case management (PCCM) systems, 376 managed care entities (MCOs and PCCMs combined), 123 mental health and substance abuse prepaid health plans (PIHPs) and 34 dental, primary care and transportation prepaid health plans (PAHP), all of which have previously been regulated as PHPs. There were a total of 25,821,196 beneficiaries enrolled in these plans (some beneficiaries are enrolled in more than one plan) in forty-eight States and the District of Columbia (Wyoming and Alaska do not currently enroll beneficiaries in any type of managed care).

A. Section 438.6 Contract Requirements

Section 438.6(c) Payments Under Risk Contracts

1. Requirement. Section 438.6(c) modifies the rules governing payments to MCOs, PIHPs, and PAHPs by doing the following: (1) Eliminating the upper payment limit (UPL) requirement; (2) requiring actuarial certification of capitation rates; (3) specifying data elements that must be included in the methodology used to set capitation rates; (4) requiring States to consider the costs for individuals with chronic illness, disability, ongoing health care needs, or catastrophic claims in developing rates; (5) requiring States to provide explanations of risk sharing or incentive methodologies; and (6) imposing special rules, including a limitation on the amount that can be paid under FFP in some of these arrangements.

2. Burden. It is difficult to quantify the burden on States of providing information to support the actuarial soundness of the capitation rates for their risk-based, managed care contracts, because the rate setting methodologies and data sources vary widely from State to State. Under the UPL requirements, States were required to provide the capitation rates and any requested supporting documentation for all rate cells used which may vary from 5 to 10 cells on one end to 60 or more on another. In addition, States needed to generate data to meet the UPL requirement using historical fee-for-service (FFS) data trended forward to

the contract year. This would be a relatively simple process for a State initiating its managed care program, where it can rely on a very recent full year of FFS data for this purpose. However, almost all States have been operating risk-based managed care programs for at least 5 to 10 years and must make numerous adjustments to that data so that it can be used for this purpose. We estimate the average burden on States to comply with the current rate setting and UPL rules to be 16 hours per contract for documenting the capitation rates (setting out and explaining rate cells, risk sharing mechanisms, etc) and 40 hours per contract for generating a UPL for comparison purposes. This results in a total burden of 56 hours per contract for 496 risk contracts, resulting in a total burden of 27,776 hours.

Under the new requirements for actuarial soundness, States will need to provide an actuarial certification and additional documentation not previously required, including: specific data elements used to set capitation rates; methodologies to consider the costs for individuals with chronic illness, disability, ongoing health care needs, or catastrophic claims; explanations of risk sharing or incentive methodologies; and documentation supporting special contract provisions. We estimate the burden to comply with these requirements to average approximately 32 hours per contract for the 496 risk contracts, resulting in a total burden of 15,872 hours. This amount is limited to the time required for the State to compile documentation the State and its actuaries would already have developed in determining the capitation rates and submitting this documentation, as required, to CMS. Since, under this new rule, States will no longer need to generate a UPL in addition to the rate setting burden, this change results in a net reduction in burden of 11,904 hours.

Section 438.6(i)(3) Advance directives

1. Requirement. This paragraph requires that MCOs, PIHPs, and certain PAHPs provide adult enrollees with written information on advance directives policies and include a description of applicable State law.

2. Burden. The burden associated with this requirement is the time it takes to furnish the information to enrollees. We assume that this information would be furnished with the rest of the information required by § 438.10 and is therefore subsumed under those requirements.

There is also an implied recordkeeping requirement associated with contracts; i.e., that would be documented. Maintaining documentation is a usual and customary business practice and does not add to the burden.

B. Section 438.8 Provisions That Apply to PIHPs and PAHPs

1. Requirement. This section specifies which of the contract requirements contained in § 438.6 apply to PIHPs and which apply to PAHPs. Requirements for advance directives apply only to PIHPs and certain limited numbers of PAHPs.

2. Burden. PHPs (now designated as PIHPs and PAHPs) have not previously been required to maintain written policies and procedures with respect to advance directives. This rule requires the PIHP and some PAHPs to provide written information to enrollees of their rights under this provision and the PIHPs policies with respect to the implementation of those rights. We project 8 hours of time for each of 123 PIHPs and 2 PAHPs to establish this policy and 2 minutes per enrollee for provision of this information, and acceptance of this right to each of approximately 6.3 million individuals enrolled in PIHPs and the specified PAHPs. The total time for this is approximately 212,000 hours.

1. Requirement. Under the physician incentive plan provision, PIHPs and PAHPs, like MCOs, will be required to provide descriptive information to States and CMS to determine whether or not there is substantial financial risk in their subcontracts. In addition, enrollees must be surveyed and provided information on the risk arrangements when substantial risk exists.

2. Burden. We are basing our projections of burden upon information published in the **Federal Register** on March 27, 1996 and December 31, 1996 (61 FR 13445 and 61 FR 69049) which contained the original regulatory provisions on physician incentive plans for Medicare and Medicaid HMOs. Based on those assumptions, we believe no more than ⅓ of the approximately 157 PIHPs and PAHPs use incentive or risk payment arrangements with their subcontracting providers. Affected PIHPs and PAHPs would be required to provide detailed responses to State surveys regarding their payment mechanisms and amounts. At the projected 100 hours per response for approximately 53 PIHPs and PAHPs the total burden would be 5,300 hours. For those PIHPs and PAHPs with substantial financial risk, there are other requirements such as stop/loss insurance and beneficiary surveys. We believe there would be minimal additional burden as a result of these requirements (because many already comply with these requirements) and that this would apply to no more than ¼ of those PIHPs and PAHPs with risk or incentive payments, or a total of 13. We estimate an additional 10 hours per plan for a total of 130 hours. Altogether, we estimate 5,430 hours of burden through imposition of this requirement on PIHPs and PAHPs.

C. Section 438.10 Information Requirements

Section 438.10(c), (d), (e), (f), (g), and (h)

1. Requirement. In summary, § 438.10 requires that each State, its contracted representative, or at the option of the State, each MCO, PIHP, PAHP, and PCCM furnish information to enrollees and potential enrollees to meet the requirements of this section. Paragraph (c)(4) requires that the State and each MCO, PIHP, PAHP, and PCCM, make oral interpretation available in languages other than English. Paragraph (c)(5) requires that beneficiaries be informed how to access those services. Paragraph (d)(2) requires that all enrollees and potential enrollees must be informed that information is available in alternative formats and how to access those formats. The basic information listed in paragraph (e)(2) must be provided to each potential enrollee by the State or its contracted representative.

The State, its contracted representative or the MCO, PIHP, PAHP, or PCCM must provide the information in paragraph (f)(6), and for MCOs and PIHPs, in paragraph (g) at least once a year. The information that must be provided includes the following:

(a) Information for potential enrollees:

(1) General information must be provided about the basic features of managed care, which populations are excluded from enrollment, subject to mandatory enrollment, or free to enroll voluntarily in an MCO or PIHP, and MCO and PIHP responsibilities for coordination of enrollee care.

(2) Information specific to each MCO, PIHP, PAHP, and PCCM serving an area that encompasses the potential enrollee's service area must be provided in summary form, or in more detail, upon request of the enrollee. This includes information on benefits covered; cost sharing if any; service area; names, locations, and telephone numbers of current network providers, including at a minimum, information on primary care physicians, specialists, and hospitals, and identification of providers that are not accepting new

patients; and benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided.

(b) Information for enrollees:

(1) The State must notify enrollees of their disenrollment rights annually. The State, or the MCO, PIHP, PAHP, and PCCM, if delegated this responsibility by the State, must provide certain information to new enrollees and notify enrollees annually of their right to request additional information. The State must give each enrollee written notice of any change (that the State defines as ''significant'') in the information specified at least 30 days before the intended effective date of the change and make a good faith effort to give written notice of termination of a contracted provider, within 15 days after receipt or issuance of the termination notice, to each enrollee who received his or her primary care from, or was seen on a regular basis by, the terminated provider.

(c) General information for all enrollees of MCOs, PIHPs, PAHPs, and PCCMs:

(1) Names, locations, and telephone numbers of, and non-English languages spoken by, current network providers, including information at least on primary care physicians, specialists, and hospitals, and identification of providers that are not accepting new patients.

(2) Any restrictions on the enrollee's freedom of choice among network providers.

(3) Enrollee rights and responsibilities as specified in § 438.100.

(4) Information on grievance and fair hearing procedures, and for MCO and PIHP enrollees, the information specified in § 438.10(g)(i).

(5) 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.

(6) Procedures for obtaining benefits, including authorization requirements.

(7) The extent to which, and how, enrollees may obtain benefits, including family planning services from out-of-town network providers.

(8) The extent to which, and how, after-hours and emergency coverage are provided.

(9) What constitutes emergency medical condition, emergency services, and post-stabilization services, with reference to the definitions in § 438.114, and the fact that prior authorization is not required for emergency services.

(10) The post-stabilization care services rules set forth at § 438.113(c) of this chapter.

(11) Policy on referrals for specialty care and for other benefits not furnished by the enrollee's primary care provider.

(12) Cost sharing, if any.

(13) How and where to access any benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided.

(14) For a counseling or referral service the MCO, PIHP, PAHP, or PCCM does not cover because of moral or religious objections, the MCO, PIHP, or PCCM need not furnish information on how and where to obtain the service. The State must furnish information about how and where to obtain the service.

(d) Specific information requirements for enrollees of MCOs and PIHPs:

(1) In addition to the requirements in § 438.10(e), MCOs and PIHPs must provide to their enrollees the following information specified in § 438.10(g):

(i) Grievance, appeal, and fair hearing procedures and timeframes, as provided in § 438.400 through 438.424, in a State-developed or State-approved description, which includes:

(ii) The right to a State fair hearing and the method for obtaining a hearing,

(iii) The rules governing representation at the hearing,

(iv) The right to file grievances and appeals

(v) The filing requirements, timeframes, and availability of assistance with the filing process,

(vi) The toll-free numbers enrollees can use to file a grievance or appeal by phone,

(vii) The fact that when requested by the enrollee, benefits will continue if the enrollee files an appeal or a request for a State fair hearing within the specified timeframes,

(viii) The possibility that the enrollee may be required to pay the cost of services furnished during the appeal process, if the final decision is adverse,

(ix) Any appeal rights that the State chooses to make available to providers to challenge the failure of the organization to cover a service,

(x) Information on advance directives, as set forth in § 438.6(i)(2) and physician incentive plans, as set forth in § 438.6(h) and

(xi) Additional information that is available upon request, including structure and operation of the MCO or PIHP

2. Burden. We believe the burden placed on States, MCOs, PIHPs, PAHPs, and PCCMs, and enrollment brokers as a result of these requirements is the time associated with modifying the content of existing information materials, as well as the time associated with distributing the materials to enrollees as specified by the regulation. We estimate that it will initially take 12 hours for each MCO, PIHP, PAHP, or PCCM system to modify existing information materials to conform to the requirements above. We further estimate that there are approximately 533 MCOs, PIHPs, PAHPs, and PCCM systems equating to an initial modification burden of approximately 6,396 hours. After the initial modification, we estimate that it will take MCOs, PIHPs, and PAHPs approximately 4 hours each to annually update the information materials, equating to an annual total burden of approximately 2,132 hours.

We estimate that that it will take MCOs, PIHPs, PAHPs, and PCCM systems approximately 5 minutes per enrollee to mail a packet of materials to potential enrollees and enrollees. We estimate that each year approximately 15 percent of the Medicaid managed care enrollee population are new enrollees. This equates to approximately 3.9 million potential enrollees a year for a total burden on the States of 65,000 hours. Mailing the annual packet of information to the 25,731,040 enrollees, at 5 minutes a packet, will result in a burden to the State, or the MCOs, PIHPs, PAHPs, and PCCMs, if delegated this responsibility by the State, of 2,144,253 hours.

We similarly estimate that it annually will take MCOs, PIHPs, PAHPs, and PCCMs 5 minutes per enrollee to supply information requested by potential enrollees and enrollees. We estimate that 10 percent of potential enrollees and enrollees will request information each year. For the 390,000 potential enrollees requesting information, this results in a burden on States of 6,500 hours. For the 2,573,104 enrollees requesting information, this results in a burden on States, or MCOs, PIHPs, PAHPs, and PCCMs if delegated this responsibility by the State, of 214,425 hours.

Section 438.10(i) Special Rules: States With Mandatory Enrollment Under State Plan Authority

1. Requirement. Under (h), if the State plan provides for mandatory MCO or PCCM enrollment under section 1932(a)(1)(A) of the Act, the State or its contracted representative must provide information in a comparative, chart-like format, to potential enrollees. The information must include the MCO's or PCCM's service area, the benefits covered under the contract, any cost

sharing imposed by the MCOs or PCCMs and, to the extent available, quality and performance indicators, including but not limited to disenrollment rates and enrollee satisfaction.

2. Burden. For the requirement to provide information in a chart-like format, we believe that the additional burden on States (i.e., not yet captured in the above provisions) is the length of time associated with creating the comparative chart. We estimate that it will take States approximately 8 hours each to create the comparative chart. Currently, 10 States per year have approved managed care under the State Plan Option, for a total annual burden of approximately 80 hours.

D. Section 438.12 Provider Discrimination Prohibited

1. Requirement. This section requires that if an MCO, PIHP, or PAHP declines to include individual or groups of providers in its network, it must give the affected providers written notice of the reason for its decision.

2. Burden. The burden associated with this requirement is the time it takes the MCO, PIHP, or PAHP to draft and furnish the providers with the requisite notice. We estimate that it will take 1 hour to draft and furnish any given notice. We estimate that on average each MCO, PIHP, and PAHP will need to produce 10 notices per year for a total of 4,960 hours.

E. Section 438.50(b) State Plan Information

1. Requirements. Each State must have a process for the design and initial implementation of the State plan that involves the public and must have methods in place to ensure ongoing public involvement once the State plan has been implemented.

2. Burden. The burden associated with this section includes the time associated with developing the process for public involvement, including annual updates. We estimate that it will take 10 current States 40 hours per State to develop the process for involving the public for a total burden of 400 hours. We estimate that ensuring ongoing public involvement will take another 20 hours per State annually for a total annual burden of 200 hours.

The recordkeeping burden involved in maintaining documentation that the requirements are met is a usual and customary business practice and imposes no additional burden.

F. Section 438.56 Disenrollment: Requirements and Limitations

Section 438.56(d)(1)

1. Requirement. In order to disenroll, the beneficiary (or his or her representative) must submit an oral or written request to the State agency (or its agent) or to the MCO, PIHP, PAHP, or PCCM where permitted.

2. Burden. We believe that the burden associated with this requirement is the length of time it would take enrollees to submit in writing a disenrollment request, if they choose to use the written format. We estimate that it will take approximately 10 minutes per enrollee to generate a written disenrollment request. We estimate that approximately 5 percent of MCO, PIHP, PAHP, and PCCM enrollees will request that they be disenrolled from an MCO, PIHP, PAHP, or PCCM. Approximately one-fourth of the enrollees will choose a written rather than an oral request. This equates to an annual burden of approximately 10 minutes multiplied by 321,638 affected enrollees (one-fourth of the 1,286,552 enrollees requesting disenrollment), or approximately 53,606 hours. We estimate a burden of 3 minutes per oral request for disenrollment (for 3/4ths of the 1,286,552 enrollees, or 964,914 enrollees) for a total burden of 48,246 hours.

Section 438.56(f)

1. Requirement. Under paragraph (f), a State that restricts disenrollment under this section must provide that enrollees and their representatives are given written notice of disenrollment rights at least 60 days before the start of each enrollment period.

2. Burden. The burden for this section is addressed in § 438.10(f).

G. Section 438.102 Enrollee-Provider Communications

1. Requirement. Section 438.102(a)(2) states that the general rule in paragraph (a)(1) of this section does not require the MCOs, PIHPs, and PAHPs to cover, furnish, or pay for a particular counseling or referral service if the MCO, PIHP, or PAHP objects to the provision of that service on moral or religious grounds; and makes written information on these policies available to (1) prospective enrollees, before and during enrollment and, (2) current enrollees, within 90 days after adopting the policy with respect to an any particular service.

2. Burden. We believe the burden associated with this requirement will affect no more than 3 MCOs or PIHPs annually since it applies only to the services they discontinue providing on moral or religious grounds during the contract period. We estimate that it takes 4 hours to devise a notice and 5 minutes to mail, affecting 52,000 enrollees, for a total burden of 4,345 hours. [12 hours + (52,000 × ½)] The burden for notification of prospective enrollees of the services not covered by the MCO, PIHP, or PAHP on these grounds is included in the overall burden arising from the Information Requirements in § 438.10.

H. Section 438.202 State Responsibilities

1. Requirement. Each State contracting with an MCO or PIHP must have a written strategy for assessing and improving the quality of managed care services offered by the MCO or PIHP, make it available for public comment before adopting it in final, and conduct periodic reviews to evaluate the effectiveness of the strategy. We expect States will conduct these periodic reviews every 3 years. Each State must also submit to CMS a copy of the initial strategy and a copy of the revised strategy whenever significant changes are made. In addition, States are required to submit to CMS regular reports on the implementation and effectiveness of the strategy, consistent with the State's own periodic review of its strategy's effectiveness.

2. Burden. The burden associated with this section is limited to those States offering managed care through MCOs or PIHPs (41) and includes the time associated with developing the proposed strategy, publicizing the proposed strategy, incorporating public comments, submitting an initial copy of the strategy to CMS prior to its implementation and whenever significant changes are made, and submitting regular reports on the implementation and effectiveness of the strategy. We estimate that it will take 40 hours per State to develop the proposed strategy for a total burden of 1,640 hours. We estimate that publicizing the proposed strategy will take 2 hours per State for a total burden of 82 hours. We estimate that incorporating public comments for the final strategy will take another 40 hours per State for a total burden of 1640 hours. We estimate it will take 1 hour per State to submit an initial copy of the strategy to CMS prior to implementation and whenever significant changes are made for a total of 41 hours. We estimate it will take 40 hours per State to create and submit a report on the implementation and effectiveness of the strategy and that these reports will be submitted at

approximately every 3 years for a total annual burden of 546 hours.

I. Section 438.204 Elements of State Quality Strategies:

1. Requirement. In the final rule we require at § 438.204(b)(2) that a State identify the race, ethnicity, and primary language spoken by each MCO and PIHP enrollee and report this information to each MCO and PIHP in which each beneficiary enrolls at the time of their enrollment.

2. Burden. We believe that most States currently track race and ethnicity data in their eligibility systems. If States do not, minor changes in their software will be needed. With respect to primary language of enrollees, there will likely be additional programming needed for all States. We estimate that this would require 4 hours of programming for each of the 41 jurisdictions for a total of 164 hours.

J. Section 438.207 Assurances of Adequate Capacity and Services

1. Requirement. Section 438.207(b) requires that each MCO, PIHP, and PAHP (where applicable) submit documentation to the State, in a format specified by the State, to demonstrate that it has the capacity to demonstrate that it complies with specified requirements and that it has the capacity to serve the expected enrollment in its service area in accordance with the State's standards for access to care and meets specified requirements.

Section 438.207(c) requires that this documentation be submitted to the State at the time the MCO, PIHP, or PAHP enters into a contract with the State and at any time there has been a significant change (as defined both by the State and this regulation) in the MCO's, PIHP's, or PAHPs operations that would affect adequate capacity and services.

Section 438.207(d) requires the State, after reviewing the MCO's, PIHP's, or PAHP's documentation, to certify to CMS that the MCO, PIHP, or PAHP has complied with the State's requirements for availability of services, as set forth at § 438.206.

2. Burden. We believe that MCOs, PIHPs, and PAHPs already collect and provide this information to State agencies as part of their customary and usual business practices and that the only additional burden on MCOs, PIHPs, and PAHPs is the length of time required for these entities to compile this information in the format specified by the State agency, and the length of time to mail the information to the State and to CMS. We estimate that it will take each MCO, PIHP, and PAHP approximately 20 hours to compile the information necessary to meet this requirement, for a total of 20 hours multiplied by 486 MCOs, PIHPs, and PAHPs with networks, or approximately 9,720 hours. In addition, we estimate that it will take MCOs, PIHPs, and PAHPs approximately 5 minutes each to mail the materials associated with this burden to the State for an annual burden of approximately 5 minutes multiplied by 486 of these entities, or approximately 4 hours.

We estimate that obtaining information on: (1) The numbers and types of persons with special health care needs that could be anticipated to enroll in the MCO or PIHP; (2) the types of experienced providers they would require; (3) the experience of the existing providers in the MCO's or PIHPs network; and (4) the numbers and types of additional experienced providers needed, would require an estimated 40 hours of work for each of the 462 MCOs, PIHP, and PAHP for a total estimated burden of 18,480 hours.

K. Section 438.208 Coordination and Continuity of Care

1. Requirement. Under paragraph (b)(3) of this section requires MCOs, PIHPs, and PAHPs to share with other MCOs, PIHPs, and PAHPs serving the enrollee the results of its identification and assessment of any enrollee with special health care needs so that those activities need not be duplicated.

2. Burden. The burden associated with this information collection requirement is the time it will take to disclose information on enrollees. We estimated that it will be necessary to disclose information on 619,709 enrollees and take it will take 45 minutes for each one, for an annual total of 464,782 hours.

L. Section 438.210 Coverage and Authorization of Services

1. Requirement. Under paragraph (b) of this section, for the processing of requests for initial and continuing authorizations of services, each contract must require that the MCO, PIHP, or PAHP and its subcontractors have in place written policies and procedures.

2. Burden. The burden associated with this requirement is the time required to develop the policies and procedures. We do not believe that this requirement will increase an entity's burden as it part of usual and customary business practices.

1. Requirement. Under paragraph (c) of this section, each contract must provide for the MCO, PIHP, or PAHP to notify the requesting provider, and give the enrollee written notice of any decision by the MCO, PIHP, or PAHP to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested.

2. Burden. The burden associated with this requirement will be the time required to notify the requesting provider and the enrollee. We believe that there will be approximately 100 notifications under this provision and that it will take 60 minutes to complete the notification (including writing it) per MCO or PIHP. There are approximately 339 MCOs and 123 PIHPs for a total of 462 for a total of 46,200.

M. Section 438.214 Provider Selection

1. Requirement. Under this section, each State must ensure, through its contracts, that each MCO, PIHP, or PAHP implements written policies and procedures for selection and retention of providers.

2. Burden. The burden associated with this requirement is the usual and customary recordkeeping collection associated with maintaining documentation.

N. Section 438.230 Subcontractual Relationships and Delegation

1. Requirement. Under paragraph (b), there must be a written agreement that specifies the activities and report responsibilities delegated to the subcontractor and provides for revoking delegation or imposing other sanctions if the subcontractor's performance is inadequate.

2. Burden. The burden associated with this requirement is the time required to write the agreement and the time required to maintain documentation of the agreement. We believe that these activities and usual and customary business practices and do not affect the entities' burden.

O. Section 438.236 Practice Guidelines

1. Requirement. Under paragraph (c) of this section, each MCO, PIHP, and PHAP must disseminate guidelines to its affected providers and, upon request, to enrollees and potential enrollees.

2. Burden. The burden associated with this requirement is the time required to disseminate the guidelines. We believe that these will be rare requests and will occur infrequently.

P. Section 438.240 Quality Assessment and Performance Improvement Program; Performance Improvement Projects

1. Requirement. Section 438.240(c) states that each MCO and PIHP must annually measure its performance using

standard measures required by the State and report its performance to the State. In addition to using and reporting on measures of its performance, § 438.240(d)(1) requires States to ensure that each MCO and PIHP have an ongoing program of performance improvement projects. In § 438.240(d)(2) each MCO and PIHP is required to report the status and results of each such project to the State as requested.

2. Burden. This regulation requires States to require each MCO and PIHP to have an ongoing program of performance improvement. Based on discussions with the 17 States with the largest Medicaid managed care enrollments, all 17 States are already doing so. Because the use of performance measures in managed care has become commonplace in commercial, Medicare, and Medicaid managed care, we do not believe that this regulatory provision imposes any new burden on MCOs, PIHPs, or States.

With respect to the requirements for ongoing performance improvement projects in § 438.240(d), we expect that, in any given year, each MCO and PIHP will complete two projects, and will have four others underway. We further expect that States will request the status and results of each MCO's and PIHP's projects annually. Accordingly, we estimate that it will take each MCO and PIHP 5 hours to prepare its report for each project, for an annual total burden of 30 hours per MCO and PIHP. In aggregate, this burden equates to 30 hours multiplied by an estimated 462 MCOs and PIHPs, or approximately 13,860 hours.

Q. Section 438.242 Health Information Systems

1. Requirement. Section 438.242(b)(1) requires the State to require each MCO and PIHP to collect data on enrollee and provider characteristics as specified by the State, and on services furnished to enrollees, through an encounter data system or other such methods as may be specified by the State. Paragraph (3) requires that the data be made available to the State and, upon request, to CMS.

2. Burden. The above information collection requirement is subject to the PRA. However, we believe that the burden associated with these information collection requirements is exempt from the Act in accordance with 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities.

R. Section 438.402 General Requirements

1. Requirement. In summary, § 438.402 requires each MCO and PIHP to have a grievance system, sets out general requirements for the system, and establishes filing requirements. It provides that grievances and appeals may be filed either orally or in writing, but that oral appeals (except those with respect to expedited service authorization decisions) must be followed by a written request.

2. Burden. We estimate that it will take approximately 5.5 hours for each MCO and PIHP to conform their existing general grievance system requirements to those in the regulation. It will take approximately 2.5 hours to create or change the filing requirements, including developing or revising templates for a notice of action and a notice of disposition or resolution. The total burden for 462 MCOs and PIHPs is 3,696 hours.

We estimate that approximately 1 percent of 23.7 million MCO and PIHP enrollees (237,000) annually will file a grievance with their MCO or PIHP and that approximately .5 percent (118,000) annually will file an appeal. For these cases, we estimate that the burden on the enrollee filing a grievance or appeal is approximately 20 minutes per case. The total annual burden on enrollees is 118,500 hours.

S. Section 438.404 Notice of Action

1. Requirement. In summary, § 438.404 states that if an MCO or PIHP intends to deny, limit, reduce, or terminate a service; deny payment; deny the request of an enrollee in a rural area with one MCO or PIHP to go out of network to obtain a service; or fails to furnish, arrange, provide, or pay for a service in a timely manner, the MCO or PIHP must give the enrollee timely written notice and sets forth the requirements of that notice.

2. Burden. We estimate that the burden associated with this requirement is the length of time it would take an MCO or PIHP to provide written notice of an intended action. We estimate that it will take MCOs and PIHP 30 seconds per action to make this notification. We estimate that approximately 5 percent (1,185,000) of the approximately 23.7 million MCO and PIHP enrollees will receive one notice of intended action per year from their MCO or PIHP for a total burden of approximately 9,875 hours.

T. Section 438.406 Handling of Grievances and Appeals

1. Requirement. In summary, § 438.406 states that each MCO and PIHP must acknowledge receipt of each grievance and appeal.

2. Burden. The above information collection requirement is not subject to the PRA. It is exempt under 5 CFR 1320.4(a) because it occurs as part of an administrative action.

U. Section 438.408 Resolution and Notification: Grievances and Appeals

1. Requirement. In summary, § 438.408 states that for grievances filed in writing or related to quality of care, the MCO or PIHP must notify the enrollee in writing of its decision within specified timeframes. The notice must also specify that the enrollee has the right to seek further review by the State and how to seek it. All decisions on appeals must be sent to the enrollee in writing within specified timeframes and for notice of expedited resolution, the MCO or PIHP must also provide oral notice. The decision notice must include the MCO or PIHP contact for the appeal and the results of the process and the date it was completed. For an oral grievance that does not relate to quality of care, the MCO or PIHP may provide oral notice unless the enrollee request that it be written.

2. Burden. The above information collection requirements are not subject to the PRA. They are exempt under 5 CFR 1320.4(a) because they occur as part of an administrative action.

V. Section 438.410 Expedited Resolution of Appeals

1. Requirement. Paragraph (c), Action following denial of a request for expedited resolution, requires each MCO and PIHP to provide written notice to an enrollee whose request for expedited resolution is denied.

2. Burden. The above information collection requirement is not subject to the PRA. It is exempt under 5 CFR 1320.4(a) because it occurs as part of an administrative action.

W. Section 438.414 Information About the Grievance System to Providers and Subcontractors

1. Requirement. Under this section, the MCO or PIHP must provide the information specified at § 438.10(g)(i) about the grievance system to all providers and subcontractors at the time they enter into a contract.

2. Burden. The burden associated with this requirement is the time required to include the necessary language in the contract. We believe that this is usual and customary business practice and does not add any burden.

X. Section 438.416 Record Keeping and Reporting Requirements

1. Requirement. This section requires the State to require MCOs and PIHPs to maintain records of grievances and appeals.

2. Burden. We estimate that approximately 95,000 (.5 percent) of the approximately 19 million MCO and PIHP enrollees will file a grievance or appeal with their MCO or PIHP (205 per MCO or PIHP). The recording and tracking burden associated with each grievance is estimated to be 1 minute per request (3.4 hours per MCO or PIHP), for a total burden of 1,583 hours (1 minute multiplied by an estimated 95,000 enrollees who would file a grievance or appeal).

Y. Section 438.604 Data That Must Be Certified

1. Requirement. The data that must be certified include, but are not limited to, enrollment information, encounter data, and other information required by the State and contained in contracts, proposals, and related documents.

2. Burden. While the requirement for MCOs and PIHPs is to certify all documents required by the State, the burden associated with these requirements is captured during the submission of such information. Therefore, we are assigning 1 token hour of burden for this requirement

Z. Section 438.608 Program Integrity Requirements.

1. Requirement. Under this section, the MCO or PIHP must have administrative and management arrangements or procedures that are designed to guard against fraud and abuse. The arrangements or procedures must include written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable Federal and State standards and the designation of a compliance officer and a compliance committee that are accountable to senior management.

2. Burden. The burden associated with this requirement is the time required to file a copy of the written procedures. We believe that this is a normal business practice and does not add any burden.

AA. Section 438.710 Due Process: Notice of Sanction and Pre-Termination Hearing

Section 438.710(a) Due Process: Notice of Sanction and Pre-Termination Hearing

1. Requirement. Section 438.710(a) states that before imposing any of the sanctions specified in this subpart, the State must give the affected MCO or PCCM written notice that explains the basis and nature of the sanction.

2. Burden. The above information collection requirement is not subject to the PRA. It is exempt under 5 CFR 1320.4(a) because it occurs as part of an administrative action.

Section 438.710(b)(2) Due Process: Notice of Sanction and Pre-Termination Hearing

1. Requirement. Section 438.710(b)(2) states that before terminating an MCO's or PCCM's contract, the State must:

(i) Give the MCO or PCCM written notice of its intent to terminate, the reason for termination, the time and place of the hearing;

(ii) After the hearing, give the entity written notice of the decision affirming or reversing the proposed termination of the contract and, for an affirming decision, the effective date of termination; and

(iii) For an affirming decision, give enrollees of the MCO or PCCM notice of the termination and information, consistent with § 438.10, on their options for receiving Medicaid services following the effective date of termination.

2. Burden. The above information collection requirement is not subject to the PRA. It is exempt under 5 CFR 1320.4(a) because it occurs as part of an administrative action.

BB. Section 438.722 Disenrollment During Termination Hearing Process

1. Requirement. Section 438.722(a) states that after a State has notified an MCO or PCCM of its intention to terminate the MCO's or PCCM's contract, the State may give the MCO's or PCCM's enrollees written notice of the State's intent to terminate the MCO's or PCCM's contract.

2. Burden. States already have the authority to terminate MCO or PCCM contracts according to State law and have been providing written notice to the MCOs or PCCMs. States are now given, at their discretion, the option of notifying the MCO's or PCCM's enrollees of the State's intent to terminate the MCO's or PCCM's contract. While it is not possible to gather an exact figure, we estimate that 12 States may terminate 1 contract per year. We estimate that it will take States 1 hour to prepare the notice to enrollees, for a total burden of 12 hours. In addition, we estimate that it will take States approximately 5 minutes per beneficiary to notify them of the termination, equating to a burden of 5 minutes multiplied by 12 States multiplied by 46,194 beneficiaries per MCO or PCCM, for a burden of approximately 46,194 hours. The total burden of preparing the notice and notifying enrollees is 46,206.

CC. Section 438.724 Notice to CMS

1. Requirement. Section 438.724 requires that the State give the CMS Regional Office written notice whenever it imposes or lifts a sanction. The notice must specify the affected MCO, the kind of sanction, and the reason for the State's decision to impose or lift a sanction.

2. Burden. We anticipate that no more than 36 States would impose or lift a sanction each year and that it would take each one 30 minutes to give the regional office notice. Thus the annual burden would be 18 hours.

DD. Section 438.730 Sanction by CMS: Special Rules for MCOs With Risk Contracts

1. Requirement. Section 438.730(b), Notice of Sanction, requires that if CMS accepts a State agency's recommendation for a sanction, the State agency gives the MCO written notice of the proposed sanction.

Paragraph (c) of this section, Informal reconsideration, requires that if the MCO submits a timely response to the notice of sanction, the State agency gives the MCO a concise written decision setting forth the factual and legal basis for the decision. In addition, if CMS reverses the State's decision, the State sends a copy to the MCO.

2. Burden. These requirements are exempt under 5 CFR 1320.4(a) because they occur as part of administrative actions.

EE. Section 438.810 Expenditures for Enrollment Broker Services

1. Requirement. Section 438.810(c) requires that a State contracting with an enrollment broker must submit the contract or memorandum of agreement (MOA) for services performed by the broker to CMS for review and approval.

2. Burden. The burden associated with this requirement is the length of time for a State to mail each contract to CMS for review. We estimated that the burden associated with this requirement is 5 minutes per enrollment broker contract, for a total annual burden of approximately 3 hours per year (5 minutes multiplied by an estimated 35 enrollment broker contracts in the States using brokers).

We have submitted a copy of this final rule to OMB for its review of the information collection requirements described above in §§ 438.6, 438.8, 438.10, 438.12, 438.50, 438.56, 438.102,

438.202, 438.204, 438.207, 438.208, 438.210, 438.214, 438.230, 438.236, 438.240, 438.242, 438.402, 438.404, 438.406, 438.408, 438.410, 438.414, 438.416, 438.608, 438.710, 438.722, 438.724, 438.730, and 438.804. These requirements are not effective until they have been approved by OMB.

If you comment on these information collection requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Information Services, DCES, SSG, Attn: Julie Brown, CMS–2104–F, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850;

and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, Desk Officer.

V. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub.L. 104–4), and Executive Order 13132. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year.) We project the cost of this rule to be between $221 and $295 million annually. The burden of these costs will be shared between States, MCOs, PIHPs, PAHPs, PCCMs, and the Federal government. It should be noted that a large portion of these costs will be born by the Federal government through its matching payments to States for Medicaid expenditures.

This rule will implement new requirements for Medicaid managed care programs which have not been previously implemented through either the previous Part 434 of the CFR or the State Medicaid Director Letters listed in section I.A. of the Preamble, or self-implemented through the BBA. The new provisions implemented under this rule are requirements governing : (1) Payments under risk contracts; (2) PIHPs and PAHPs; (3) information that must be provided to beneficiaries; quality assessment and performance improvement for managed care programs; and (4) grievances and appeals.

The RFA requires agencies to analyze options for regulatory relief of small entities. We have provided an analysis of alternatives to these rules in section V.C. of the Preamble.

This final rule primarily impacts beneficiaries, State agencies, enrollment brokers, MCOs, PIHPs, PAHPs, and PCCMs. Small entities include small businesses in the health care sector that are HMO medical centers or health practitioners as prepaid health plans with receipts of less than $8.5 million, nonprofit organizations, and other entities. (See 65 FR 69432). For purposes of the RFA, individuals and State governments are not included in this definition. In the proposed rule we invited comments on alternatives to provisions of the proposed rule that would reduce burden on small entities. We did not receive any comments in response to this invitation.

As of June 2000, there were 339 MCOs, 123 PIHPs, 34 PAHPs, and 37 PCCM systems. We believe that only a few of these entities qualify as small entities. Specifically, we believe that 16 MCOs, 14 PIHPs, 11 PAHPs, and most managed care entities in the 37 PCCM systems are likely to be small entities. We estimate that there are 4.8 million beneficiaries enrolled in these small entities. We believe that the remaining MCOs, PIHPs, and PAHPs have annual receipts from Medicaid contracts and other business interests in excess of $8.5 million.

The primary impact on small entities will be through the requirements placed on PIHPs and PAHPs by § 438.8. Under this rule, PIHPs will be subject to nearly all of the requirements for MCOs, including the requirements for quality assessment and improvement and grievances and appeals. PAHPs are not subject to the grievance and appeals requirements, but will be subject to quality requirements like network adequacy and coverage and authorization of services where it is determined to be applicable. The impact on these entities from these provisions is discussed later in this section. However, we are identifying additional burden on the 14 PIHPs and 11 PAHPs, which we project to be small entities of 2,000 hours from the requirement for advance directives and 900 hours on information on solvency requirements, for a total burden of 2,900 hours. Using the mean hourly wage the average wage for the health care service sector of $16.34 (Bureau of Labor Statistics, March 2001), this will result in a total cost to these small entities of $47,386.

The most significant burden relates to providing information to enrollees. Specifically, MCOs, PIHPs, PAHPs, and PCCMs are required to make written materials available in languages that are prevalent in its service area (as determined by the State) and provide oral interpretation services when needed. The final rule requires MCOs, PIHPs, PAHPs, and PCCMs to make oral interpretation services available to each potential enrollee or enrollee requesting them. This requirement is actually derived from the provisions of Title VI of the Civil Rights Act of 1964 and Executive Order 13166, and not created by this rule. We estimate that less than 1% of the enrollees of these entities (or 48,000 individuals) will require this service an average of 2 times per year. Using the baseline commercial language line charges of $2.20 per minute with a one hour minimum, we estimate the cost of providing oral interpretation services to be $12.7 million annually. We believe that this estimate may overstate the impact of this requirement, because: (1) Many providers are bilingual or have staff that are bilingual (particularly in areas with relatively a large percentage of non-English speaking individuals); (2) there are less costly alternatives than the example we have used to provide oral interpretation; (3) many enrollees in need of oral interpretation will prefer to use a friend or relative; and (4) these specific costs should be mitigated by the costs of complying with current civil rights requirements to provide translation services.

We do not believe that there is significant burden as a result of the remainder of this section. PCCMs or PAHPs do not normally provide much written material directly to enrollees since, in the final rule, we place the responsibility on States, rather than PCCMs and PAHPs. We believe that States will usually prepare this information so that the only burden on PCCMs and PAHPs will be to distribute the information when it is requested by an enrollee. For the small entities who must perform this function themselves, including those MCOs and PIHPs identified as such we have projected a burden of 36,000 hours for compliance with the requirements in the information section. This results in an additional burden of $588,240.

The final rule also imposes requirements for quality assessment and improvement in subpart D on all MCOs

and PIHPs and those PAHPs designated by the State. Based on the estimates in the Collection of Information section of this preamble, we project a burden of 3,800 hours or $62,092.

In addition, Subpart F of this rule requires the 16 MCOs and 14 PIHPs that are small entities to develop and implement a grievance system as described in that section. While most of these entities would have had a system in place already, they will, at a minimum, need to modify the current system to comply with the requirements of this section. We project the burden for these modifications and operation of the grievance systems by these entities to be a total of 8 hours per entity for the development and modification of the current system and an average of 4 hours each for the resolution of the expected 1440 grievances and appeals filed by the enrollees of these entities (based on the estimates contained in section IV of this preamble on Information Collection Requirements). This results in a total burden of 6,000 hours at the mean hourly wage of $16.34, for a total cost of $98,040.

We do not believe that the remaining impact of the provisions of this final rule are great on the small entities that we have identified. These small entities must meet certain contract requirements, however, these are consistent with the nature of their business in contracting with the State for the provision of services to Medicaid enrollees. They, likewise, must meet requirements related to disenrollment of enrollees for cause, including receipt and initial processing of disenrollment requests if the State delegates this function to the entity. However, all enrollees have an annual opportunity to disenroll, and historically the number of disenrollment requests for cause are small. In addition, these entities must submit marketing material to the State for review and approval, and those MCOs, PIHPs, and PAHPs which are at risk for emergency services must cover and pay for emergency services based on the prudent layperson standard. However, the provisions governing marketing materials and emergency services have already been implemented through State Medicaid Director Letters.

We have clarified that PAHP enrollees have the right to a State fair hearing under subpart E of part 431, although this is not a new requirement. Additionally, PAHPs may not discriminate against providers seeking to participate in the plan. This requirement imposes no burden as it would reflect their usual and customary business operations.

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

We do not anticipate that the provisions in this final rule will have a substantial economic impact on most hospitals, including small rural hospitals. The BBA provisions include some new requirements on States, MCOs, and PIHPs, but no new direct requirements on individual hospitals. However, the prudent layperson standard for emergency services should benefit these hospitals by providing a uniform standard on which to determine the potential for coverage of these services across all MCOs. The impact on individual hospitals will vary according to each hospital's current and future contractual relationships with MCOs and PIHPs, but any additional burden on small rural hospitals should be negligible.

We have determined that we are not preparing analysis for either the RFA or section 1102(b) of the Act because we have determined, and we certify that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals in comparison to total revenues of these entities.

B. Anticipated Effects

This final rule implements the Medicaid provisions as directed by the BBA. The primary objectives of these provisions are to provide greater beneficiary protections and quality assurance standards and to allow for greater flexibility for State agencies to participate in Medicaid managed care programs. The final rule addresses pertinent areas of concern between States and MCOs, PIHPs, PAHPs and PCCMs.

Specific provisions of the regulation include the following:

- Permitting States to require in their State plan that Medicaid beneficiaries be enrolled in managed care. (This provision was implemented through a State Medicaid Director (SMD) Letter dated December 17, 1997, but this rule adds requirements for public involvement in the process.)
- Eliminating the requirement that no more than 75 percent of enrollees in an MCO or PHP be Medicaid or Medicare enrollees. (This provision was implemented through an SMD Letter dated January 14, 1998.)
- Specifying a grievance and appeal procedure for MCO and PIHP enrollees.
- Providing for the types of information that must be given to enrollees and potential enrollees, including requirements related to language and format.
- Requiring that MCOs, PIHPs and PAHPs document for the States that they have adequate capacity to serve their enrollees and that States certify this to us.
- Specifying quality standards for States, MCOs, and PIHPs.
- Increasing program integrity protections and requiring certification of data by MCOs and PIHPs.
- Increasing the threshold for prior approval of MCO contracts. (This provision was implemented through an SMD Letter dated January 14, 1998.)
- Permitting cost sharing for managed care enrollees under the same circumstances as permitted in fee-for-service. (This provision was implemented through an SMD Letter dated December 30, 1997.)
- Expanding the managed care population for which States can provide 6 months of guaranteed eligibility. (This provision was implemented through an SMD Letter dated March 23, 1998.)
- Revising the rules for setting capitation rates.

It is extremely difficult to accurately quantify the overall impact of this regulation on States, MCOs, PIHPs, PAHPs, and PCCMs because there is enormous variation among States and these entities regarding their current regulatory and contract requirements, as well as organizational structure and capacity. Any generalization would mask important variations in the impact by State or managed care program type. The Lewin Group, under a contract with the Center for Health Care Strategies, released a study of the cost impact of the earlier proposed regulation published on September 29, 1998 the **Federal Register** (63 FR 52022). Because this new final rule addresses the same areas as the September 29, 1998 proposed rule and includes many similar provisions, the Lewin study remains the best information we have available on the potential incremental impact of this final rule. However, the provisions discussed in the study were more prescriptive, and thus more costly to implement, than the provisions contained in this final rule. Consequently, we believe that these

estimates are higher than the actual costs will be to implement these requirements.

The Lewin study did not analyze the original proposed regulation in total, but focused on four areas within the original proposed regulation: individual treatment plans, initial health assessments, quality improvement programs, and grievance systems/State fair hearings. These areas are discussed in more detail in the specific section of the Impact Analysis addressing that provision. While the study's focus is limited to selected provisions of the previous regulation, and some of the details of the provisions in this final rule differ from the earlier proposed rule, nevertheless, we believe that the overall cost conclusions are relevant to this final rule. In addition to examining the four regulatory requirements, the Lewin study cited the need to evaluate both the incremental and aggregate effects of the rule; the affect on different managed care environments (for example, overall enrollment; the Medicare, commercial, and Medicaid mix; geographic location); and differing regulatory requirements of the State (for example, State patient rights laws, regulation of noninsurance entities). The Lewin report also points out that many of the BBA provisions were implemented through previous guidance to the States, so the regulatory impact only captures a subset of the actual impact of the totality of BBA requirements.

In summary, according to the Lewin Study, States and their contracting managed care plans have already implemented many provisions of the BBA. While there are incremental costs associated with these regulatory requirements, they will vary widely based on characteristics of individual managed care plans and States. Finally, the BBA requirements are being implemented in an increasingly regulatory environment at the State level. Therefore, States, MCOs, and PIHPs will likely face additional costs not related to these regulatory requirements absent these new regulations. Thus, the incremental impact of these requirements on costs to be incurred would be difficult if not impossible to project.

We believe that the overall impact of this final rule will be beneficial to Medicaid beneficiaries, MCOs, PIHPs, PAHPs, PCCMs, States, and CMS. Many of the BBA Medicaid managed care requirements merely codify the Federal statute standards widely in place in State law or in the managed care industry. Some of the BBA provisions represent new requirements for States, MCOs, PIHPs, PAHPs, and PCCMs, but also provide expanded opportunities for participation in Medicaid managed care.

It is clear that all State agencies will be affected by this final Medicaid rule but in varying degrees. Much of the burden will be on MCOs, PIHPs, PAHPs, and PCCMs contracting with States, but this will also vary by existing and continuing relationships between State agencies and MCOs, PIHPs, PAHPs, and PCCMs. This regulation is intended to provide important beneficiary protections while giving States flexibility and minimizing the compliance cost to States, MCOs, PIHPs, PAHPs, and PCCMs to the extent possible consistent with the detailed BBA requirements. We believe the final rule provisions will result in improved patient care outcomes and satisfaction over the long term.

Recognizing that a large number of entities, such as hospitals, State agencies, MCOs, PIHPs, PAHPs, and PCCMs will be affected by the implementation of these statutory provisions, and a substantial number of these entities may be required to make changes in their operations, we have prepared the following analysis. This analysis, in combination with the rest of the preamble, is consistent with the standards for analysis set forth by both the RFA and RIA.

1. State Options To Use Managed Care

Under this provision, a State agency may amend its State plan to require all Medicaid beneficiaries in the State to enroll in either an MCO or PCCM without the need to apply for a waiver of ''freedom of choice'' requirements under either section 1915(b) or 1115 of the Act. However, waivers will still be required to include certain exempted populations in mandatory managed care programs, notably dual Medicare-Medicaid eligibles, Indians, and groups of children with special needs. Federal review will be limited to a one-time State plan amendment approval, while States will no longer need to request waiver renewals every 2 years for section 1915(b) of the Act and 3–5 years for section 1115 of the Act waivers. State agencies may include ''exempted'' populations as voluntary enrollees in the State plan managed care programs or as mandatory enrollees in State waiver programs. Currently, ten States use State plan amendments to require beneficiary enrollment in MCOs and PCCMs. In short, the new State plan option provides State agencies with a new choice of method to require participation in managed care. The ability of States to require enrollment in managed care through their State plans rather than through a waiver will not alter the standards of care practiced by MCOs and health care providers and, therefore, will not change the cost of providing care to managed care enrollees.

Pursuing the State plan amendment option rather than a waiver under section 1915(b) or 1115 of the Act waiver may reduce State administrative costs because it will eliminate the need for States to go through the waiver renewal process. Likewise, we will benefit from a reduced administrative burden if fewer waiver applications and renewals are requested. However, we believe the overall reduction in administrative burden to both the States and Federal government of approximately 40 hours annually per State will be offset by an additional burden of approximately 40 hours annually to develop and maintain the public process required by this rule.

2. Elimination of 75/25 Rule

Before the passage of the BBA, nearly all MCOs, and PHPs contracting with Medicaid were required to limit combined Medicare and Medicaid participation to 75 percent of their enrollment, and State agencies had to verify enrollment composition as a contract requirement. Elimination of this rule allows MCOs, PIHPs, and PAHPs to participate without meeting this requirement and eliminates the need for States to monitor enrollment composition in contracting MCOs, PIHPs, and PAHPs. This will broaden the number of MCOs, PIHPs, and PAHPs available to States for contracting, leading to more choice for beneficiaries. This provision results in no additional burden on States since it merely eliminates a previous statutory requirement and has already been implemented through the BBA amendment and the State Medicaid Director Letter in 1998.

3. Increased Beneficiary Protection—Grievance Procedures

The BBA requires MCOs to establish internal grievance procedures that permit an eligible enrollee, or a provider on behalf of an enrollee, to challenge the denials of medical assistance or denials of payment. Prior to the enactment of the BBA, the regulations at 42 CFR 434.59, required MCOs and PHPs to have an internal grievance procedure. While the regulations do not specify a procedure for MCOs or PIHPs to follow for their grievance process, we believe that these entities have grievance systems that are similar in their processes to the requirements of this final regulation. This belief is supported

by surveys of State Medicaid agencies, such as the survey of 10 States conducted by the National Academy for State Health Policy in 1999, and the survey of 13 States conducted by the American Public Human Services Association in 1997. Therefore, while this regulation will require uniform procedures across MCOs and PIHPs, and will require MCOs and PIHPs to change their procedures to conform to the regulation, the requirements of the final rule will not impose significant additional requirements on MCOs and PIHPs, beyond the 8 hours per entity we estimated in the Collection of Information section of this preamble (and included in the totals below) to make current systems conform with the provisions of this rule. For States, we estimate an additional burden for the development of an expedited process for State fair hearings of 20 hours per State for the 40 States that contract with MCOs and/or PIHPs for a total burden of 800 hours and a cost of $13,640.

In the Collection of Information section of this preamble, we assigned 9,875 burden hours to MCOs and PIHPs for the notice requirements of the grievance system, and 1,583 hours for the record keeping requirements and summary reports to be prepared by MCOs and PIHPs and submitted to the States. This results in 11,458 total burden hours. Using the mean hourly wage for the health care service sector (the Bureau of Labor Statistics, March 2001) of $16.34, this would result in a total cost to MCOs and PIHPs of $187,224.

4. Provision of Information

In mandatory managed care programs, we require that beneficiaries be informed of the choices available to them when enrolling with MCOs, PIHPs, PAHPs, and PCCMs. Section 1932(a)(5) of the Act, enacted in section 4701(a)(5) of the BBA, describes the kind of information that must be made available to Medicaid enrollees and potential enrollees. It also requires that this information, and all enrollment notices and instructional materials related to enrollment in MCOs, PIHPs, PAHPs, and PCCMs be in a format that can be easily understood by the individuals to whom it is directed. We do not believe that these requirements deviate substantially from current practice, including the new mechanism requirement. Programs operated under section 1915(b) and 1115 authority have always had more stringent beneficiary protections. Furthermore, there is no way to quantify the degree of burden on State agencies, MCOs, PIHPs, PAHPs, and PCCMs for several reasons. We do not have State-specific data on what information States currently provide, or the manner in which they provide it. Variability among States indicates that implementing or continuing enrollee information requirements will represent different degrees of difficulty and expense.

The information requirements for MCOs and PCCMs in the final rule are required under the BBA. In this final rule, however, we extend requirements to PIHPs and PAHPs. In the Collection of Information section of this Preamble, we have estimated the total burden on States, MCOs, PIHPs, PAHPs, and PCCMs of 2,358,678 hours to comply with these requirements. Using a weighted average between the mean hourly wages for State employees and the health care service sector of $16.70, this results in a total cost of $39,389,923.

As a requirement under the provision of information section, State agencies opting to implement mandatory managed care programs under the State plan amendment option are required to provide comparative information on MCOs and PCCMs to potential enrollees. Currently only ten States have exercised the option to use a State plan amendment to require beneficiary enrollment in managed care. However, for States that do select this option, we do not believe that providing the comparative data in itself represents an additional burden, as these are elements of information that most States currently provide. The regulation specifies that the information must be presented in a comparative or chart-like form that facilitates comparison among MCOs, and PCCMs. This may be perceived as a burden to States that have previously provided this information in some other manner; however, it is our belief that even in the absence of the regulation, the trend is for States, and many accreditation bodies such as the National Committee for Quality Assurance (NCQA), to use chart-like formats. Consequently, enrollees will benefit from having better information for selecting MCOs, and PCCMs. Only a few States have opted for State plan amendments so far, but it is anticipated that more States will participate over the long term. States that participate in the future will benefit from any comparative tools developed by other States. We state in the Collection of Information section of this preamble that ten States availed themselves of the State Plan option, and thereby will be required to display information on a comparative chart. We are assuming it will take 8 hours each to create the comparative chart, or 80 hours for 10 States. Using the mean hourly wage for State employees (the Bureau of Labor Statistics, March 2001) of $17.05, this would result in total costs to States of $1364. We estimate that there may be additional costs associated with the production of these charts of $2,000—$5,000 per state that are not reflected in the Collection of Information requirements. This results in a total estimated cost from $21,364 to $51,364 to comply with this requirement

5. Demonstration of Adequate Capacity and Services

The BBA requires Medicaid MCOs to provide the State and the Secretary of HHS with assurances of adequate capacity and services, including service coverage, within reasonable timeframes. States currently require assurances of adequate capacity and services as part of their existing contractual arrangements with MCOs, PIHPs and PAHPs. However, certification of adequacy has not been routinely provided to us in the past. Under this rule, each State retains its authority to establish standards for adequate capacity and services within MCO, PIHP and PAHP contracts. This may be perceived as a burden to MCOs, PIHPs and PAHPs, and for States that have not been required to formally certify that an MCO, PIHP or PAHP meets the States' capacity and service requirements. However, certification to us will ensure an important beneficiary protection while imposing only a minor burden on States to issue a certification to us of the information that should already be in their possession.

Each State agency has its own documentation requirements and its own procedures to assure adequate capacity and services. This regulation contemplates that States continue to have that flexibility.

Under this regulation, State agencies must determine and specify both the detail and type of documentation to be submitted by the MCO, PIHP or PAHP as applicable, to assure adequate capacity and services and the type of certification to be submitted to us. We believe the 24 PAHPs contracting as dental plans or transportation providers will need to meet this requirement. Accordingly, variability among State agencies implementing this regulation represents different degrees of detail and expense. Regardless of the level of additional burden on MCOs, PIHPs, PAHPs, State agencies, and us, Medicaid beneficiaries will receive continued protections in access to health care under both State and Federal statute. For purposes of the Collection of Information section of this preamble, we assume that it would take 20 hours per

MCO, PIHP, or PAHP to complete this requirement. For the 486 MCOs, PIHPs, and PAHPs, this requirement would take 9,720 hours to complete annually. Based on a mix of clerical and administrative salaries to produce, verify, and submit this information, we project a total cost of $174,960 (9720 hours at $18 per hour) to MCOs, PIHPs, and PAHPs to comply with this requirement.

6. New Quality Standards

The BBA requires that each State agency have an ongoing quality assessment and improvement strategy for its Medicaid managed care contracting program. The strategy, among other things, must include: (1) Standards for access to care so that covered services are available within reasonable timeframes and in a manner that ensures continuity of care and adequate capacity of primary care and specialized services providers; (2) examination of other aspects of care and service directly related to quality of care, including grievance procedures and information standards; (3) procedures for monitoring and evaluating the quality and appropriateness of care and service to enrollees; and (4) periodic reviews to evaluate the effectiveness of the State's quality strategy.

The provisions of this final rule impose requirements for State quality strategies and requirements for MCOs and PIHPs that States are to incorporate as part of their quality strategy. These MCO and PIHP requirements address: (1) MCO and PIHP structure and operations; (2) Medicaid enrollees' access to care; and (3) MCO and PIHP responsibilities for measuring and improving quality. While these new Medicaid requirements are a significant increase in Medicaid regulatory requirements in comparison to the regulatory requirements that existed before the BBA, we believe the increases are appropriate because many of the requirements are either identical to or consistent with quality requirements placed on MCOs by private sector purchasers, the Medicare program, State licensing agencies, and private sector accreditation organizations. While these new requirements also will have implications for State Medicaid agencies that are responsible for monitoring for compliance with the new requirements, we believe that a number of recent statutory, regulatory, and private sector developments will enable State Medicaid agencies to more easily monitor for compliance than in the past at potentially less cost to the State.

Prior to issuance of that proposed rule, we worked closely with State Technical Advisory Groups (TAGs) in developing the managed care quality regulations and standards. Requirements under this final regulation build on a variety of initiatives of State Medicaid agencies and us to promote the assessment and improvement of quality in plans contracting with Medicaid, including:

The Quality Improvement System for Managed Care (QISMC), an initiative with State and Federal officials, beneficiary advocates, and the managed care industry to develop a coordinated quality oversight system for Medicare and Medicaid that reduces duplicate or conflicting efforts and emphasizes demonstrable and measurable improvement.

QARI, serving as a foundation to the development of QISMC, highlights the key elements in the Health Care Quality Improvement System (HCQIS), including internal quality assurance programs, State agency monitoring, and Federal oversight. This guidance emphasizes quality standards developed in conjunction with all system participants, such as managed care contractors, State regulators, Medicaid beneficiaries or their representatives, and external review organizations.

Further, we have built on efforts in other sectors in developing these quality requirements in order to capitalize on current activities and trends in the health care industry. For example, many employers and cooperative purchasing groups and some State agencies already require that organizations be accredited by the National Committee on Quality Assurance (NCQA), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the American Accreditation Healthcare Commission (AAHC), or other independent bodies. Many also require that organizations report their performance using Health Plan Employer Data & Information Set (HEDIS), Foundation for Accountability (FACCT), or other measures and conduct enrollee surveys using the Consumer Assessment of Health Plans Study (CAHPS) or other instruments. NCQA estimates that more than 90 percent of plans are collecting some or all of HEDIS data for their commercial population. Also, States have heightened their regulatory efforts through insurance or licensing requirements, and the National Association of Insurance Commissioners (NAIC) has developed model acts on network adequacy, quality assessment and improvement, and utilization review.

While we anticipate that many organizations will need to invest in new staff and information systems in order to perform these new quality improvement activities, it is difficult to quantify these financial and operational ''investments,'' as State agencies, MCOs, and PIHPs across the country exhibit varying capabilities in meeting these standards. These new quality requirements may present administrative challenges for some State agencies, MCOs, and PIHPs. However, States have significant latitude in how these requirements are implemented. Acknowledging that there likely will be some degree of burden on States, MCOs, and PIHPs, we also believe that the long-term benefits of greater accountability and improved quality in care delivery outweigh the costs of implementing and maintaining these processes over time.

According to the MCOs included in the Lewin study, many of the quality provisions in the September 1998 proposed rule (as well as those in this final rule) are not expected to have large incremental costs. The study mainly focused on the assessment and treatment management components of the regulation, as well as the quality improvement projects. For example, they estimate the cost of an initial assessment (called ''screening'' in this final regulation) as ranging from $0.17 to $0.26 per member per month (PMPM), but for an MCO that currently performs an initial assessment, the incremental cost is estimated as $0.03 to $0.06 PMPM. Extrapolating these estimates to the population of Medicaid managed care enrollees, if all enrollees were enrolled in plans doing initial assessments, the total cost would range from $6.8 million to $13.5 million. If all enrollees were enrolled in plans that did not perform initial assessments, the total cost would be $38 million to $58 million.

Similarly, the costs of quality improvement projects can vary from $60,000 to $100,000 per project in the first year (start-up), $80,000 to $100,000 in the second and third years (the intervention and improvement measurement cycle), and $40,000 to $50,000 for the forth and subsequent years (ongoing performance measurement). If we assume that each of the approximately 339 MCOs and 123 PIHPs were to have one quality improvement project in each year, these costs will range from $180,000 to $230,000 per MCO or PIHP for a total cost of between $83 and $106 million.

7. Administration

a. Certifications and Program Integrity Protections. Sections 1902(a)(4) and (19) of BBA require that States conduct appropriate processes and methods to ensure the efficient operation of the health plans. This includes mechanisms to not only safeguard against fraud and abuse but also to ensure accurate reporting of data among health plans, States, and us.

Section 438.602 of the final rule addresses the importance of reliable data that are submitted to States and requires MCOs and PIHPs to certify the accuracy of these data to the State. These data include enrollment information, encounter data, or other information that is used for payment determination. Even if States do not use encounter data to set capitation rates for MCOs and PIHPs, these data, along with provider and enrollment data, are useful for States in measuring quality performance and other monitoring of health plans. The provision of the final rule that requires plans to attest to the validity of data presents an additional step in the process of data submission. MCOs and PHPs have historically worked closely with States when reporting Medicaid data in order to affirm that the data are accurate and complete. Submitting a certification of validity of data submitted does not represent a significant burden to health plans.

Section 438.606 requires MCOs and PIHPs to have effective operational capabilities to guard against fraud and abuse. As a result, MCOs and PIHPs will uncover information about possible violations of law that they would be required to report to the State. We do not believe that these will be frequent or large in number and, therefore, will not result in burdens to the MCOs and PIHPs beyond what is usual in the course of business.

b. Change in Threshold from $100,000 to $1 Million. Before the passage of the BBA, the Secretary's prior approval was required for all HMO contracts involving expenditures of $100,000 or more. Under the BBA, the threshold amount is increased to $1 million. This change in threshold will have minimal impact on plans currently contracting with State agencies for Medicaid managed care. Currently, only one or two plans in the country have annual Medicaid expenditures of under $1 million. Therefore, this final rule provision will not affect a significant number of plans or States.

8. Permitting Same Copayments in Managed Care as in FFP

Under section 4708(c) of the BBA, States may now allow copayments for services provided by MCOs to the same extent that they allow copayments under fee-for-service. Imposition of copayments in commercial markets typically results in lower utilization of medical services, depending on the magnitude of payments required of the enrollee. Thus, we normally expect State agencies that implement copayments for MCO enrollees to achieve some savings. However, applying copayments to Medicaid enrollees may cause States and MCOs to incur administrative costs that more than offset these savings. This is due to several factors. First, the amount of copayments allowed by statute are significantly lower than typical commercial copayments. Second, it is difficult to ensure compliance with these payments, especially given that the enrollees have limited income. Third, to achieve maximum compliance, collection efforts will be necessary on the part of MCOs or PHPs. It is also possible that, if State agencies take advantage of this option, Medicaid managed care enrollees may defer receipt of health care services, their health conditions may deteriorate, and the costs of medical treatment may be greater over the long term. For these reasons, it is difficult to predict how many States will take advantage of this option or of the net costs or savings that would result.

9. Six-Month Guaranteed Eligibility

The legislation expanded the States' option to guarantee up to 6 months eligibility in two ways. First, it expands the types of MCOs whose members may have guaranteed eligibility, in that it now includes anyone who is enrolled with a Medicaid managed care organization as defined in section 1903(m)(1)(A) of the Act. Second, it expands the option to include those enrolled with a PCCM as defined in section 1905(t) of the Act. These changes were effective October 1, 1997. To the extent that State agencies choose this option, we expect MCOs, PIHPs, PAHPs, and PCCMs in those States to support the use of this provision since it affords health plans with assurance of membership for a specified period of time. Likewise, beneficiaries will gain from this coverage expansion, and continuity of care would be enhanced. The table below displays our estimates of the impact of the expanded option for 6 months of guaranteed eligibility under section 4709 of the BBA.

COST OF 6-MONTH GUARANTEED ELIGIBILITY OPTION

[Dollars in millions rounded to the nearest $5 million]

	FY 2002	FY 2003	FY 2004	FY 2005
Federal	80	115	165	230
State	60	90	125	175
Total ...	140	205	290	405

Because this provision was effective shortly after enactment of the BBA, the estimates of Federal costs have been reflected in our Medicaid budget since FY 1998. The estimates assume that half of the current Medicaid population is enrolled in managed care and that this proportion would increase to about two-thirds by 2003. We also assume that 15 percent of managed care enrollees were covered by guaranteed eligibility under rules in effect prior to enactment of the BBA and that the effect of the expanded option under section 4709 of the BBA would be to increase this rate to 20 percent initially and to 30 percent by 2003. The guaranteed eligibility provision is assumed to increase average enrollment by 3 percent in populations covered by the option. This assumption is based on computer simulations of enrollment and turnover in the Medicaid program. Per capita costs used for the estimate were taken from the President's FY 1999 budget projections and the costs for children take into account the interaction of this provision with the State option for 12 months of continuous eligibility under section 4731 of the BBA. The distribution between Federal and State costs is based on the average Federal share representing 57 percent of the total costs.

In States electing the 6-month guaranteed eligibility option, Medicaid beneficiaries will have access to increased continuity of care, which should result in better health care management and improved clinical outcomes.

10. Financial Impact of Revised Rules for Setting Capitation Payments

This final rule replaces the current UPL requirement at § 447.361 with new rate-setting rules incorporating an expanded requirement for actuarial soundness of capitation rates as described in detail in § 438.6(c). In general, we do not expect a major budget impact from the use of these new rate setting rules. While the rate setting rules may provide some States additional flexibility in setting higher capitation rates than what would have

been allowed under current rules, we believe that the requirements for actuarial certification of rates, along with budgetary considerations by State policy makers, would serve to limit increases to within reasonable amounts. Moreover, the Secretary retains the authority to look behind rates that appear questionable and disapprove any that do not comply with the rate setting requirements.

Because we cannot predict State behavior in these areas, we are unable to quantify the impact of potential rate increases that may be triggered by these new rules. However, as an illustration of the potential impact, we can compare states such as Oregon and Tennessee, which have had the upper payment limit requirement waived under their health care reform demonstrations to the other states providing managed care through contracts with MCOs. The capitation rates paid by these states do no vary significantly from most states operating under the UPL requirement.

Another example to consider is pediatric dental care, where low payment rates have frequently been cited as a barrier to access. Using Medicaid statistical and financial data, we estimate that the average Medicaid payment for dental services to children, on a per member per month (PMPM) basis, is about $10. A recent study by the Milbank Memorial Fund recommended a model pediatric dental program that is estimated to cost $14.50 PMPM, or 45 percent higher than the current average.

If these new rules induced 10 percent of States (on a dollar volume basis) to adopt the Millbank program or its monetary equivalent, annual Federal and State premium costs for children would rise by about 0.3 percent, or approximately $50 million. As indicated above, such increases in spending could be achieved under current rules, so it is difficult to predict the extent to which the proposed changes to rate setting requirements would precipitate these or any other additional costs to the Medicaid program.

As discussed in the Collection of Information section of this Preamble, we expect a net reduction in administrative burden on states of 11,904 hours through this change, resulting in a projected savings of $202,963.

11. Costs to States and Providers of Provisions Assigned Burden Hours

The Collection of Information Requirements section of this preamble includes estimates of the number of hours it will take States, providers, and enrollees to provide information required under this regulation. For States, the total hours are estimated to be 2,481,076. To estimate the cost impact of these requirements on States, we assume the total cost of these requirements to be the sum of the estimated hours times the mean hourly wage for State employees of $17.05 (the Bureau of Labor Statistics, March, 2001), or $42,302,346. Because the Federal government shares the general administrative costs of the Medicaid program with the States, we estimate the total cost of these requirements to States to be approximately $21 million dollars annually.

For MCOs, PIHPs, PAHPs, and PCCMs, we estimate that the Collection and Information Requirements will take 1,264,461.5 hours annually to complete. To estimate the cost impact of these requirements on providers, we multiplied these hours by the mean hourly wage for health care service workers of $16.34 (the Bureau of Labor Statistics, March, 2001) to estimate the cost of these requirements to be approximately $20.7 million.

12. Contract Monitoring

This final rule requires States to include certain specifications in their contracts with MCOs, PIHPs, PAHPs, and PCCMs and to monitor compliance with those contract provisions. It also requires States to take a proactive role in monitoring the quality of their managed care program. These requirements add some administrative burden and costs to States. The amount of additional administrative cost will vary by State depending on how inclusive current practice is of the new requirements. In addition, for those States not using like requirements at present, we believe that most will be adopting similar requirements on their own in the future absent this final rule.

The final rule also increases Federal responsibilities for monitoring State performance in managing their managed care programs. However, no new Federal costs are expected as we plan to use existing staff to monitor these new requirements.

C. Alternatives Considered

In publishing this final rule implementing the BBA Medicaid managed care provisions, we considered two main alternatives. The first alternative was to allow the January 19, 2001 final rule with comment to become effective as published. The second alternative was to implement the BBA statute as written and not regulate beyond the statutory language. We believe that this final rule as now written maintains an appropriate balance between these two alternatives.

We realized that allowing the more prescriptive January 2001 rule to become effective would cost states and health plans more to implement and could potentially restrict access if states and health plans became unwilling to participate in Medicaid managed care. We heard from several key stakeholders that the January 2001 final rule with comment was overly burdensome and did not allow sufficient State flexibility. In addition, others stated that the January 2001 final rule was a micro-managing approach to Medicaid managed care and would make it increasingly difficult for State Medicaid agencies to provide access to quality health care through managed care, since MCOs and other providers would not be willing to participate. Many felt that the requirements would be administratively burdensome to implement, particularly for small entities, and created significant business risks for MCOs. The rules would have resulted in an increase in health plan compliance costs and a significant additional burden on small entities without meaningfully improving patient care. Particular examples of provisions, which would increase costs significantly, were the requirements for specific timeframes for conducting initial health screenings, performing comprehensive health assessments and the detailed requirements under the notice of action provisions. Based on these concerns we decided that we needed more time to understand the impact of the January 2001 final rule. In the interim we believed the best approach was to streamline the January 2001 provisions and republish as a proposed rule. The removal of the highly prescriptive requirements will enhance States' abilities to continue innovations with their managed care programs leading to improved efficiencies and reduced costs. Further the new rate setting provisions will result in rates that more appropriately reflect the cost of health services.

On the other hand, implementing the BBA statutory language as written would not have provided adequate patient protections and may have resulted in lower overall quality of care. In addition to the broad patient protection and quality provisions in the BBA statute, this final rule provides consumers with comprehensive, easy-to-understand information about their health plan, establishes timeframes for review of grievance and appeals, requires adequate provider networks sufficient to meet the needs of enrolled individuals, requires identification of individuals with special health care

needs, specifies timeframes for service authorization decisions and requires continuity and coordination of care. In addition, States must have an overall strategy to ensure the delivery of quality health care by its MCOs, PIHPs and PAHPs. Further, MCOs and PIHPs are required to conduct performance improvement projects that must be designed to achieve significant improvement in clinical care and nonclinical care areas that are expected to have a favorable effect on health outcomes and enrollee satisfaction. We believe that all of these provisions, while consistent with the BBA's intent will work to improve overall quality of care for Medicaid beneficiaries enrolled in Medicaid managed care. Through enhanced care coordination and quality monitoring, the final rule's provisions will enable the earlier identification of serious medical conditions and the effective management of individuals with special health care needs. States will be able to highlight quality of care, which will result in decreased costs for health plans and States. All of these requirements will work together to improve patient outcomes and possibly reduce health complications and costly procedures.

These new rules appropriately balance the necessary protections for all beneficiaries enrolled in MMC and state flexibility to manage their programs. They create a framework for States to design managed care programs that will permit innovation and support program growth. This final rule is written to recognize the responsibilities of States and the need to employ different approaches to achieving the same goal of strong, viable Medicaid managed care programs that deliver high quality health care within State marketplaces and health care delivery systems.

D. Conclusion

This BBA managed care final rule will affect States, MCOs, PIHPs, PAHPs, PCCMs, providers, and beneficiaries and us in different ways. The initial investments that are needed by State agencies and MCOs, PIHPs, PAHPs, and PCCMs will result in improved and more consistent standards for the delivery of health care to Medicaid beneficiaries. Greater consumer safeguards will result from new quality improvement and protection provisions, which meet or exceed those in other public or private health care plans. In addition, this rule provides a degree of flexibility in how these new requirements are met, so that necessary changes can be phased in by states and health plans in ways that work best in a particular state's Medicaid program. Further, the new rules on payments under risk contracts remove the limitation on payment rates at historical fee-for-service costs, giving states some added flexibility in establishing payment systems that maintain or expand their current managed care programs, thus enhancing choice for Medicaid consumers and their ability to find a medical home. Consequently, long term savings will be derived from more consistent standards across States, MCOs, PIHPs, PAHPs, and PCCMs and increased opportunities for provider and beneficiary involvement in improved access, outcomes, and satisfaction.

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

E. Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any 1 year by State, local, and tribal governments, in the aggregate, or by the private sector, of $110 million or more (adjusted annually for inflation). We have determined that this final rule does not impose any mandates on State, local, or tribal governments, or the private sector that will result in an annual expenditure of $110 million or more.

F. Federalism

Under Executive Order 13132, we are required to adhere to certain criteria regarding Federalism in developing regulations. We have determined that this final rule would not significantly affect States rights, roles, and responsibilities. This regulation supersedes existing State laws regulating managed care, unless State laws are more restrictive.

The BBA requires States that contract with organizations under section 1903(m) of the Act to have certain beneficiary protections in place when mandating managed care enrollment. This rule implements those BBA provisions in accordance with the Administrative Procedure Act. This rule also eliminates certain requirements viewed by States as impediments to the growth of managed care programs, such as disenrollment without cause at any time and the inability to require enrollment in managed care without a waiver. We also apply many of these requirements to prepaid health plans that provide for inpatient hospital and institutional services. We believe this is consistent with the intent of the Congress in enacting the quality and beneficiary protection provisions of the BBA. We worked with States in developing this final regulation. In 1997–1998, when we were developing the original proposed rule, published in September 1998, we consulted with State Medicaid agency representatives in order to understand the potential impacts of the provisions of the regulations then being considered. In November 1997 we met with the Executive Board of the National Association of State Medicaid Directors (NASMD) and discussed the process for providing initial guidance to States about the Medicaid provisions of the BBA. We provided this guidance in a series of over 50 letters to State Medicaid Directors. Much of the policy included in this final regulation relating to the State plan option provision was included in these letters. In May 1998, we briefed the Executive Committee of NASMD on the general content of the proposed regulation. More specific State input was obtained through discussions throughout the spring of 1998 with the Medicaid Technical Advisory Groups (TAGs) on Managed Care and Quality. These groups are comprised of Medicaid agency staff with notable expertise in the subject area and our regional office staff and are staffed by the American Public Human Services Association. The Managed Care TAG devoted much of its agenda for several monthly meetings to BBA issues. The Quality TAG participated in two conference calls exclusively devoted to discussion of BBA quality issues. Through these contacts, we explored with State agencies their preferences regarding policy issues and the feasibility and practicality of implementing policy under consideration. We also invited public comments as part of the rulemaking process and received comments from over 380 individuals and organizations. Most of the commenters had substantial comments that addressed many provisions of the regulation.

Following publication of the final rule with comment on January 19, 2001, the new Administration delayed the effective date of the January 2001 rule three times to provide it an opportunity to conduct its own review of the regulation. During this additional review period, we heard from key stakeholders in the Medicaid managed care program, including States, provider organizations, and advocates for beneficiaries. Some of these parties expressed serious concerns about the regulation. After further consideration of the regulations and the issues raised,

in August 2001 we published an interim final rule with comment period to further delay the effective date of the January 2001 final rule with comment. Immediately following the further delay, on August 20, 2001 we published a new Medicaid managed care proposed rule to implement the Medicaid managed care provisions of the BBA and to give consideration to all the concerns that were communicated to us.

We received comments from over 300 parties (States, managed care organizations, providers, provider organizations and advocates for beneficiaries) on the August 2001 proposed rule. Many of the recommendations made by commenters have been incorporated into this final rule. For recommendations not accepted, a response has been included in this preamble. Moreover, we discussed technical issues with State experts through the TAGS to make certain that the final rule could be practically applied.

List of Subjects

42 CFR Part 400

Grant programs-health, Health facilities, Health maintenance organizations (HMO), Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 430

Administrative practice and procedure, Grant programs-health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 431

Grant programs-health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 434

Grant programs-health, Health maintenance organizations (HMO), Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 435

Aid to Families with Dependent Children, Grant programs-health, Medicaid, Reporting and recordkeeping requirements, Supplemental Security Income (SSI), Wages.

42 CFR Part 438

Grant programs-health, Managed care entities, Medicaid, Quality assurance, Reporting and recordkeeping requirements.

42 CFR Part 440

Grant programs-health, Medicaid.

For the reasons set forth in the preamble, 42 CFR chapter IV is amended as set forth below:

PART 400—INTRODUCTION; DEFINITIONS

1. The authority citation for part 400 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. In § 400.203, the following definitions for ''PCCM'' and ''PCP'' are added, in alphabetical order, and the definition of ''provider'' is revised to read as follows:

§ 400.203 Definitions specific to Medicaid.

* * * * *

PCCM stands for primary care case manager.

PCP stands for primary care physician.

Provider means either of the following:

(1) For the fee-for-service program, any individual or entity furnishing Medicaid services under an agreement with the Medicaid agency.

(2) For the managed care program, 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.

* * * * *

PART 430—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

1. The authority citation for part 430 continues to read as follows:

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

2. New § 430.5 is added to read as follows:

§ 430.5 Definitions.

As used in this subchapter, unless the context indicates otherwise—

Contractor means any entity that contracts with the State agency, under the State plan, in return for a payment, to process claims, to provide or pay for medical services, or to enhance the State agency's capability for effective administration of the program.

Representative has the meaning given the term by each State consistent with its laws, regulations, and policies.

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

1. The authority citation for part 431 continues to read as follows:

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

2. Section 431.51 is amended as follows:

a. In paragraph (a) introductory text, the phrase ''and 1915(a) and (b) of the Act'' is revised to read ''1915(a) and (b) and 1932(a)(3) of the Act.'' b. Paragraphs (a)(4) and (a)(5) are revised and a new paragraph (a)(6) is added, to read as set forth below.

c. In paragraph (b)(1) introductory text, ''and part 438 of this chapter'' is added immediately before the comma that follows ''this section''.

d. In paragraph (b)(2), ''an HMO'' is revised to read ''a Medicaid MCO''.

§ 431.51 Free choice of providers.

(a) * * *

(4) Section 1902(a)(23) of the Act provides that a recipient enrolled in a primary care case management system or Medicaid managed care organization (MCO) may not be denied freedom of choice of qualified providers of family planning services.

(5) Section 1902(e)(2) of the Act provides that an enrollee who, while completing a minimum enrollment period, is deemed eligible only for services furnished by or through the MCO or PCCM, may, as an exception to the deemed limitation, seek family planning services from any qualified provider.

(6) Section 1932(a) of the Act permits a State to restrict the freedom of choice required by section 1902(a)(23), under specified circumstances, for all services except family planning services.

* * * * *

3. In § 431.55, a sentence is added at the end of paragraph (c)(1)(i), to read as follows:

§ 431.55 Waiver of other Medicaid requirements.

* * * * *

(c) * * *

(1) * * *

(i) * * * The person or agency must comply with the requirements set forth in part 438 of this chapter for primary care case management contracts and systems.

* * * * *

4. Section 431.200 is revised to read as follows:

§ 431.200 Basis and scope.

This subpart—

(a) Implements section 1902(a)(3) of the Act, which requires that a State plan provide an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly;

(b) Prescribes procedures for an opportunity for a hearing if the State agency or PAHP takes action, as stated in this subpart, to suspend, terminate, or reduce services, or an MCO or PIHP

takes action under subpart F of part 438 of this chapter; and

(c) Implements sections 1919(f)(3) and 1919(e)(7)(F) of the Act by providing an appeals process for any person who—

(1) Is subject to a proposed transfer or discharge from a nursing facility; or

(2) Is adversely affected by the pre-admission screening or the annual resident review that are required by section 1919(e)(7) of the Act.

5. In § 431.201, the following definition is added in alphabetical order:

§ 431.201 Definitions.

* * * * *

Service authorization request means a managed care enrollee's request for the provision of a service.

6. In § 431.220, the introductory text of paragraph (a) is revised, the semicolons after paragraphs (a)(1), (a)(2), and (a)(3) and the ''and'' at the end of paragraph (a)(3) are removed and periods are added in their place, and new paragraphs (a)(5) and (a)(6) are added, to read as follows:

§ 431.220 When a hearing is required.

(a) The State agency must grant an opportunity for a hearing to the following:

* * *

(5) Any MCO or PIHP enrollee who is entitled to a hearing under subpart F of part 438 of this chapter.

(6) Any PAHP enrollee who has an action as stated in this subpart.

* * * * *

7. In § 431.244, paragraph (f) is revised to read as follows:

§ 431.244 Hearing decisions.

* * * * *

(f) The agency must take final administrative action as follows:

(1) Ordinarily, within 90 days from the earlier of the following:

(i) The date the enrollee filed an MCO or PIHP appeal, not including the number of days the enrollee took to subsequently file for a State fair hearing; or

(ii) If permitted by the State, the date the enrollee filed for direct access to a State fair hearing.

(2) As expeditiously as the enrollee's health condition requires, but no later than 3 working days after the agency receives, from the MCO or PIHP, the case file and information for any appeal of a denial of a service that, as indicated by the MCO or PIHP—

(i) Meets the criteria for expedited resolution as set forth in § 438.410(a) of this chapter, but was not resolved within the timeframe for expedited resolution; or

(ii) Was resolved within the timeframe for expedited resolution, but reached a decision wholly or partially adverse to the enrollee.

(3) If the State agency permits direct access to a State fair hearing, as expeditiously as the enrollee's health condition requires, but no later than 3 working days after the agency receives, directly from an MCO or PIHP enrollee, a fair hearing request on a decision to deny a service that it determines meets the criteria for expedited resolution, as set forth in § 438.410(a) of this chapter.

* * * * *

PART 434—CONTRACTS

1. The authority citation for part 434 continues to read as follows:

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

2. In § 434.1, paragraph (a) is revised to read as follows:

§ 434.1 Basis and scope.

(a) *Statutory basis.* This part is based on section 1902(a)(4) of the Act, which requires that the State plan provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.

* * * * *

§ 434.2 [Amended]

3. In § 434.2, the definitions of ''capitation fee'', ''clinical laboratory'', ''contractor'', ''enrolled recipient'', ''Federally qualified HMO'', ''health insuring organization'', ''Health maintenance organization (HMO)'', ''nonrisk'', ''Prepaid health plan (PHP) ''provisional status HMO'', and ''risk or underwriting risk'' are removed.

§ 434.6 [Amended]

4. In paragraph (a)(1), the term ''appendix G'' is removed.

§§ 434.20 through 434.38 (Subpart C) [Removed]

5. Subpart C, consisting of §§ 434.20 through 434.38, is removed and reserved.

§§ 434.42 through 434.44 [Removed]

6. In subpart D, §§ 434.42 and 434.44 are removed.

§§ 434.50 through 434.67 (Subpart E) [Removed]

7. Subpart E, consisting of §§ 434.50 through 434.67, is removed and reserved.

8. Section 434.70 is revised to read as follows:

§ 434.70 Conditions for Federal financial participation (FFP).

(a) *Basic requirements.* FFP is available only for periods during which the contract—

(1) Meets the requirements of this part;

(2) Meets the applicable requirements of 45 CFR part 74; and

(3) Is in effect.

(b) *Basis for withholding.* CMS may withhold FFP for any period during which the State fails to meet the State plan requirements of this part.

§§ 434.71 through 434.75 and 434.80 [Removed]

9. Sections 434.71 through 434.75, and 434.80 are removed.

PART 435—ELIGIBILITY IN THE STATES, THE DISTRICT OF COLUMBIA, THE NORTHERN MARIANA ISLANDS, AND AMERICAN SAMOA

1. The authority citation for part 435 continues to read as follows:

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

§ 435.212 [Amended]

2. Amend § 435.212 as follows:

a. Throughout the section, ''HMO'', wherever it appears, is revised to read ''MCO''.

b. The section heading and the introductory text is revised to read as follows:

§ 435.212 Individuals who would be ineligible if they were not enrolled in an MCO or PCCM.

The State agency may provide that a recipient who is enrolled in an MCO or PCCM and who becomes ineligible for Medicaid is considered to continue to be eligible—

* * * * *

3. Section 435.326 is revised to read as follows:

§ 435.326 Individuals who would be ineligible if they were not enrolled in an MCO or PCCM.

If the agency provides Medicaid to the categorically needy under § 435.212, it may provide it under the same rules to medically needy recipients who are enrolled in MCOs or PCCMs.

§ 435.1002 [Amended]

4. In §§ 435.1002, in paragraph (a), ''§§ 435.1007 and 435.1008'' is revised to read ''§§ 435.1007, 435.1008, and 438.814 of this chapter''.

5. A new part 438 is added to chapter IV to read as follows:

PART 438—MANAGED CARE

Subpart A—General Provisions

Subpart B—State Responsibilities

Subpart C—Enrollee Rights and Protections

Subpart D—Quality Assessment and Performance Improvement

Access Standards

Structure and Operation Standards

Measurement and Improvement Standards

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

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

Subpart A—General Provisions

§ 438.1 Basis and scope.

(a) *Statutory basis.* This part is based on sections 1902(a)(4), 1903(m), 1905(t), and 1932 of the Act.

(1) Section 1902(a)(4) requires that States provide for methods of administration that the Secretary finds necessary for proper and efficient operation of the State plan. The application of the requirements of this part to PIHPs and PAHPs that do not meet the statutory definition of an MCO or a PCCM is under the authority in section 1902(a)(4).

(2) Section 1903(m) contains requirements that apply to comprehensive risk contracts.

(3) Section 1903(m)(2)(H) provides that an enrollee who loses Medicaid eligibility for not more than 2 months may be enrolled in the succeeding month in the same MCO or PCCM if that MCO or PCCM still has a contract with the State.

(4) Section 1905(t) contains requirements that apply to PCCMs.

(5) Section 1932—

(i) Provides that, with specified exceptions, a State may require Medicaid recipients to enroll in MCOs or PCCMs;

(ii) Establishes the rules that MCOs, PCCMs, the State, and the contracts between the State and those entities must meet, including compliance with requirements in sections 1903(m) and 1905(t) of the Act that are implemented in this part;

(iii) Establishes protections for enrollees of MCOs and PCCMs;

(iv) Requires States to develop a quality assessment and performance improvement strategy;

(v) Specifies certain prohibitions aimed at the prevention of fraud and abuse;

(vi) Provides that a State may not enter into contracts with MCOs unless it has established intermediate sanctions that it may impose on an MCO that fails to comply with specified requirements; and

(vii) Makes other minor changes in the Medicaid program.

(b) *Scope.* This part sets forth requirements, prohibitions, and procedures for the provision of Medicaid services through MCOs, PIHPs, PAHPs, and PCCMs. Requirements vary depending on the type of entity and on the authority under which the State contracts with the entity. Provisions that apply only when the contract is under a mandatory managed care program authorized by section 1932(a)(1)(A) of the Act are identified as such.

§ 438.2 Definitions.

As used in this part—

Capitation payment means a payment the State agency makes periodically to a contractor on behalf of each recipient enrolled under a contract for the provision of medical services under the State plan. The State agency makes the payment regardless of whether the particular recipient receives services during the period covered by the payment.

Comprehensive risk contract means a risk contract that covers comprehensive services, that is, 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.

(9) Home health services.

Federally qualified HMO means an HMO that CMS has determined is a qualified HMO under section 1310(d) of the PHS Act.

Health care professional means a physician or any of the following: a podiatrist, optometrist, chiropractor, psychologist, dentist, physician assistant, physical or occupational therapist, therapist assistant, speech-language pathologist, audiologist, registered or practical nurse (including nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, and certified nurse midwife), licensed certified social worker, registered respiratory therapist, and certified respiratory therapy technician.

Health insuring organization (*HIO*) means a county operated entity, that in exchange for capitation payments, covers services for recipients—

(1) Through payments to, or arrangements with, providers;

(2) Under a comprehensive risk contract with the State; and

(3) Meets the following criteria—

(i) First became operational prior to January 1, 1986; or

(ii) Is described in section 9517(e)(3) of the Omnibus Budget Reconciliation Act of 1985 (as amended by section 4734 of the Omnibus Budget Reconciliation Act of 1990).

Managed care organization (*MCO*) means an entity that has, or is seeking to qualify for, a comprehensive risk contract under this part, and that is—

(1) A Federally qualified HMO that meets the advance directives requirements of subpart I of part 489 of this chapter; or

(2) Any public or private entity that meets the advance directives requirements and is determined to also meet the following conditions:

(i) Makes the services it provides to its Medicaid enrollees as accessible (in terms of timeliness, amount, duration, and scope) as those services are to other Medicaid recipients within the area served by the entity.

(ii) Meets the solvency standards of § 438.116.

Nonrisk contract means a contract under which the contractor—

(1) Is not at financial risk for changes in utilization or for costs incurred under the contract that do not exceed the upper payment limits specified in § 447.362 of this chapter; and

(2) May be reimbursed by the State at the end of the contract period on the basis of the incurred costs, subject to the specified limits.

Prepaid ambulatory health plan (PAHP) means an entity that—

(1) Provides medical services to enrollees under contract with the State agency, and on the basis of prepaid capitation payments, or other payment arrangements that do not use State plan payment rates;

(2) Does not provide or arrange for, and is not otherwise responsible for the provision of any inpatient hospital or institutional services for its enrollees; and

(3) Does not have a comprehensive risk contract.

Prepaid inpatient health plan (PIHP) means an entity that—

(1) Provides medical services to enrollees under contract with the State agency, and on the basis of prepaid capitation payments, or other payment arrangements that do not use State plan payment rates;

(2) Provides, arranges for, or otherwise has responsibility for the provision of any inpatient hospital or institutional services for its enrollees; and

(3) Does not have a comprehensive risk contract.

Primary care means all health care services and laboratory services customarily furnished by or through a general practitioner, family physician, internal medicine physician, obstetrician/gynecologist, or pediatrician, to the extent the furnishing of those services is legally authorized in the State in which the practitioner furnishes them.

Primary care case management means a system under which a PCCM contracts with the State to furnish case management services (which include the location, coordination and monitoring of primary health care services) to Medicaid recipients.

Primary care case manager (PCCM) means a physician, a physician group practice, an entity that employs or arranges with physicians to furnish primary care case management services or, at State option, any of the following:

(1) A physician assistant.

(2) A nurse practitioner.

(3) A certified nurse-midwife.

Risk contract means a contract under which the contractor—

(1) Assumes risk for the cost of the services covered under the contract; and

(2) Incurs loss if the cost of furnishing the services exceeds the payments under the contract.

§ 438.6 Contract requirements.

(a) *Regional office review.* The CMS Regional Office must review and approve all MCO, PIHP, and PAHP contracts, including those risk and nonrisk contracts that, on the basis of their value, are not subject to the prior approval requirement in § 438.806.

(b) *Entities eligible for comprehensive risk contracts.* A State agency may enter into a comprehensive risk contract only with the following:

(1) An MCO.

(2) The entities identified in section 1903(m)(2)(B)(i), (ii), and (iii) of the Act.

(3) Community, Migrant, and Appalachian Health Centers identified in section 1903(m)(2)(G) of the Act. Unless they qualify for a total exemption under section 1903(m)(2)(B) of the Act, these entities are subject to the regulations governing MCOs under this part.

(4) An HIO that arranges for services and became operational before January 1986.

(5) An HIO described in section 9517(c)(3) of the Omnibus Budget Reconciliation Act of 1985 (as added by section 4734(2) of the Omnibus Budget Reconciliation Act of 1990).

(c) *Payments under risk contracts.*

(1) *Terminology.* As used in this paragraph, the following terms have the indicated meanings:

(i) *Actuarially sound capitation rates* means capitation rates that—

(A) Have been developed in accordance with generally accepted actuarial principles and practices;

(B) Are appropriate for the populations to be covered, and the services to be furnished under the contract; and

(C) Have been certified, as meeting the requirements of this paragraph (c), by actuaries who meet the qualification standards established by the American Academy of Actuaries and follow the practice standards established by the Actuarial Standards Board.

(ii) *Adjustments to smooth data* means adjustments made, by cost-neutral methods, across rate cells, to compensate for distortions in costs, utilization, or the number of eligibles.

(iii) *Cost neutral* means that the mechanism used to smooth data, share risk, or adjust for risk will recognize

both higher and lower expected costs and is not intended to create a net aggregate gain or loss across all payments.

(iv) *Incentive arrangement* 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.

(v) *Risk corridor* means a risk sharing mechanism in which States and contractors share in both profits and losses under the contract outside of predetermined threshold amount, so that after an initial corridor in which the contractor 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.

(2) *Basic requirements.* (i) All payments under risk contracts and all risk-sharing mechanisms in contracts must be actuarially sound.

(ii) The contract must specify the payment rates and any risk-sharing mechanisms, and the actuarial basis for computation of those rates and mechanisms.

(3) *Requirements for actuarially sound rates.* In setting actuarially sound capitation rates, the State must apply the following elements, or explain why they are not applicable:

(i) Base utilization and cost data that are derived from the Medicaid population, or if not, are adjusted to make them comparable to the Medicaid population.

(ii) Adjustments made to smooth data and adjustments to account for factors such as medical trend inflation, incomplete data, MCO, PIHP, or PAHP administration (subject to the limits in paragraph (c)(4)(ii) of this section), and utilization;

(iii) Rate cells specific to the enrolled population, by—

(A) Eligibility category;

(B) Age;

(C) Gender;

(D) Locality/region; and

(E) Risk adjustments based on diagnosis or health status (if used).

(iv) Other payment mechanisms and utilization and cost assumptions that are appropriate for individuals with chronic illness, disability, ongoing health care needs, or catastrophic claims, using risk adjustment, risk sharing, or other appropriate cost-neutral methods.

(4) *Documentation.* The State must provide the following documentation:

(i) The actuarial certification of the capitation rates.

(ii) An assurance (in accordance with paragraph (c)(3) of this section) that all payment rates are—

(A) Based only upon services covered under the State plan (or costs directly related to providing these services, for example, MCO, PIHP, or PAHP administration).

(B) Provided under the contract to Medicaid-eligible individuals.

(iii) The State's projection of expenditures under its previous year's contract (or under its FFS program if it did not have a contract in the previous year) compared to those projected under the proposed contract.

(iv) An explanation of any incentive arrangements, or stop-loss, reinsurance, or any other risk-sharing methodologies under the contract.

(5) *Special contract provisions.*

(i) Contract provisions for reinsurance, stop-loss limits or other risk-sharing methodologies must be computed on an actuarially sound basis.

(ii) If risk corridor arrangements result in payments that exceed the approved capitation rates, these excess payments will not be considered actuarially sound to the extent that they result in total payments that exceed the amount Medicaid would have paid, on a fee-for-service basis, for the State plan services actually furnished to enrolled individuals, plus an amount for MCO, PIHP, or PAHP administrative costs directly related to the provision of these services.

(iii) Contracts with incentive arrangements may not provide for payment in excess of 105 percent of the approved capitation payments attributable to the enrollees or services covered by the incentive arrangement, since such total payments will not be considered to be actuarially sound.

(iv) For all incentive arrangements, the contract must provide that the arrangement is—

(A) For a fixed period of time;

(B) Not to be renewed automatically;

(C) Made available to both public and private contractors;

(D) Not conditioned on intergovernmental transfer agreements; and

(E) Necessary for the specified activities and targets.

(v) If a State makes payments to providers for graduate medical education (GME) costs under an approved State plan, the State must adjust the actuarially sound capitation rates to account for the GME payments to be made on behalf of enrollees covered under the contract, not to exceed the aggregate amount that would have been paid under the approved State plan for FFS. States must first establish actuarially sound capitation rates prior to making adjustments for GME.

(d) *Enrollment discrimination prohibited.* Contracts with MCOs, PIHPs, PAHPs, and PCCMs must provide as follows:

(1) The MCO, PIHP, PAHP, or PCCM accepts individuals eligible for enrollment in the order in which they apply without restriction (unless authorized by the Regional Administrator), up to the limits set under the contract.

(2) Enrollment is voluntary, except in the case of mandatory enrollment programs that meet the conditions set forth in § 438.50(a).

(3) The MCO, PIHP, PAHP, or PCCM will not, on the basis of health status or need for health care services, discriminate against individuals eligible to enroll.

(4) The MCO, PIHP, PAHP, or PCCM will not discriminate against individuals eligible to enroll on the basis of race, color, or national origin, and will not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin.

(e) *Services that may be covered.* An MCO, PIHP, or PAHP contract may cover, for enrollees, services that are in addition to those covered under the State plan, although the cost of these services cannot be included when determining the payment rates under § 438.6(c).

(f) *Compliance with contracting rules.* All contracts under this subpart must:

(1) Comply with all applicable Federal and State laws and regulations including title VI of the Civil Rights Act of 1964; title IX of the Education Amendments of 1972 (regarding education programs and activities); the Age Discrimination Act of 1975; the Rehabilitation Act of 1973; and the Americans with Disabilities Act; and

(2) Meet all the requirements of this section.

(g) *Inspection and audit of financial records.* Risk contracts must provide that the State agency and the Department may inspect and audit any financial records of the entity or its subcontractors.

(h) *Physician incentive plans.* (1) MCO, PIHP, and PAHP contracts must provide for compliance with the requirements set forth in §§ 422.208 and 422.210 of this chapter.

(2) In applying the provisions of §§ 422.208 and 422.210 of this chapter, references to ''M+C organization'', ''CMS'', and ''Medicare beneficiaries'' must be read as references to ''MCO, PIHP, or PAHP'', ''State agency'' and ''Medicaid recipients'', respectively.

(i) *Advance directives.* (1) All MCO and PIHP contracts must provide for

compliance with the requirements of § 422.128 of this chapter for maintaining written policies and procedures for advance directives.

(2) All PAHP contracts must provide for compliance with the requirements of § 422.128 of this chapter for maintaining written policies and procedures for advance directives if the PAHP includes, in its network, any of those providers listed in § 489.102(a) of this chapter.

(3) The MCO, PIHP, or PAHP subject to this requirement must provide adult enrollees with written information on advance directives policies, and include a description of applicable State law.

(4) The information must reflect changes in State law as soon as possible, but no later than 90 days after the effective date of the change.

(j) *Special rules for certain HIOs.* Contracts with HIOs that began operating on or after January 1, 1986, and that the statute does not explicitly exempt from requirements in section 1903(m) of the Act, are subject to all the requirements of this part that apply to MCOs and contracts with MCOs. These HIOs may enter into comprehensive risk contracts only if they meet the criteria of paragraph (a) of this section.

(k) *Additional rules for contracts with PCCMs.* A PCCM contract must meet the following requirements:

(1) Provide for reasonable and adequate hours of operation, including 24-hour availability of information, referral, and treatment for emergency medical conditions.

(2) Restrict 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.

(3) Provide for arrangements with, or referrals to, sufficient numbers of physicians and other practitioners to ensure that services under the contract can be furnished to enrollees promptly and without compromise to quality of care.

(4) Prohibit discrimination in enrollment, disenrollment, and re-enrollment, based on the recipient's health status or need for health care services.

(5) Provide that enrollees have the right to disenroll from their PCCM in accordance with § 438.56(c).

(l) *Subcontracts.* All subcontracts must fulfill the requirements of this part that are appropriate to the service or activity delegated under the subcontract.

(m) *Choice of health professional.* The contract must allow each enrollee to choose his or her health professional to the extent possible and appropriate.

§ 438.8 Provisions that apply to PIHPs and PAHPs.

(a) The following requirements and options apply to PIHPs, PIHP contracts, and States with respect to PIHPs, to the same extent that they apply to MCOs, MCO contracts, and States for MCOs.

(1) The contract requirements of § 438.6, except for requirements that pertain to HIOs.

(2) The information requirements in § 438.10.

(3) The provision against provider discrimination in § 438.12.

(4) The State responsibility provisions of subpart B of this part except § 438.50.

(5) The enrollee rights and protection provisions in subpart C of this part.

(6) The quality assessment and performance improvement provisions in subpart D of this part to the extent that they are applicable to services furnished by the PIHP.

(7) The grievance system provisions in subpart F of this part.

(8) The certification and program integrity protection provisions set forth in subpart H of this part.

(b) The following requirements and options for PAHPs apply to PAHPs, PAHP contracts, and States.

(1) The contract requirements of § 438.6, except requirements for—

(i) HIOs.

(ii) Advance directives (unless the PAHP includes any of the providers listed in § 489.102) of this chapter.

(2) All applicable portions of the information requirements in § 438.10.

(3) The provision against provider discrimination in § 438.12.

(4) The State responsibility provisions of subpart B of this part except § 438.50.

(5) The provisions on enrollee rights and protections in subpart C of this part.

(6) Designated portions of subpart D of this part.

(7) An enrollee's right to a State fair hearing under subpart E of part 431 of this chapter.

§ 438.10 Information requirements.

(a) *Terminology.* As used in this section, the following terms have the indicated meanings:

Enrollee means a Medicaid recipient who is currently enrolled in an MCO, PIHP, PAHP, or PCCM in a given managed care program.

Potential enrollee means a Medicaid recipient who is subject to mandatory enrollment or may voluntarily elect to enroll in a given managed care program, but is not yet an enrollee of a specific MCO, PIHP, PAHP, or PCCM.

(b) *Basic rules.* (1) Each State, enrollment broker, MCO, PIHP, PAHP, and PCCM must provide all enrollment notices, informational materials, and instructional materials relating to enrollees and potential enrollees in a manner and format that may be easily understood.

(2) The State must have in place a mechanism to help enrollees and potential enrollees understand the State's managed care program.

(3) Each MCO and PIHP must have in place a mechanism to help enrollees and potential enrollees understand the requirements and benefits of the plan.

(c) *Language.* The State must do the following:

(1) Establish a methodology for identifying the prevalent non-English languages spoken by enrollees and potential enrollees throughout the State. ''Prevalent'' means a non-English language spoken by a significant number or percentage of potential enrollees and enrollees in the State.

(2) Make available written information in each prevalent non-English language.

(3) Require each MCO, PIHP, PAHP, and PCCM to make its written information available in the prevalent non-English languages in its particular service area.

(4) Make oral interpretation services available and require each MCO, PIHP, PAHP, and PCCM to make those services available free of charge to each potential enrollee and enrollee. This applies to all non-English languages, not just those that the State identifies as prevalent.

(5) Notify enrollees and potential enrollees, and require each MCO, PIHP, PAHP, and PCCM to notify its enrollees—

(i) That oral interpretation is available for any language and written information is available in prevalent languages; and

(ii) How to access those services.

(d) *Format.* (1) Written material must—

(i) Use easily understood language and format; and

(ii) Be available in alternative formats and in an appropriate manner that takes into consideration the special needs of those who, for example, are visually limited or have limited reading proficiency.

(2) All enrollees and potential enrollees must be informed that information is available in alternative formats and how to access those formats.

(e) *Information for potential enrollees.*

(1) The State or its contracted representative must provide the information specified in paragraph (e)(2) of this section to each potential enrollee as follows:

(i) At the time the potential enrollee first becomes eligible to enroll in a voluntary program, or is first required to enroll in a mandatory enrollment program.

(ii) Within a timeframe that enables the potential enrollee to use the information in choosing among available MCOs, PIHP, PAHPs, or PCCMs.

(2) The information for potential enrollees must include the following:

(i) General information about—

(A) The basic features of managed care;

(B) Which populations are excluded from enrollment, subject to mandatory enrollment, or free to enroll voluntarily in the program; and

(C) MCO, PIHP, PAHP, and PCCM responsibilities for coordination of enrollee care;

(ii) Information specific to each MCO, PIHP, PAHP, or PCCM program operating in potential enrollee's service area. A summary of the following information is sufficient, but the State must provide more detailed information upon request:

(A) Benefits covered.

(B) Cost sharing, if any.

(C) Service area.

(D) Names, locations, telephone numbers of, and non-English language spoken by current contracted providers, and including identification of providers that are not accepting new patients. For MCOs, PIHPs, and PAHPs, this includes at a minimum information on primary care physicians, specialists, and hospitals.

(E) Benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided. For a counseling or referral service that the MCO, PIHP, PAHP, or PCCM does not cover because of moral or religious objections, the State must provide information about where and how to obtain the service.

(f) *General information for all enrollees of MCOs, PIHPs, PAHPs, and PCCMs.* Information must be furnished to MCO, PIHP, PAHP, and PCCM enrollees as follows:

(1) The State must notify all enrollees of their disenrollment rights, at a minimum, annually. For States that choose to restrict disenrollment for periods of 90 days or more, States must send the notice no less than 60 days before the start of each enrollment period.

(2) The State, its contracted representative, or the MCO, PIHP, PAHP, or PCCM must notify all enrollees of their right to request and obtain the information listed in paragraph (f)(6) of this section and, if applicable, paragraphs (g) and (h) of this section, at least once a year.

(3) The State, its contracted representative, or the MCO, PIHP, PAHP, or PCCM must furnish to each of its enrollees the information specified in paragraph (f)(6) of this section and, if applicable, paragraphs (g) and (h) of this section, within a reasonable time after the MCO, PIHP, PAHP, or PCCM receives, from the State or its contracted representative, notice of the recipient's enrollment.

(4) The State, its contracted representative, or the MCO, PIHP, PAHP, or PCCM must give each enrollee written notice of any change (that the State defines as ''significant'') in the information specified in paragraphs (f)(6) of this section and, if applicable, paragraphs (g) and (h) of this section, at least 30 days before the intended effective date of the change.

(5) The MCO, PIHP, and, when appropriate, the PAHP or PCCM, must make a good faith effort to give written notice of termination of a contracted provider, within 15 days after receipt or issuance of the termination notice, to each enrollee who received his or her primary care from, or was seen on a regular basis by, the terminated provider.

(6) The State, its contracted representative, or the MCO, PIHP, PAHP, or PCCM must provide the following information to all enrollees:

(i) Names, locations, telephone numbers of, and non-English languages spoken by current contracted providers in the enrollee's service area, including identification of providers that are not accepting new patients. For MCOs, PIHPs, and PAHPs this includes, at a minimum, information on primary care physicians, specialists, and hospitals.

(ii) Any restrictions on the enrollee's freedom of choice among network providers.

(iii) Enrollee rights and protections, as specified in § 438.100.

(iv) Information on grievance and fair hearing procedures, and for MCO and PIHP enrollees, the information specified in § 438.10(g)(1), and for PAHP enrollees, the information specified in § 438.10(h).

(v) 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.

(vi) Procedures for obtaining benefits, including authorization requirements.

(vii) The extent to which, and how, enrollees may obtain benefits, including family planning services, from out-of-network providers.

(viii) The extent to which, and how, after-hours and emergency coverage are provided, including:

(A) What constitutes emergency medical condition, emergency services, and poststabilization services, with reference to the definitions in § 438.114(a).

(B) The fact that prior authorization is not required for emergency services.

(C) The process and procedures for obtaining emergency services, including use of the 911-telephone system or its local equivalent.

(D) The locations of any emergency settings and other locations at which providers and hospitals furnish emergency services and poststabilization services covered under the contract.

(E) The fact that, subject to the provisions of this section, the enrollee has a right to use any hospital or other setting for emergency care.

(ix) The poststabilization care services rules set forth at § 422.113(c) of this chapter.

(x) Policy on referrals for specialty care and for other benefits not furnished by the enrollee's primary care provider.

(xi) Cost sharing, if any.

(xii) How and where to access any benefits that are available under the State plan but are not covered under the contract, including any cost sharing, and how transportation is provided. For a counseling or referral service that the MCO, PIHP, PAHP, or PCCM does not cover because of moral or religious objections, the MCO, PIHP, PAHP, or PCCM need not furnish information on how and where to obtain the service. The State must provide information on how and where to obtain the service.

(g) *Specific information requirements for enrollees of MCOs and PIHPs.* In addition to the requirements in § 438.10(f), the State, its contracted representative, or the MCO and PIHP must provide the following information to their enrollees:

(1) Grievance, appeal, and fair hearing procedures and timeframes, as provided in §§ 438.400 through 438.424, in a State-developed or State-approved description, that must include the following:

(i) For State fair hearing—

(A) The right to hearing;

(B) The method for obtaining a hearing; and

(C) The rules that govern representation at the hearing.

(ii) The right to file grievances and appeals.

(iii) The requirements and timeframes for filing a grievance or appeal.

(iv) The availability of assistance in the filing process.

(v) The toll-free numbers that the enrollee can use to file a grievance or an appeal by phone.

(vi) The fact that, when requested by the enrollee—

(A) Benefits will continue if the enrollee files an appeal or a request for State fair hearing within the timeframes specified for filing; and

(B) The enrollee may be required to pay the cost of services furnished while the appeal is pending, if the final decision is adverse to the enrollee.

(vii) Any appeal rights that the State chooses to make available to providers to challenge the failure of the organization to cover a service.

(2) Advance directives, as set forth in § 438.6(i)(2).

(3) Additional information that is available upon request, including the following:

(i) Information on the structure and operation of the MCO or PIHP.

(ii) Physician incentive plans as set forth in § 438.6(h) of this chapter.

(h) *Specific information for PAHPs.* The State, its contracted representative, or the PAHP must provide the following information to their enrollees:

(1) The right to a State fair hearing, including the following:

(i) The right to a hearing.

(ii) The method for obtaining a hearing.

(iii) The rules that govern representation.

(2) Advance directives, as set forth in § 438.6(i)(2), to the extent that the PAHP includes any of the providers listed in § 489.102(a) of this chapter.

(3) Upon request, physician incentive plans as set forth in § 438.6(h).

(i) *Special rules: States with mandatory enrollment under State plan authority*—(1) *Basic rule.* If the State plan provides for mandatory enrollment under § 438.50, the State or its contracted representative must provide information on MCOs and PCCMs (as specified in paragraph (i)(3) of this section), either directly or through the MCO or PCCM.

(2) *When and how the information must be furnished.* The information must be furnished as follows:

(i) For potential enrollees, within the timeframe specified in § 438.10(e)(1).

(ii) For enrollees, annually and upon request.

(iii) In a comparative, chart-like format.

(3) *Required information.* Some of the information is the same as the information required for potential enrollees under paragraph (e) of this section and for enrollees under paragraph (f) of this section. However, all of the information in this paragraph is subject to the timeframe and format requirements of paragraph (i)(2) of this section, and includes the following for each contracting MCO or PCCM in the potential enrollee and enrollee's service area:

(i) The MCO's or PCCM's service area.

(ii) The benefits covered under the contract.

(iii) Any cost sharing imposed by the MCO or PCCM.

(iv) To the extent available, quality and performance indicators, including enrollee satisfaction.

§ 438.12 Provider discrimination prohibited.

(a) *General rules.* (1) An MCO, PIHP, or PAHP may not discriminate for the participation, reimbursement, or indemnification of any provider who is acting within the scope of his or her license or certification under applicable State law, solely on the basis of that license or certification. If an MCO, PIHP, or PAHP declines to include individual or groups of providers in its network, it must give the affected providers written notice of the reason for its decision.

(2) In all contracts with health care professionals, an MCO, PIHP, or PAHP must comply with the requirements specified in § 438.214.

(b) *Construction.* Paragraph (a) of this section may not be construed to—

(1) Require the MCO, PIHP, or PAHP to contract with providers beyond the number necessary to meet the needs of its enrollees;

(2) Preclude the MCO, PIHP, or PAHP from using different reimbursement amounts for different specialties or for different practitioners in the same specialty; or

(3) Preclude the MCO, PIHP, or PAHP from establishing measures that are designed to maintain quality of services and control costs and are consistent with its responsibilities to enrollees.

Subpart B—State Responsibilities

§ 438.50 State Plan requirements.

(a) *General rule.* A State plan that requires Medicaid recipients to enroll in managed care entities must comply with the provisions of this section, except when the State imposes the requirement—

(1) As part of a demonstration project under section 1115 of the Act; or

(2) Under a waiver granted under section 1915(b) of the Act.

(b) *State plan information.* The plan must specify—

(1) The types of entities with which the State contracts;

(2) The payment method it uses (for example, whether fee-for-service or capitation);

(3) Whether it contracts on a comprehensive risk basis; and

(4) The process the State uses to involve the public in both design and initial implementation of the program and the methods it uses to ensure ongoing public involvement once the State plan has been implemented.

(c) *State plan assurances.* The plan must provide assurances that the State meets applicable requirements of the following statute and regulations:

(1) Section 1903(m) of the Act, for MCOs and MCO contracts.

(2) Section 1905(t) of the Act, for PCCMs and PCCM contracts.

(3) Section 1932(a)(1)(A) of the Act, for the State's option to limit freedom of choice by requiring recipients to receive their benefits through managed care entities.

(4) This part, for MCOs and PCCMs.

(5) Part 434 of this chapter, for all contracts.

(6) Section 438.6(c), for payments under any risk contracts, and § 447.362 of this chapter for payments under any nonrisk contracts.

(d) *Limitations on enrollment.* The State must provide assurances that, in implementing the State plan managed care option, it will not require the following groups to enroll in an MCO or PCCM:

(1) Recipients who are also eligible for Medicare.

(2) Indians who are members of Federally recognized tribes, except when the MCO or PCCM is—

(i) The Indian Health Service; or

(ii) An Indian health program or Urban Indian program operated by a tribe or tribal organization under a contract, grant, cooperative agreement or compact with the Indian Health Service.

(3) Children under 19 years of age who are—

(i) Eligible for SSI under title XVI;

(ii) Eligible under section 1902(e)(3) of the Act;

(iii) In foster care or other out-of-home placement;

(iv) Receiving foster care or adoption assistance; or

(v) Receiving services through a family-centered, community-based, coordinated care system that receives grant funds under section 501(a)(1)(D) of title V, and is defined by the State in terms of either program participation or special health care needs.

(e) *Priority for enrollment.* The State must have an enrollment system under which recipients already enrolled in an MCO or PCCM are given priority to

continue that enrollment if the MCO or PCCM does not have the capacity to accept all those seeking enrollment under the program.

(f) *Enrollment by default.* (1) For recipients who do not choose an MCO or PCCM during their enrollment period, the State must have a default enrollment process for assigning those recipients to contracting MCOs and PCCMs.

(2) The process must seek to preserve existing provider-recipient relationships and relationships with providers that have traditionally served Medicaid recipients. If that is not possible, the State must distribute the recipients equitably among qualified MCOs and PCCMs available to enroll them, excluding those that are subject to the intermediate sanction described in § 438.702(a)(4).

(3) An ''existing provider-recipient relationship'' is one in which the provider was the main source of Medicaid services for the recipient during the previous year. This may be established through State records of previous managed care enrollment or fee-for-service experience, or through contact with the recipient.

(4) A provider is considered to have ''traditionally served'' Medicaid recipients if it has experience in serving the Medicaid population.

§ 438.52 Choice of MCOs, PIHPs, PAHPs, and PCCMs.

(a) *General rule.* Except as specified in paragraphs (b) and (c) of this section, a State that requires Medicaid recipients to enroll in an MCO, PIHP, PAHP, or PCCM must give those recipients a choice of at least two entities.

(b) *Exception for rural area residents.* (1) Under any of the following programs, and subject to the requirements of paragraph (b)(2) of this section, a State may limit a rural area resident to a single MCO, PIHP, PAHP, or PCCM system:

(i) A program authorized by a plan amendment under section 1932(a) of the Act.

(ii) A waiver under section 1115 of the Act.

(iii) A waiver under section 1915(b) of the Act.

(2) A State that elects the option provided under paragraph (b)(1) of this section, must permit the recipient—

(i) To choose from at least two physicians or case managers; and

(ii) To obtain services from any other provider under any of the following circumstances:

(A) The service or type of provider (in terms of training, experience, and specialization) is not available within the MCO, PIHP, PAHP, or PCCM network.

(B) The provider is not part of the network, but is the main source of a service to the recipient, provided that—

(*1*) The provider is given the opportunity to become a participating provider under the same requirements for participation in the MCO, PIHP, PAHP, or PCCM network as other network providers of that type.

(*2*) If the provider chooses not to join the network, or does not meet the necessary qualification requirements to join, the enrollee will be transitioned to a participating provider within 60 days (after being given an opportunity to select a provider who participates).

(C) The only plan or provider available to the recipient does not, because of moral or religious objections, provide the service the enrollee seeks.

(D) The recipient's primary care provider or other provider determines that the recipient needs related services that would subject the recipient to unnecessary risk if received separately (for example, a cesarean section and a tubal ligation) and not all of the related services are available within the network.

(E) The State determines that other circumstances warrant out-of-network treatment.

(3) As used in this paragraph, ''rural area'' is any area other than an ''urban area'' as defined in § 412.62(f)(1)(ii) of this chapter.

(c) *Exception for certain health insuring organizations (HIOs).* The State may limit recipients to a single HIO if—

(1) The HIO is one of those described in section 1932(a)(3)(C) of the Act; and

(2) The recipient who enrolls in the HIO has a choice of at least two primary care providers within the entity.

(d) *Limitations on changes between primary care providers.* For an enrollee of a single MCO, PIHP, PAHP, or HIO under paragraph (b)(2) or (b)(3) of this section, any limitation the State imposes on his or her freedom to change between primary care providers may be no more restrictive than the limitations on disenrollment under § 438.56(c).

§ 438.56 Disenrollment: Requirements and limitations.

(a) *Applicability.* The provisions of this section apply to all managed care arrangements whether enrollment is mandatory or voluntary and whether the contract is with an MCO, a PIHP, a PAHP, or a PCCM.

(b) *Disenrollment requested by the MCO, PIHP, PAHP, or PCCM.* All MCO, PIHP, PAHP, and PCCM contracts must—(1) Specify the reasons for which the MCO, PIHP, PAHP, or PCCM may request disenrollment of an enrollee;

(2) Provide that the MCO, PIHP, PAHP, or PCCM may not request disenrollment because of an adverse change in the enrollee's health status, or because of the enrollee's utilization of medical services, diminished mental capacity, or uncooperative or disruptive behavior resulting from his or her special needs (except when his or her continued enrollment in the MCO, PIHP, PAHP, or PCCM seriously impairs the entity's ability to furnish services to either this particular enrollee or other enrollees); and

(3) Specify the methods by which the MCO, PIHP, PAHP, or PCCM assures the agency that it does not request disenrollment for reasons other than those permitted under the contract.

(c) *Disenrollment requested by the enrollee.* If the State chooses to limit disenrollment, its MCO, PIHP, PAHP, and PCCM contracts must provide that a recipient may request disenrollment as follows:

(1) For cause, at any time.

(2) Without cause, at the following times:

(i) During the 90 days following the date of the recipient's initial enrollment with the MCO, PIHP, PAHP, or PCCM, or the date the State sends the recipient notice of the enrollment, whichever is later.

(ii) At least once every 12 months thereafter.

(iii) Upon automatic reenrollment under paragraph (g) of this section, if the temporary loss of Medicaid eligibility has caused the recipient to miss the annual disenrollment opportunity.

(iv) When the State imposes the intermediate sanction specified in § 438.702(a)(3).

(d) *Procedures for disenrollment*— (1) *Request for disenrollment.* The recipient (or his or her representative) must submit an oral or written request—

(i) To the State agency (or its agent); or

(ii) To the MCO, PIHP, PAHP, or PCCM, if the State permits MCOs, PIHP, PAHPs, and PCCMs to process disenrollment requests.

(2) *Cause for disenrollment.* The following are cause for disenrollment:

(i) The enrollee moves out of the MCO's, PIHP's, PAHP's, or PCCM's service area.

(ii) The plan does not, because of moral or religious objections, cover the service the enrollee seeks.

(iii) The enrollee needs related services (for example a cesarean section and a tubal ligation) to be performed at the same time; not all related services are available within the network; and the enrollee's primary care provider or

another provider determines that receiving the services separately would subject the enrollee to unnecessary risk.

(iv) Other reasons, including but not limited to, poor quality of care, lack of access to services covered under the contract, or lack of access to providers experienced in dealing with the enrollee's health care needs.

(3) *MCO, PIHP, PAHP, or PCCM action on request.* (i) An MCO, PIHP, PAHP, or PCCM may either approve a request for disenrollment or refer the request to the State.

(ii) If the MCO, PIHP, PAHP, PCCM, or State agency (whichever is responsible) fails to make a disenrollment determination so that the recipient can be disenrolled within the timeframes specified in paragraph (e)(1) of this section, the disenrollment is considered approved.

(4) *State agency action on request.* For a request received directly from the recipient, or one referred by the MCO, PIHP, PAHP, or PCCM, the State agency must take action to approve or disapprove the request based on the following:

(i) Reasons cited in the request.

(ii) Information provided by the MCO, PIHP, PAHP, or PCCM at the agency's request.

(iii) Any of the reasons specified in paragraph (d)(2) of this section.

(5) *Use of the MCO, PIHP, PAHP, or PCCM grievance procedures.* (i) The State agency may require that the enrollee seek redress through the MCO, PIHP, PAHP, or PCCM's grievance system before making a determination on the enrollee's request.

(ii) The grievance process, if used, must be completed in time to permit the disenrollment (if approved) to be effective in accordance with the timeframe specified in § 438.56(e)(1).

(iii) If, as a result of the grievance process, the MCO, PIHP, PAHP, or PCCM approves the disenrollment, the State agency is not required to make a determination.

(e) *Timeframe for disenrollment determinations.* (1) Regardless of the procedures followed, the effective date of an approved disenrollment must be no later than the first day of the second month following the month in which the enrollee or the MCO, PIHP, PAHP, or PCCM files the request.

(2) If the MCO, PIHP, PAHP, or PCCM or the State agency (whichever is responsible) fails to make the determination within the timeframes specified in paragraph (e)(1) of this section, the disenrollment is considered approved.

(f) *Notice and appeals.* A State that restricts disenrollment under this section must take the following actions:

(1) Provide that enrollees and their representatives are given written notice of disenrollment rights at least 60 days before the start of each enrollment period.

(2) Ensure access to State fair hearing for any enrollee dissatisfied with a State agency determination that there is not good cause for disenrollment.

(g) *Automatic reenrollment: Contract requirement.* If the State plan so specifies, the contract must provide for automatic reenrollment of a recipient who is disenrolled solely because he or she loses Medicaid eligibility for a period of 2 months or less.

§ 438.58 Conflict of interest safeguards.

(a) As a condition for contracting with MCOs, PIHPs, or PAHPs, a State must have in effect safeguards against conflict of interest on the part of State and local officers and employees and agents of the State who have responsibilities relating to the MCO, PIHP, or PAHP contracts or the default enrollment process specified in § 438.50(f).

(b) These safeguards must be at least as effective as the safeguards specified in section 27 of the Office of Federal Procurement Policy Act (41 U.S.C. 423).

§ 438.60 Limit on payment to other providers.

The State agency must ensure that no payment is made to a provider other than the MCO, PIHP, or PAHP for services available under the contract between the State and the MCO, PIHP, or PAHP, except when these payments are provided for in title XIX of the Act, in 42 CFR, or when the State agency has adjusted the capitation rates paid under the contract, in accordance with § 438.6(c)(5)(v), to make payments for graduate medical education.

§ 438.62 Continued services to recipients.

The State agency must arrange for Medicaid services to be provided without delay to any Medicaid enrollee of an MCO, PIHP, PAHP, or PCCM whose contract is terminated and for any Medicaid enrollee who is disenrolled from an MCO, PIHP, PAHP, or PCCM for any reason other than ineligibility for Medicaid.

§ 438.66 Monitoring procedures.

The State agency must have in effect procedures for monitoring the MCO's, PIHP's, or PAHP's operations, including, at a minimum, operations related to the following:

(a) Recipient enrollment and disenrollment.

(b) Processing of grievances and appeals.

(c) Violations subject to intermediate sanctions, as set forth in subpart I of this part.

(d) Violations of the conditions for FFP, as set forth in subpart J of this part.

(e) All other provisions of the contract, as appropriate.

Subpart C—Enrollee Rights and Protections

§ 438.100 Enrollee rights.

(a) *General rule.* The State must ensure that—

(1) Each MCO and PIHP has written policies regarding the enrollee rights specified in this section; and

(2) Each MCO, PIHP, PAHP, and PCCM complies with any applicable Federal and State laws that pertain to enrollee rights, and ensures that its staff and affiliated providers take those rights into account when furnishing services to enrollees.

(b) *Specific rights*— (1) *Basic requirement.* The State must ensure that each managed care enrollee is guaranteed the rights as specified in paragraphs (b)(2) and (b)(3) of this section.

(2) An enrollee of an MCO, PIHP, PAHP, or PCCM has the following rights: The right to —

(i) Receive information in accordance with § 438.10.

(ii) Be treated with respect and with due consideration for his or her dignity and privacy.

(iii) Receive information on available treatment options and alternatives, presented in a manner appropriate to the enrollee's condition and ability to understand. (The information requirements for services that are not covered under the contract because of moral or religious objections are set forth in § 438.10(f)(6)(xiii).)

(iv) Participate in decisions regarding his or her health care, including the right to refuse treatment.

(v) Be free from any form of restraint or seclusion used as a means of coercion, discipline, convenience or retaliation, as specified in other Federal regulations on the use of restraints and seclusion.

(vi) If the privacy rule, as set forth in 45 CFR parts 160 and 164 subparts A and E, applies, request and receive a copy of his or her medical records, and request that they be amended or corrected, as specified in 45 CFR § 164.524 and 164.526.

(3) An enrollee of an MCO, PIHP, or PAHP (consistent with the scope of the PAHP's contracted services) has the right to be furnished health care services

in accordance with §§ 438.206 through 438.210.

(c) *Free exercise of rights.* The State must 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.

(d) *Compliance with other Federal and State laws.* The State must ensure that each MCO, PIHP, PAHP, and PCCM complies with any other applicable Federal and State laws (such as: title VI of the Civil Rights Act of 1964 as implemented by regulations at 45 CFR part 80; the Age Discrimination Act of 1975 as implemented by regulations at 45 CFR part 91; the Rehabilitation Act of 1973; and titles II and III of the Americans with Disabilities Act; and other laws regarding privacy and confidentiality).

§ 438.102 Provider-enrollee communications.

(a) *General rules.* (1) An MCO, PIHP, or PAHP may not prohibit, or otherwise restrict, a health care professional acting within the lawful scope of practice, from advising or advocating on behalf of an enrollee who is his or her patient, for the following:

(i) The enrollee's health status, medical care, or treatment options, including any alternative treatment that may be self-administered.

(ii) Any information the enrollee needs in order to decide among all relevant treatment options.

(iii) The risks, benefits, and consequences of treatment or nontreatment.

(iv) The enrollee's right to participate in decisions regarding his or her health care, including the right to refuse treatment, and to express preferences about future treatment decisions.

(2) Subject to the information requirements of paragraph (b) of this section, an MCO, PIHP, or PAHP that would otherwise be required to provide, reimburse for, or provide coverage of, a counseling or referral service because of the requirement in paragraph (a)(1) of this section is not required to do so if the MCO, PIHP, or PAHP objects to the service on moral or religious grounds.

(b) *Information requirements: MCO, PIHP, and PAHP responsibility.* (1) An MCO, PIHP, or PAHP that elects the option provided in paragraph (a)(2) of this section must furnish information about the services it does not cover as follows:

(i) To the State—

(A) With its application for a Medicaid contract; and

(B) Whenever it adopts the policy during the term of the contract.

(ii) Consistent with the provisions of § 438.10—

(A) To potential enrollees, before and during enrollment; and

(B) To enrollees, within 90 days after adopting the policy with respect to any particular service. (Although this timeframe would be sufficient to entitle the MCO, PIHP, or PAHP to the option provided in paragraph (a)(2) of this section, the overriding rule in § 438.10(f)(4) requires the State, its contracted representative, or MCO, PIHP, or PAHP to furnish the information at least 30 days before the effective date of the policy.)

(2) As specified in § 438.10(e) and (f), the information that MCOs, PIHPs, and PAHPs must furnish to enrollees and potential enrollees does not include how and where to obtain the service excluded under paragraph (a)(2) of this section.

(c) *Information requirements: State responsibility.* For each service excluded by an MCO, PIHP, or PAHP under paragraph (a)(2) of this section, the State must provide information on how and where to obtain the service, as specified in § 438.10(e)(2)(ii) and (f)(6)(xii).

(d) *Sanction.* An MCO that violates the prohibition of paragraph (a)(1) of this section is subject to intermediate sanctions under subpart I of this part.

§ 438.104 Marketing activities.

(a) *Terminology.* As used in this section, the following terms have the indicated meanings:

Cold-call marketing means any unsolicited personal contact by the MCO, PIHP, PAHP, or PCCM with a potential enrollee for the purpose of marketing as defined in this paragraph.

Marketing means any communication, from an MCO, PIHP, PAHP, or PCCM to a Medicaid recipient who is not enrolled in that entity, that can reasonably be interpreted as intended to influence the recipient to enroll in that particular MCO's, PIHP's, PAHP's, or PCCM's Medicaid product, or either to not enroll in, or to disenroll from, another MCO's, PIHP's, PAHP's, or PCCM's Medicaid product.

Marketing materials means materials that—

(1) Are produced in any medium, by or on behalf of an MCO, PIHP, PAHP, or PCCM; and

(2) Can reasonably be interpreted as intended to market to potential enrollees.

MCO, PIHP, PAHP, or PCCM include any of the entity's employees, affiliated providers, agents, or contractors.

(b) *Contract requirements.* Each contract with an MCO, PIHP, PAHP, or PCCM must comply with the following requirements:

(1) Provide that the entity—

(i) Does not distribute any marketing materials without first obtaining State approval;

(ii) Distributes the materials to its entire service area as indicated in the contract;

(iii) Complies with the information requirements of § 438.10 to ensure that, before enrolling, the recipient receives, from the entity or the State, the accurate oral and written information he or she needs to make an informed decision on whether to enroll;

(iv) Does not seek to influence enrollment in conjunction with the sale or offering of any private insurance; and

(v) Does not, directly or indirectly, engage in door-to-door, telephone, or other cold-call marketing activities.

(2) Specify the methods by which the entity assures the State agency that marketing, including plans and materials, is accurate and does not mislead, confuse, or defraud the recipients or the State agency. Statements that will be considered inaccurate, false, or misleading include, but are not limited to, any assertion or statement (whether written or oral) that—

(i) The recipient must enroll in the MCO, PIHP, PAHP, or PCCM in order to obtain benefits or in order to not lose benefits; or

(ii) The MCO, PIHP, PAHP, or PCCM is endorsed by CMS, the Federal or State government, or similar entity.

(c) *State agency review.* In reviewing the marketing materials submitted by the entity, the State must consult with the Medical Care Advisory Committee established under § 431.12 of this chapter or an advisory committee with similar membership.

§ 438.106 Liability for payment.

Each MCO, PIHP, and PAHP must provide that its Medicaid enrollees are not held liable for any of the following:

(a) The MCO's, PIHP's, or PAHP's debts, in the event of the entity's insolvency.

(b) Covered services provided to the enrollee, for which—

(1) The State does not pay the MCO, PIHP, or PAHP; or

(2) The State, or the MCO, PIHP, or PAHP does not pay the individual or health care provider that furnishes the services under a contractual, referral, or other arrangement.

(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 enrollee would owe if

the MCO, PIHP, or PAHP provided the services directly.

§ 438.108 Cost sharing.

The contract must provide that any cost sharing imposed on Medicaid enrollees is in accordance with §§ 447.50 through 447.60 of this chapter.

§ 438.114 Emergency and poststabilization services.

(a) *Definitions.* As used in this section—

Emergency medical condition means 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 the following:

(1) Placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy.

(2) Serious impairment to bodily functions.

(3) Serious dysfunction of any bodily organ or part.

Emergency services means covered inpatient and outpatient services that are as follows:

(1) Furnished by a provider that is qualified to furnish these services under this title.

(2) Needed to evaluate or stabilize an emergency medical condition.

Poststabilization care services means covered services, related to an emergency medical condition that are provided after an enrollee is stabilized in order to maintain the stabilized condition, or, under the circumstances described in paragraph (e) of this section, to improve or resolve the enrollee's condition.

(b) *Coverage and payment: General rule.* The following entities are responsible for coverage and payment of emergency services and poststabilization care services.

(1) The MCO, PIHP, or PAHP.

(2) The PCCM that has a risk contract that covers these services.

(3) The State, in the case of a PCCM that has a fee-for-service contract.

(c) *Coverage and payment: Emergency services.* (1) The entities identified in paragraph (b) of this section—

(i) Must cover and pay for emergency services regardless of whether the provider that furnishes the services has a contract with the MCO, PIHP, PAHP, or PCCM; and

(ii) May not deny payment for treatment obtained under either of the following circumstances:

(A) An enrollee had an emergency medical condition, including cases in which the absence of immediate medical attention would not have had the outcomes specified in paragraphs (1), (2), and (3) of the definition of *emergency medical condition* in paragraph (a) of this section.

(B) A representative of the MCO, PIHP, PAHP, or PCCM instructs the enrollee to seek emergency services.

(2) A PCCM must—

(i) Allow enrollees to obtain emergency services outside the primary care case management system regardless of whether the case manager referred the enrollee to the provider that furnishes the services; and

(ii) Pay for the services if the manager's contract is a risk contract that covers those services.

(d) *Additional rules for emergency services.* (1) The entities specified in paragraph (b) of this section may not—

(i) Limit what constitutes an emergency medical condition with reference to paragraph (a) of this section, on the basis of lists of diagnoses or symptoms; and

(ii) Refuse to cover emergency services based on the emergency room provider, hospital, or fiscal agent not notifying the enrollee's primary care provider, MCO, or applicable State entity of the enrollee's screening and treatment within 10 calendar days of presentation for emergency services.

(2) An enrollee who has an emergency medical condition may not be held liable for payment of subsequent screening and treatment needed to diagnose the specific condition or stabilize the patient.

(3) The attending emergency physician, or the provider actually treating the enrollee, is responsible for determining when the enrollee is sufficiently stabilized for transfer or discharge, and that determination is binding on the entities identified in paragraph (b) of this section as responsible for coverage and payment.

(e) *Coverage and payment: Poststabilization care services.* Poststabilization care services are covered and paid for in accordance with provisions set forth at § 422.113(c) of this chapter. In applying those provisions, reference to ''M+C organization'' must be read as reference to the entities responsible for Medicaid payment, as specified in paragraph (b) of this section.

(f) *Applicability to PIHPs and PAHPs.* To the extent that services required to treat an emergency medical condition fall within the scope of the services for which the PIHP or PAHP is responsible, the rules under this section apply.

§ 438.116 Solvency standards.

(a) *Requirement for assurances* (1) Each MCO, PIHP, and PAHP that is not a Federally qualified HMO (as defined in section 1310 of the Public Health Service Act) must provide assurances satisfactory to the State showing that its provision against the risk of insolvency is adequate to ensure that its Medicaid enrollees will not be liable for the MCO's, PIHP's, or PAHP's debts if the entity becomes insolvent.

(2) Federally qualified HMOs, as defined in section 1310 of the Public Health Service Act, are exempt from this requirement.

(b) *Other requirements*—(1) *General rule.* Except as provided in paragraph (b)(2) of this section, an MCO, PIHP, and PAHP must meet the solvency standards established by the State for private health maintenance organizations, or be licensed or certified by the State as a risk-bearing entity.

(2) *Exception.* Paragraph (b)(1) of this section does not apply to an MCO, PIHP, or PAHP that meets any of the following conditions:

(i) Does not provide both inpatient hospital services and physician services.

(ii) Is a public entity.

(iii) Is (or is controlled by) one or more Federally qualified health centers and meets the solvency standards established by the State for those centers.

(iv) Has its solvency guaranteed by the State.

Subpart D—Quality Assessment and Performance Improvement

§ 438.200 Scope.

This subpart implements section 1932(c)(1) of the Act and sets forth specifications for quality assessment and performance improvement strategies that States must implement to ensure the delivery of quality health care by all MCOs, PIHPs, and PAHPs. It also establishes standards that States, MCOs, PIHPs, and PAHPs must meet.

§ 438.202 State responsibilities.

Each State contracting with an MCO or PIHP must do the following:

(a) Have a written strategy for assessing and improving the quality of managed care services offered by all MCOs and PIHPs.

(b) Obtain the input of recipients and other stakeholders in the development of the strategy and make the strategy available for public comment before adopting it in final.

(c) Ensure that MCOs, PIHPs, and PAHPs comply with standards established by the State, consistent with this subpart.

(d) Conduct periodic reviews to evaluate the effectiveness of the strategy, and update the strategy periodically, as needed.

(e) Submit to CMS the following:

(1) A copy of the initial strategy, and a copy of the revised strategy whenever significant changes are made.

(2) Regular reports on the implementation and effectiveness of the strategy.

§ 438.204 Elements of State quality strategies.

At a minimum, State strategies must include the following:

(a) The MCO and PIHP contract provisions that incorporate the standards specified in this subpart.

(b) Procedures that—

(1) Assess the quality and appropriateness of care and services furnished to all Medicaid enrollees under the MCO and PIHP contracts, and to individuals with special health care needs.

(2) Identify the race, ethnicity, and primary language spoken of each Medicaid enrollee. States must provide this information to the MCO and PIHP for each Medicaid enrollee at the time of enrollment.

(3) Regularly monitor and evaluate the MCO and PIHP compliance with the standards.

(c) For MCOs and PIHPs, any national performance measures and levels that may be identified and developed by CMS in consultation with States and other relevant stakeholders.

(d) Arrangements for annual, external independent reviews of the quality outcomes and timeliness of, and access to, the services covered under each MCO and PIHP contract.

(e) For MCOs, appropriate use of intermediate sanctions that, at a minimum, meet the requirements of subpart I of this part.

(f) An information system that supports initial and ongoing operation and review of the State's quality strategy.

(g) Standards, at least as stringent as those in the following sections of this subpart, for access to care, structure and operations, and quality measurement and improvement.

Access Standards

§ 438.206 Availability of services.

(a) *Basic rule.* Each State must ensure that all services covered under the State plan are available and accessible to enrollees of MCOs, PIHPs, and PAHPs.

(b) *Delivery network.* The State must ensure, through its contracts, that each MCO, and each PIHP and PAHP consistent with the scope of the PIHP's or PAHP's contracted services, meets the following requirements:

(1) Maintains and monitors a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to all services covered under the contract. In establishing and maintaining the network, each MCO, PIHP, and PAHP must consider the following:

(i) The anticipated Medicaid enrollment.

(ii) The expected utilization of services, taking into consideration the characteristics and health care needs of specific Medicaid populations represented in the particular MCO, PIHP, and PAHP.

(iii) The numbers and types (in terms of training, experience, and specialization) of providers required to furnish the contracted Medicaid services.

(iv) The numbers of network providers who are not accepting new Medicaid patients.

(v) The geographic location of providers and Medicaid enrollees, considering distance, travel time, the means of transportation ordinarily used by Medicaid enrollees, and whether the location provides physical access for Medicaid enrollees with disabilities.

(2) Provides female enrollees with direct access to a women's health specialist within the network for covered care necessary to provide women's routine and preventive health care services. This is in addition to the enrollee's designated source of primary care if that source is not a women's health specialist.

(3) Provides for a second opinion from a qualified health care professional within the network, or arranges for the enrollee to obtain one outside the network, at no cost to the enrollee.

(4) If the network is unable to provide necessary services, covered under the contract, to a particular enrollee, the MCO, PIHP, or PAHP must adequately and timely cover these services out of network for the enrollee, for as long as the MCO, PIHP, or PAHP is unable to provide them.

(5) Requires out-of-network providers to coordinate with the MCO or PIHP with respect to payment and ensures that cost to the enrollee is no greater than it would be if the services were furnished within the network.

(6) Demonstrates that its providers are credentialed as required by § 438.214.

(c) *Furnishing of services.* The State must ensure that each MCO, PIHP, and PAHP contract complies with the requirements of this paragraph.

(1) *Timely access.* Each MCO, PIHP, and PAHP must do the following:

(i) Meet and require its providers to meet State standards for timely access to care and services, taking into account the urgency of the need for services.

(ii) Ensure that the network providers offer hours of operation that are no less than the hours of operation offered to commercial enrollees or comparable to Medicaid fee-for-service, if the provider serves only Medicaid enrollees.

(iii) Make services included in the contract available 24 hours a day, 7 days a week, when medically necessary.

(iv) Establish mechanisms to ensure compliance by providers.

(v) Monitor providers regularly to determine compliance.

(vi) Take corrective action if there is a failure to comply.

(2) *Cultural considerations.* Each MCO, PIHP, and PAHP participates 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.

§ 438.207 Assurances of adequate capacity and services.

(a) *Basic rule.* The State must ensure, through its contracts, that each MCO, PIHP, and PAHP gives assurances to the State and provides supporting documentation that demonstrates that it has the capacity to serve the expected enrollment in its service area in accordance with the State's standards for access to care under this subpart.

(b) *Nature of supporting documentation.* Each MCO, PIHP, and PAHP must submit documentation to the State, in a format specified by the State to demonstrate that it complies with the following requirements:

(1) Offers an appropriate range of preventive, primary care, and specialty services that is adequate for the anticipated number of enrollees for the service area.

(2) Maintains a network of providers that is sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees in the service area.

(c) *Timing of documentation.* Each MCO, PIHP, and PAHP must submit the documentation described in paragraph (b) of this section as specified by the State, but no less frequently than the following:

(1) At the time it enters into a contract with the State.

(2) At any time there has been a significant change (as defined by the State) in the MCO's, PIHP's, or PAHP's operations that would affect adequate capacity and services, including—

(i) Changes in MCO, PIHP, or PAHP services, benefits, geographic service area or payments; or

(ii) Enrollment of a new population in the MCO, PIHP, or PAHP.

(d) *State review and certification to CMS.* After the State reviews the documentation submitted by the MCO, PIHP, or PAHP, the State must certify to CMS that the MCO, PIHP, or PAHP has complied with the State's requirements for availability of services, as set forth in § 438.206.

(e) *CMS' right to inspect documentation.* The State must make available to CMS, upon request, all documentation collected by the State from the MCO, PIHP, or PAHP.

§ 438.208 Coordination and continuity of care.

(a) *Basic requirement*—(1) *General rule.* Except as specified in paragraphs (a)(2) and (a)(3) of this section, the State must ensure through its contracts, that each MCO, PIHP, and PAHP complies with the requirements of this section.

(2) *PIHP and PAHP exception.* For PIHPs and PAHPs, the State determines, based on the scope of the entity's services, and on the way the State has organized the delivery of managed care services, whether a particular PIHP or PAHP is required to—

(i) Meet the primary care requirement of paragraph (b)(1) of this section; and

(ii) Implement mechanisms for identifying, assessing, and producing a treatment plan for an individual with special health care needs, as specified in paragraph (c) of this section.

(3) *Exception for MCOs that serve dually eligible enrollees.* (i) For each MCO that serves enrollees who are also enrolled in and receive Medicare benefits from a Medicare+Choice plan, the State determines to what extent the MCO must meet the primary care coordination, identification, assessment, and treatment planning provisions of paragraphs (b) and (c) of this section with respect to dually eligible individuals.

(ii) The State bases its determination on the services it requires the MCO to furnish to dually eligible enrollees.

(b) *Primary care and coordination of health care services for all MCO, PIHP, and PAHP enrollees.* Each MCO, PIHP, and PAHP must implement procedures to deliver primary care to and coordinate health care service for all MCO, PIHP, and PAHP enrollees. These procedures must meet State requirements and must do the following:

(1) Ensure that each enrollee has an ongoing source of primary care appropriate to his or her needs and a person or entity formally designated as primarily responsible for coordinating the health care services furnished to the enrollee.

(2) Coordinate the services the MCO, PIHP, or PAHP furnishes to the enrollee with the services the enrollee receives from any other MCO, PIHP, or PAHP.

(3) Share with other MCOs, PIHPs, and PAHPs serving the enrollee with special health care needs the results of its identification and assessment of that enrollee's needs to prevent duplication of those activities.

(4) Ensure that in the process of coordinating care, each enrollee's privacy is protected in accordance with the privacy requirements in 45 CFR parts 160 and 164 subparts A and E, to the extent that they are applicable.

(c) *Additional services for enrollees with special health care needs.*

(1) *Identification.* The State must implement mechanisms to identify persons with special health care needs to MCOs, PIHPs and PAHPs, as those persons are defined by the State. These identification mechanisms—

(i) Must be specified in the State's quality improvement strategy in § 438.202; and

(ii) May use State staff, the State's enrollment broker, or the State's MCOs, PIHPs and PAHPs.

(2) *Assessment.* Each MCO, PIHP, and PAHP must implement mechanisms to assess each Medicaid enrollee identified by the State (through the mechanism specified in paragraph (c)(1) of this section) and identified to the MCO, PIHP, and PAHP by the State as having special health care needs in order to identify any ongoing special conditions of the enrollee that require a course of treatment or regular care monitoring. The assessment mechanisms must use appropriate health care professionals.

(3) *Treatment plans.* If the State requires MCOs, PIHPs, and PAHPs to produce a treatment plan for enrollees with special health care needs who are determined through assessment to need a course of treatment or regular care monitoring, the treatment plan must be—

(i) Developed by the enrollee's primary care provider with enrollee participation, and in consultation with any specialists caring for the enrollee;

(ii) Approved by the MCO, PIHP, or PAHP in a timely manner, if this approval is required by the MCO, PIHP, or PAHP; and

(iii) In accord with any applicable State quality assurance and utilization review standards.

(4) *Direct access to specialists.* For enrollees with special health care needs determined through an assessment by appropriate health care professionals (consistent with § 438.208(c)(2)) to need a course of treatment or regular care monitoring, each MCO, PIHP, and PAHP must have a mechanism in place to allow enrollees to directly access a specialist (for example, through a standing referral or an approved number of visits) as appropriate for the enrollee's condition and identified needs.

§ 438.210 Coverage and authorization of services.

(a) *Coverage.* Each contract with an MCO, PIHP, or PAHP must do the following:

(1) Identify, define, and specify the amount, duration, and scope of each service that the MCO, PIHP, or PAHP is required to offer.

(2) Require that the services identified in paragraph (a)(1) of this section be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services furnished to beneficiaries under fee-for-service Medicaid, as set forth in § 440.230.

(3) Provide that the MCO, PIHP, or PAHP—

(i) Must ensure that the services are sufficient in amount, duration, or scope to reasonably be expected to achieve the purpose for which the services are furnished.

(ii) May not arbitrarily deny or reduce the amount, duration, or scope of a required service solely because of diagnosis, type of illness, or condition of the beneficiary;

(iii) May place appropriate limits on a service—

(A) On the basis of criteria applied under the State plan, such as medical necessity; or

(B) For the purpose of utilization control, provided the services furnished can reasonably be expected to achieve their purpose, as required in paragraph (a)(3)(i) of this section; and

(4) Specify what constitutes ''medically necessary services'' in a manner that—

(i) Is no more restrictive than that used in the State Medicaid program as indicated in State statutes and regulations, the State Plan, and other State policy and procedures; and

(ii) Addresses the extent to which the MCO, PIHP, or PAHP is responsible for covering services related to the following:

(A) The prevention, diagnosis, and treatment of health impairments.

(B) The ability to achieve age-appropriate growth and development.

(C) The ability to attain, maintain, or regain functional capacity.

(b) *Authorization of services.* For the processing of requests for initial and continuing authorizations of services, each contract must require—

(1) That the MCO, PIHP, or PAHP and its subcontractors have in place, and follow, written policies and procedures.

(2) That the MCO, PIHP, or PAHP—

(i) Have in effect mechanisms to ensure consistent application of review criteria for authorization decisions; and

(ii) Consult with the requesting provider when appropriate.

(3) That any decision to deny a service authorization request or to authorize a service in an amount, duration, or scope that is less than requested, be made by a health care professional who has appropriate clinical expertise in treating the enrollee's condition or disease.

(c) *Notice of adverse action.* Each contract must provide for the MCO, PIHP, or PAHP to notify the requesting provider, and give the enrollee written notice of any decision by the MCO, PIHP, or PAHP to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested. For MCOs and PIHPs, the notice must meet the requirements of § 438.404, except that the notice to the provider need not be in writing.

(d) *Timeframe for decisions.* Each MCO, PIHP, or PAHP contract must provide for the following decisions and notices:

(1) *Standard authorization decisions.* For standard authorization decisions, provide notice as expeditiously as the enrollee's health condition requires and within State-established timeframes that may not exceed 14 calendar days following receipt of the request for service, with a possible extension of up to 14 additional calendar days, if—

(i) The enrollee, or the provider, requests extension; or

(ii) The MCO, PIHP, or PAHP justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.

(2) *Expedited authorization decisions.* (i) For cases in which a provider indicates, or the MCO, PIHP, or PAHP determines, that following the standard timeframe could seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function, the MCO, PIHP, or PAHP must make an expedited authorization decision and provide notice as expeditiously as the enrollee's health condition requires and no later than 3 working days after receipt of the request for service.

(ii) The MCO, PIHP, or PAHP may extend the 3 working days time period by up to 14 calendar days if the enrollee requests an extension, or if the MCO, PIHP, or PAHP justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.

(e) *Compensation for utilization management activities.* Each contract must provide that, consistent with § 438.6(h), and § 422.208 of this chapter, compensation to individuals or entities that conduct utilization management activities is not structured so as to provide incentives for the individual or entity to deny, limit, or discontinue medically necessary services to any enrollee.

Structure and Operation Standards

§ 438.214 Provider selection.

(a) *General rules.* The State must ensure, through its contracts, that each MCO, PIHP, or PAHP implements written policies and procedures for selection and retention of providers and that those policies and procedures include, at a minimum, the requirements of this section.

(a) *Credentialing and recredentialing requirements.* (1) Each State must establish a uniform credentialing and recredentialing policy that each MCO, PIHP, and PAHP must follow.

(2) Each MCO, PIHP, and PAHP must follow a documented process for credentialing and recredentialing of providers who have signed contracts or participation agreements with the MCO, PIHP, or PAHP.

(c) *Nondiscrimination.* MCO, PIHP, and PAHP provider selection policies and procedures, consistent with § 438.12, must not discriminate against particular providers that serve high-risk populations or specialize in conditions that require costly treatment.

(d) *Excluded providers.* MCOs, PIHPs, and PAHPs may not employ or contract with providers excluded from participation in Federal health care programs under either section 1128 or section 1128A of the Act.

(e) *State requirements.* Each MCO, PIHP, and PAHP must comply with any additional requirements established by the State.

§ 438.218 Enrollee information.

The requirements that States must meet under § 438.10 constitute part of the State's quality strategy at § 438.204.

§ 438.224 Confidentiality.

The State must ensure, through its contracts, that (consistent with subpart F of part 431 of this chapter), for medical records and any other health and enrollment information that identifies a particular enrollee, each MCO, PIHP, and PAHP uses and discloses such individually identifiable health information in accordance with the privacy requirements in 45 CFR parts 160 and 164, subparts A and E, to the extent that these requirements are applicable.

§ 438.226 Enrollment and disenrollment.

The State must ensure that each MCO, PIHP, and PAHP contract complies with the enrollment and disenrollment requirements and limitations set forth in § 438.56.

§ 438.228 Grievance systems.

(a) The State must ensure, through its contracts, that each MCO and PIHP has in effect a grievance system that meets the requirements of subpart F of this part.

(b) If the State delegates to the MCO or PIHP responsibility for notice of action under subpart E of part 431 of this chapter, the State must conduct random reviews of each delegated MCO or PIHP and its providers and subcontractors to ensure that they are notifying enrollees in a timely manner.

§ 438.230 Subcontractual relationships and delegation.

(a) *General rule.* The State must ensure, through its contracts, that each MCO, PIHP, and PAHP—

(1) Oversees and is accountable for any functions and responsibilities that it delegates to any subcontractor; and

(2) Meets the conditions of paragraph (b) of this section.

(b) *Specific conditions.* (1) Before any delegation, each MCO, PIHP, and PAHP evaluates the prospective subcontractor's ability to perform the activities to be delegated.

(2) There is a written agreement that—

(i) Specifies the activities and report responsibilities delegated to the subcontractor; and

(ii) Provides for revoking delegation or imposing other sanctions if the subcontractor's performance is inadequate.

(3) The MCO, PIHP, or PAHP monitors the subcontractor's performance on an ongoing basis and subjects it to formal review according to a periodic schedule established by the State, consistent with industry standards or State MCO laws and regulations.

(4) If any MCO, PIHP, or PAHP identifies deficiencies or areas for improvement, the MCO, PIHP, or PAHP and the subcontractor take corrective action.

Measurement and Improvement Standards

§ 438.236 Practice guidelines.

(a) *Basic rule:* The State must ensure, through its contracts, that each MCO and, when applicable, each PIHP and PAHP meets the requirements of this section.

(b) *Adoption of practice guidelines.* Each MCO and, when applicable, each PIHP and PAHP adopts practice guidelines that meet the following requirements:

(1) Are based on valid and reliable clinical evidence or a consensus of health care professionals in the particular field.

(2) Consider the needs of the MCO's, PIHP's, or PAHP's enrollees.

(3) Are adopted in consultation with contracting health care professionals.

(4) Are reviewed and updated periodically as appropriate.

(c) *Dissemination of guidelines.* Each MCO, PIHP, and PAHP disseminates the guidelines to all affected providers and, upon request, to enrollees and potential enrollees.

(d) *Application of guidelines.* Decisions for utilization management, enrollee education, coverage of services, and other areas to which the guidelines apply are consistent with the guidelines.

§ 438.240 Quality assessment and performance improvement program.

(a) *General rules.* (1) The State must require, through its contracts, that each MCO and PIHP have an ongoing quality assessment and performance improvement program for the services it furnishes to its enrollees.

(2) CMS, in consultation with States and other stakeholders, may specify performance measures and topics for performance improvement projects to be required by States in their contracts with MCOs and PIHPs.

(b) *Basic elements of MCO and PIHP quality assessment and performance improvement programs.* At a minimum, the State must require that each MCO and PIHP comply with the following requirements:

(1) Conduct performance improvement projects as described in paragraph (d) of this section. These projects must be designed to achieve, through ongoing measurements and intervention, significant improvement, sustained over time, in clinical care and nonclinical care areas that are expected to have a favorable effect on health outcomes and enrollee satisfaction.

(2) Submit performance measurement data as described in paragraph (c) of this section.

(3) Have in effect mechanisms to detect both underutilization and overutilization of services.

(4) Have in effect mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs.

(c) *Performance measurement.* Annually each MCO and PIHP must—

(1) Measure and report to the State its performance, using standard measures required by the State including those that incorporate the requirements of § 438.204(c) and § 438.240(a)(2);

(2) Submit to the State, data specified by the State, that enables the State to measure the MCO's or PIHP's performance; or

(3) Perform a combination of the activities described in paragraphs (c)(1) and (c)(2) of this section.

(d) *Performance improvement projects.* (1) MCOs and PIHPs must have an ongoing program of performance improvement projects that focus on clinical and nonclinical areas, and that involve the following:

(i) Measurement of performance using objective quality indicators.

(ii) Implementation of system interventions to achieve improvement in quality.

(iii) Evaluation of the effectiveness of the interventions.

(iv) Planning and initiation of activities for increasing or sustaining improvement.

(2) Each MCO and PIHP must report the status and results of each project to the State as requested, including those that incorporate the requirements of § 438.240(a)(2). Each performance improvement project must be completed in a reasonable time period so as to generally allow information on the success of performance improvement projects in the aggregate to produce new information on quality of care every year.

(e) *Program review by the State.*

(1) The State must review, at least annually, the impact and effectiveness of each MCO's and PIHP's quality assessment and performance improvement program. The review must include—

(i) The MCO's and PIHP's performance on the standard measures on which it is required to report; and

(ii) The results of each MCO's and PIHP's performance improvement projects.

(2) The State may require that an MCO or PIHP have in effect a process for its own evaluation of the impact and effectiveness of its quality assessment and performance improvement program.

§ 438.242 Health information systems.

(a) *General rule.* The State must ensure, through its contracts, that each MCO and PIHP maintains a health information system that collects, analyzes, integrates, and reports data and can achieve the objectives of this subpart. The system must provide information on areas including, but not limited to, utilization, grievances and appeals, and disenrollments for other than loss of Medicaid eligibility.

(b) *Basic elements of a health information system.* The State must require, at a minimum, that each MCO and PIHP comply with the following:

(1) Collect data on enrollee and provider characteristics as specified by the State, and on services furnished to enrollees through an encounter data system or other methods as may be specified by the State.

(2) Ensure that data received from providers is accurate and complete by—

(i) Verifying the accuracy and timeliness of reported data;

(ii) Screening the data for completeness, logic, and consistency; and

(iii) Collecting service information in standardized formats to the extent feasible and appropriate.

(3) Make all collected data available to the State and upon request to CMS, as required in this subpart.

Subpart E—[Reserved]

Subpart F—Grievance System

§ 438.400 Statutory basis and definitions.

(a) *Statutory basis.* This subpart is based on sections 1902(a)(3), 1902(a)(4), and 1932(b)(4) of the Act.

(1) Section 1902(a)(3) requires that a State plan provide an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly.

(2) Section 1902(a)(4) requires that the State plan provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.

(3) Section 1932(b)(4) requires Medicaid managed care organizations to establish internal grievance procedures under which Medicaid enrollees, or providers acting on their behalf, may challenge the denial of coverage of, or payment for, medical assistance.

(b) *Definitions.* As used in this subpart, the following terms have the indicated meanings:

Action means—

In the case of an MCO or PIHP—

(1) The denial or limited authorization of a requested service, including the type or level of service;

(2) The reduction, suspension, or termination of a previously authorized service;

(3) The denial, in whole or in part, of payment for a service;

(4) The failure to provide services in a timely manner, as defined by the State;

(5) The failure of an MCO or PIHP to act within the timeframes provided in § 438.408(b); or

(6) For a resident of a rural area with only one MCO, the denial of a Medicaid enrollee's request to exercise his or her right, under § 438.52(b)(2)(ii), to obtain services outside the network.

Appeal means a request for review of an action, as ''action'' is defined in this section.

Grievance means an expression of dissatisfaction about any matter other than an action, as ''action'' is defined in this section. The term is also used to refer to the overall system that includes grievances and appeals handled at the MCO or PIHP level and access to the State fair hearing process. (Possible subjects for grievances include, but are not limited to, the quality of care or services provided, and aspects of interpersonal relationships such as rudeness of a provider or employee, or failure to respect the enrollee's rights.)

§ 438.402 General requirements.

(a) *The grievance system.* Each MCO and PIHP must have a system in place for enrollees that includes a grievance process, an appeal process, and access to the State's fair hearing system.

(b) *Filing requirements*—(1) *Authority to file.*—(i) An enrollee may file a grievance and an MCO or PIHP level appeal, and may request a State fair hearing.

(ii) A provider, acting on behalf of the enrollee and with the enrollee's written consent, may file an appeal. A provider may file a grievance or request a State fair hearing on behalf of an enrollee, if the State permits the provider to act as the enrollee's authorized representative in doing so.

(2) *Timing.* The State specifies a reasonable timeframe that may be no less than 20 days and not to exceed 90 days from the date on the MCO's or PIHP's notice of action. Within that timeframe—

(i) The enrollee or the provider may file an appeal; and

(ii) In a State that does not require exhaustion of MCO and PIHP level appeals, the enrollee may request a State fair hearing.

(3) *Procedures.* (i) The enrollee may file a grievance either orally or in writing and, as determined by the State, either with the State or with the MCO or the PIHP.

(ii) The enrollee or the provider may file an appeal either orally or in writing, and unless he or she requests expedited resolution, must follow an oral filing with a written, signed, appeal.

§ 438.404 Notice of action.

(a) *Language and format requirements.* The notice must be in writing and must meet the language and format requirements of § 438.10(c) and (d) to ensure ease of understanding.

(b) *Content of notice.* The notice must explain the following:

(1) The action the MCO or PIHP or its contractor has taken or intends to take.

(2) The reasons for the action.

(3) The enrollee's or the provider's right to file an MCO or PIHP appeal.

(4) If the State does not require the enrollee to exhaust the MCO or PIHP level appeal procedures, the enrollee's right to request a State fair hearing.

(5) The procedures for exercising the rights specified in this paragraph.

(6) The circumstances under which expedited resolution is available and how to request it.

(7) The enrollee's right to have benefits continue pending resolution of the appeal, how to request that benefits be continued, and the circumstances under which the enrollee may be required to pay the costs of these services.

(c) *Timing of notice.* The MCO or PIHP must mail the notice within the following timeframes:

(1) For termination, suspension, or reduction of previously authorized Medicaid-covered services, within the timeframes specified in §§ 431.211, 431.213, and 431.214 of this chapter.

(2) For denial of payment, at the time of any action affecting the claim.

(3) For standard service authorization decisions that deny or limit services, within the timeframe specified in § 438.210(d)(1).

(4) If the MCO or PIHP extends the timeframe in accordance with § 438.210(d)(1), it must—

(i) Give the enrollee written notice of the reason for the decision to extend the timeframe and inform the enrollee of the right to file a grievance if he or she disagrees with that decision; and

(ii) Issue and carry out its determination as expeditiously as the enrollee's health condition requires and no later than the date the extension expires.

(5) For service authorization decisions not reached within the timeframes specified in § 438.210(d) (which constitutes a denial and is thus an adverse action), on the date that the timeframes expire.

(6) For expedited service authorization decisions, within the timeframes specified in § 438.210(d).

§ 438.406 Handling of grievances and appeals.

(a) *General requirements.* In handling grievances and appeals, each MCO and each PIHP must meet the following requirements:

(1) Give enrollees any reasonable assistance in completing forms and taking other procedural steps. This includes, but is not limited to, providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability.

(2) Acknowledge receipt of each grievance and appeal.

(3) Ensure that the individuals who make decisions on grievances and appeals are individuals—

(i) Who were not involved in any previous level of review or decision-making; and

(ii) Who, if deciding any of the following, are health care professionals who have the appropriate clinical expertise, as determined by the State, in treating the enrollee's condition or disease.

(A) An appeal of a denial that is based on lack of medical necessity.

(B) A grievance regarding denial of expedited resolution of an appeal.

(C) A grievance or appeal that involves clinical issues.

(b) *Special requirements for appeals.* The process for appeals must:

(1) Provide that oral inquiries seeking to appeal an action are treated as appeals (to establish the earliest possible filing date for the appeal) and must be confirmed in writing, unless the enrollee or the provider requests expedited resolution.

(2) Provide the enrollee a reasonable opportunity to present evidence, and allegations of fact or law, in person as well as in writing. (The MCO or PIHP must inform the enrollee of the limited time available for this in the case of expedited resolution.)

(3) Provide the enrollee and his or her representative opportunity, before and during the appeals process, to examine the enrollee's case file, including medical records, and any other documents and records considered during the appeals process.

(4) Include, as parties to the appeal—

(i) The enrollee and his or her representative; or

(ii) The legal representative of a deceased enrollee's estate.

§ 438.408 Resolution and notification: Grievances and appeals.

(a) *Basic rule.* The MCO or PIHP must dispose of each grievance and resolve

each appeal, and provide notice, as expeditiously as the enrollee's health condition requires, within State-established timeframes that may not exceed the timeframes specified in this section.

(b) *Specific timeframes.*— (1) *Standard disposition of grievances.* For standard disposition of a grievance and notice to the affected parties, the timeframe is established by the State but may not exceed 90 days from the day the MCO or PIHP receives the grievance.

(2) *Standard resolution of appeals.* For standard resolution of an appeal and notice to the affected parties, the State must establish a timeframe that is no longer than 45 days from the day the MCO or PIHP receives the appeal. This timeframe may be extended under paragraph (c) of this section.

(3) *Expedited resolution of appeals.* For expedited resolution of an appeal and notice to affected parties, the State must establish a timeframe that is no longer than 3 working days after the MCO or PIHP receives the appeal. This timeframe may be extended under paragraph (c) of this section.

(c) *Extension of timeframes.*—(1) The MCO or PIHP may extend the timeframes from paragraph (b) of this section by up to 14 calendar days if—

(i) The enrollee requests the extension; or

(ii) The MCO or PIHP shows (to the satisfaction of the State agency, upon its request) that there is need for additional information and how the delay is in the enrollee's interest.

(2) *Requirements following extension.* If the MCO or PIHP extends the timeframes, it must—for any extension not requested by the enrollee, give the enrollee written notice of the reason for the delay.

(d) *Format of notice.*— (1) *Grievances.* The State must establish the method MCOs and PIHPs will use to notify an enrollee of the disposition of a grievance.

(2) *Appeals.* (i) For all appeals, the MCO or PIHP must provide written notice of disposition.

(ii) For notice of an expedited resolution, the MCO or PIHP must also make reasonable efforts to provide oral notice.

(e) *Content of notice of appeal resolution.* The written notice of the resolution must include the following:

(1) The results of the resolution process and the date it was completed.

(2) For appeals not resolved wholly in favor of the enrollees—

(i) The right to request a State fair hearing, and how to do so;

(ii) The right to request to receive benefits while the hearing is pending, and how to make the request; and

(iii) That the enrollee may be held liable for the cost of those benefits if the hearing decision upholds the MCO's or PIHP's action.

(f) *Requirements for State fair hearings.*—(1) *Availability.* The State must permit the enrollee to request a State fair hearing within a reasonable time period specified by the State, but not less than 20 or in excess of 90 days from whichever of the following dates applies—

(i) If the State requires exhaustion of the MCO or PIHP level appeal procedures, from the date of the MCO's or PIHP's notice of resolution; or

(ii) If the State does not require exhaustion of the MCO or PIHP level appeal procedures and the enrollee appeals directly to the State for a fair hearing, from the date on the MCO's or PIHP's notice of action.

(2) *Parties.* The parties to the State fair hearing include the MCO or PIHP as well as the enrollee and his or her representative or the representative of a deceased enrollee's estate.

§ 438.410 Expedited resolution of appeals.

(a) *General rule.* Each MCO and PIHP must establish and maintain an expedited review process for appeals, when the MCO or PIHP determines (for a request from the enrollee) or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request) that taking the time for a standard resolution could seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function.

(b) *Punitive action.* The MCO or PIHP must ensure that punitive action is neither taken against a provider who requests an expedited resolution or supports an enrollee's appeal.

(c) *Action following denial of a request for expedited resolution.* If the MCO or PIHP denies a request for expedited resolution of an appeal, it must—

(1) Transfer the appeal to the timeframe for standard resolution in accordance with § 438.408(b)(2);

(2) Make reasonable efforts to give the enrollee prompt oral notice of the denial, and follow up within two calendar days with a written notice.

§ 438.414 Information about the grievance system to providers and subcontractors.

The MCO or PIHP must provide the information specified at § 438.10(g)(1) about the grievance system to all providers and subcontractors at the time they enter into a contract.

§ 438.416 Recordkeeping and reporting requirements.

The State must require MCOs and PIHPs to maintain records of grievances and appeals and must review the information as part of the State quality strategy.

§ 438.420 Continuation of benefits while the MCO or PIHP appeal and the State fair hearing are pending.

(a) *Terminology.* As used in this section, ''timely'' filing means filing on or before the later of the following:

(1) Within ten days of the MCO or PIHP mailing the notice of action.

(2) The intended effective date of the MCO's or PIHP's proposed action.

(b) *Continuation of benefits.* The MCO or PIHP must continue the enrollee's benefits if—

(1) The enrollee or the provider files the appeal timely;

(2) The appeal involves the termination, suspension, or reduction of a previously authorized course of treatment;

(3) The services were ordered by an authorized provider;

(4) The original period covered by the original authorization has not expired; and

(5) The enrollee requests extension of benefits.

(c) *Duration of continued or reinstated benefits.* If, at the enrollee's request, the MCO or PIHP continues or reinstates the enrollee's benefits while the appeal is pending, the benefits must be continued until one of following occurs:

(1) The enrollee withdraws the appeal.

(2) Ten days pass after the MCO or PIHP mails the notice, providing the resolution of the appeal against the enrollee, unless the enrollee, within the 10-day timeframe, has requested a State fair hearing with continuation of benefits until a State fair hearing decision is reached.

(3) A State fair hearing Office issues a hearing decision adverse to the enrollee.

(4) The time period or service limits of a previously authorized service has been met.

(d) *Enrollee responsibility for services furnished while the appeal is pending.* If the final resolution of the appeal is adverse to the enrollee, that is, upholds the MCO's or PIHP's action, the MCO or PIHP may recover the cost of the services furnished to the enrollee while the appeal is pending, to the extent that they were furnished solely because of the requirements of this section, and in accordance with the policy set forth in § 431.230(b) of this chapter.

§ 438.424 Effectuation of reversed appeal resolutions.

(a) *Services not furnished while the appeal is pending.* If the MCO or PIHP, or the State fair hearing officer reverses a decision to deny, limit, or delay services that were not furnished while the appeal was pending, the MCO or PIHP must authorize or provide the disputed services promptly, and as expeditiously as the enrollee's health condition requires.

(b) *Services furnished while the appeal is pending.* If the MCO or PIHP, or the State fair hearing officer reverses a decision to deny authorization of services, and the enrollee received the disputed services while the appeal was pending, the MCO or the PIHP or the State must pay for those services, in accordance with State policy and regulations.

Subpart G—[Reserved]

Subpart H—Certifications and Program Integrity

§ 438.600 Statutory basis.

This subpart is based on sections 1902(a)(4), 1902(a)(19), 1903(m), and 1932(d)(1) of the Act.

(a) Section 1902(a)(4) requires that the State plan provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.

(b) Section 1902(a)(19) requires that the State plan provide the safeguards necessary to ensure that eligibility is determined and services are provided in a manner consistent with simplicity of administration and the best interests of the recipients.

(c) Section 1903(m) establishes conditions for payments to the State with respect to contracts with MCOs.

(d) Section 1932(d)(1) prohibits MCOs and PCCMs from knowingly having certain types of relationships with individuals excluded under Federal regulations from participating in specified activities, or with affiliates of those individuals.

§ 438.602 Basic rule.

As a condition for receiving payment under the Medicaid managed care program, an MCO, PCCM, PIHP, or PAHP must comply with the applicable certification, program integrity and prohibited affiliation requirements of this subpart.

§ 438.604 Data that must be certified.

(a) *Data certifications.* When State payments to an MCO or PIHP are based on data submitted by the MCO or PIHP, the State must require certification of the data as provided in § 438.606. The data that must be certified include, but are not limited to, enrollment information, encounter data, and other information required by the State and contained in contracts, proposals, and related documents.

(b) *Additional certifications.* Certification is required, as provided in § 438.606, for all documents specified by the State.

§ 438.606 Source, content, and timing of certification.

(a) *Source of certification.* For the data specified in § 438.604, the data the MCO or PIHP submits to the State must be certified by one of the following:

(1) The MCO's or PIHP's Chief Executive Officer.

(2) The MCO's or PIHP's Chief Financial Officer.

(3) An individual who has delegated authority to sign for, and who reports directly to, the MCO's or PIHP's Chief Executive Officer or Chief Financial Officer.

(b) *Content of certification.* The certification must attest, based on best knowledge, information, and belief, as follows:

(1) To the accuracy, completeness and truthfulness of the data.

(2) To the accuracy, completeness and truthfulness of the documents specified by the State.

(c) *Timing of certification.* The MCO or PIHP must submit the certification concurrently with the certified data.

§ 438.608 Program integrity requirements.

(a) *General requirement.* The MCO or PIHP must have administrative and management arrangements or procedures, including a mandatory compliance plan, that are designed to guard against fraud and abuse.

(b) *Specific requirements.* The arrangements or procedures must include the following:

(1) Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable Federal and State standards.

(2) The designation of a compliance officer and a compliance committee that are accountable to senior management.

(3) Effective training and education for the compliance officer and the organization's employees.

(4) Effective lines of communication between the compliance officer and the organization's employees.

(5) Enforcement of standards through well-publicized disciplinary guidelines.

(6) Provision for internal monitoring and auditing.

(7) Provision for prompt response to detected offenses, and for development of corrective action initiatives relating to the MCO's or PIHP's contract.

§ 438.610 Prohibited Affiliations with Individuals Debarred by Federal Agencies.

(a) *General requirement.* An MCO, PCCM, PIHP, or PAHP may not knowingly have a relationship of the type described in paragraph (b) of this section with the following:

(1) An individual who is debarred, suspended, or otherwise excluded from participating in procurement activities under the Federal Acquisition Regulation or from participating in nonprocurement activities under regulations issued under Executive Order No. 12549 or under guidelines implementing Executive Order No. 12549.

(2) An individual who is an affiliate, as defined in the Federal Acquisition Regulation, of a person described in paragraph (a)(1) of this section.

(b) *Specific requirements.* The relationships described in this paragraph are as follow:

(1) A director, officer, or partner of the MCO, PCCM, PIHP, or PAHP.

(2) A person with beneficial ownership of five percent or more of the MCO's, PCCM's, PIHP's, or PAHP's equity.

(3) A person with an employment, consulting or other arrangement with the MCO, PCCM, PIHP, or PAHP for the provision of items and services that are significant and material to the MCO's, PCCM's, PIHP's, or PAHP's obligations under its contract with the State.

(c) *Effect of Noncompliance.* If a State finds that an MCO, PCCM, PIHP, or PAHP is not in compliance with paragraphs (a) and (b) of this section, the State:

(1) Must notify the Secretary of the noncompliance.

(2) May continue an existing agreement with the MCO, PCCM, PIHP, or PAHP unless the Secretary directs otherwise.

(3) May not renew or otherwise extend the duration of an existing agreement with the MCO, PCCM, PIHP, or PAHP unless the Secretary provides to the State and to Congress a written statement describing compelling reasons that exist for renewing or extending the agreement.

(d) *Consultation with the Inspector General.* Any action by the Secretary described in paragraphs (c)(2) or (c)(3) of this section is taken in consultation with the Inspector General.

Subpart I—Sanctions

§ 438.700 Basis for imposition of sanctions.

(a) Each State that contracts with an MCO must, and each State that contracts with a PCCM may, establish intermediate sanctions, as specified in § 438.702, that it may impose if it makes any of the determinations specified in paragraphs (b) through (d) of this section. The State may base its determinations on findings from onsite surveys, enrollee or other complaints, financial status, or any other source.

(b) A State determines whether an MCO acts or fails to act as follows:

(1) Fails substantially to provide medically necessary services that the MCO is required to provide, under law or under its contract with the State, to an enrollee covered under the contract.

(2) Imposes on enrollees premiums or charges that are in excess of the premiums or charges permitted under the Medicaid program.

(3) Acts to discriminate among enrollees on the basis of their health status or need for health care services. This includes termination of enrollment or refusal to reenroll a recipient, except as permitted under the Medicaid program, or any practice that would reasonably be expected to discourage enrollment by recipients whose medical condition or history indicates probable need for substantial future medical services.

(4) Misrepresents or falsifies information that it furnishes to CMS or to the State.

(5) Misrepresents or falsifies information that it furnishes to an enrollee, potential enrollee, or health care provider.

(6) Fails to comply with the requirements for physician incentive plans, as set forth (for Medicare) in §§ 422.208 and 422.210 of this chapter.

(c) A State determines whether an MCO, PIHP, PAHP or PCCM has distributed directly, or indirectly through any agent or independent contractor, marketing materials that have not been approved by the State or that contain false or materially misleading information.

(d) A State determines whether—

(1) An MCO has violated any of the other requirements of sections1903(m) or 1932 of the Act, and any implementing regulations;

(2) A PCCM has violated any of the other applicable requirements of sections 1932 or 1905(t)(3) of the Act and any implementing regulations;

(3) For any of the violations under paragraphs (d)(1) and (d)(2) of this section, only the sanctions specified in § 438.702, paragraphs (a)(3), (a)(4), and (a)(5) may be imposed.

§ 438.702 Types of intermediate sanctions.

(a) The types of intermediate sanctions that a State may impose under this subpart include the following:

(1) Civil money penalties in the amounts specified in § 438.704.

(2) Appointment of temporary management for an MCO as provided in § 438.706.

(3) Granting enrollees the right to terminate enrollment without cause and notifying the affected enrollees of their right to disenroll.

(4) Suspension of all new enrollment, including default enrollment, after the effective date of the sanction.

(5) Suspension of payment for recipients enrolled after the effective date of the sanction and until CMS or the State is satisfied that the reason for imposition of the sanction no longer exists and is not likely to recur.

(b) State agencies retain authority to impose additional sanctions under State statutes or State regulations that address areas of noncompliance specified in § 438.700, as well as additional areas of noncompliance. Nothing in this subpart prevents State agencies from exercising that authority.

§ 438.704 Amounts of civil money penalties.

(a) *General rule.* The limit on, or the maximum civil money penalty the State may impose varies depending on the nature of the MCO's or PCCM's action or failure to act, as provided in this section.

(b) *Specific limits.* (1) The limit is $25,000 for each determination under the following paragraphs of § 438.700:

(i) Paragraph (b)(1) (Failure to provide services).

(ii) Paragraph (b)(5) (Misrepresentation or false statements to enrollees, potential enrollees, or health care providers).

(iii) Paragraph (b)(6) (Failure to comply with physician incentive plan requirements).

(iv) Paragraph (c) (Marketing violations).

(2) The limit is $100,000 for each determination under paragraph (b)(3) (discrimination) or (b)(4) (Misrepresentation or false statements to CMS or the State) of § 438.700.

(3) The limit is $15,000 for each recipient the State determines was not enrolled because of a discriminatory practice under paragraph (b)(3) of § 438.700. (This is subject to the overall limit of $100,000 under paragraph (b)(2) of this section).

(c) *Specific amount.* For premiums or charges in excess of the amounts permitted under the Medicaid program, the maximum amount of the penalty is $25,000 or double the amount of the excess charges, whichever is greater. The State must deduct from the penalty the amount of overcharge and return it to the affected enrollees.

§ 438.706 Special rules for temporary management.

(a) *Optional imposition of sanction.* The State may impose temporary management only if it finds (through onsite survey, enrollee complaints, financial audits, or any other means) that—

(1) There is continued egregious behavior by the MCO, including but not limited to behavior that is described in § 438.700, or that is contrary to any requirements of sections 1903(m) and 1932 of the Act; or

(2) There is substantial risk to enrollees' health; or

(3) The sanction is necessary to ensure the health of the MCO's enrollees—

(i) While improvements are made to remedy violations under § 438.700; or

(ii) Until there is an orderly termination or reorganization of the MCO.

(b) *Required imposition of sanction.* The State must impose temporary management (regardless of any other sanction that may be imposed) if it finds that an MCO has repeatedly failed to meet substantive requirements in section 1903(m) or section 1932 of the Act, or this subpart. The State must also grant enrollees the right to terminate enrollment without cause, as described in § 438.702(a)(3), and must notify the affected enrollees of their right to terminate enrollment.

(c) *Hearing.* The State may not delay imposition of temporary management to provide a hearing before imposing this sanction.

(d) *Duration of sanction.* The State may not terminate temporary management until it determines that the MCO can ensure that the sanctioned behavior will not recur.

§ 438.708 Termination of an MCO or PCCM contract.

A State has the authority to terminate an MCO or PCCM contract and enroll that entity's enrollees in other MCOs or PCCMs, or provide their Medicaid benefits through other options included in the State plan, if the State determines that the MCO or PCCM has failed to do either of the following:

(a) Carry out the substantive terms of its contract; or

(b) Meet applicable requirements in sections 1932, 1903(m), and 1905(t) of the Act.

§ 438.710 Due process: Notice of sanction and pre-termination hearing.

(a) *Notice of sanction.* Except as provided in § 438.706(c), before imposing any of the intermediate sanctions specified in this subpart, the State must give the affected entity timely written notice that explains the following:

(1) The basis and nature of the sanction.

(2) Any other due process protections that the State elects to provide.

(b) *Pre-termination hearing*— (1) *General rule.* Before terminating an MCO or PCCM contract under § 438.708, the State must provide the entity a pre-termination hearing.

(2) *Procedures.* The State must do the following:

(i) Give the MCO or PCCM written notice of its intent to terminate, the reason for termination, and the time and place of the hearing;

(ii) After the hearing, give the entity written notice of the decision affirming or reversing the proposed termination of the contract and, for an affirming decision, the effective date of termination; and

(iii) For an affirming decision, give enrollees of the MCO or PCCM notice of the termination and information, consistent with § 438.10, on their options for receiving Medicaid services following the effective date of termination.

§ 438.722 Disenrollment during termination hearing process.

After a State notifies an MCO or PCCM that it intends to terminate the contract, the State may do the following:

(a) Give the entity's enrollees written notice of the State's intent to terminate the contract.

(b) Allow enrollees to disenroll immediately without cause.

§ 438.724 Notice to CMS.

(a) The State must give the CMS Regional Office written notice whenever it imposes or lifts a sanction for one of the violations listed in § 438.700.

(b) The notice must—

(1) Be given no later than 30 days after the State imposes or lifts a sanction; and

(2) Specify the affected MCO, the kind of sanction, and the reason for the State's decision to impose or lift a sanction.

§ 438.726 State plan requirement.

(a) The State plan must include a plan to monitor for violations that involve the actions and failures to act specified in this part and to implement the provisions of this part.

(b) A contract with an MCO must provide that payments provided for under the contract will be denied for new enrollees when, and for so long as, payment for those enrollees is denied by CMS under section 438.730(e).

§ 438.730 Sanction by CMS: Special rules for MCOs

(a) *Basis for sanction.* (1) A State agency may recommend that CMS impose the denial of payment sanction specified in paragraph (e) of this section on an MCO with a contract under this part if the agency determines that the MCO acts or fails to act as specified in § 438.700(b)(1) through (b)(6).

(b) *Effect of an Agency Determination.* (1) The State agency's determination becomes CMS's determination for purposes of section 1903(m)(5)(A) of the Act unless CMS reverses or modifies it within 15 days.

(2) When the agency decides to recommend imposing the sanction described in paragraph (e) of this section, this recommendation becomes CMS's decision, for purposes of section 1903(m)(5)(B)(ii) of the Act, unless CMS rejects this recommendation within 15 days.

(c) *Notice of sanction.* If the State agency's determination becomes CMS's determination under section (b)(2), the State agency takes the following actions:

(1) Gives the MCO written notice of the nature and basis of the proposed sanction;

(2) Allows the MCO 15 days from the date it receives the notice to provide evidence that it has not acted or failed to act in the manner that is the basis for the recommended sanction;

(3) May extend the initial 15-day period for an additional 15 days if—

(i) the MCO submits a written request that includes a credible explanation of why it needs additional time;

(ii) the request is received by CMS before the end of the initial period; and

(iii) CMS has not determined that the MCO's conduct poses a threat to an enrollee's health or safety.

(d) *Informal reconsideration.* (1) If the MCO submits a timely response to the notice of sanction, the State agency—

(i) Conducts an informal reconsideration that includes review of the evidence by a State agency official who did not participate in the original recommendation;

(ii) Gives the MCO a concise written decision setting forth the factual and legal basis for the decision; and

(iii) Forwards the decision to CMS.

(2) The agency decision under paragraph (d)(1)(ii) of this section becomes CMS's decision unless CMS reverses or modifies the decision within 15 days from date of receipt by CMS.

(3) If CMS reverses or modifies the State agency decision, the agency sends the MCO a copy of CMS's decision.

(e) *Denial of payment.* (1) CMS, based upon the recommendation of the agency, may deny payment to the State for new enrollees of the HMO under section 1903(m)(5)(B)(ii) of the Act in the following situations:

(i) If a CMS determination that an MCO has acted or failed to act, as described in paragraphs (b)(1) through (b)(6) of § 438.700, is affirmed on review under paragraph (d) of this section.

(ii) If the CMS determination is not timely contested by the MCO under paragraph (c) of this section.

(2) Under § 438.726(b), CMS's denial of payment for new enrollees automatically results in a denial of agency payments to the HMO for the same enrollees. (A new enrollee is an enrollee that applies for enrollment after the effective date in paragraph (f)(1) of this section.)

(f) *Effective date of sanction.* (1) If the MCO does not seek reconsideration, a sanction is effective 15 days after the date the MCO is notified under paragraph (b) of this section of the decision to impose the sanction.

(2) If the MCO seeks reconsideration, the following rules apply:

(i) Except as specified in paragraph (d)(2)(ii) of this section, the sanction is effective on the date specified in CMS's reconsideration notice.

(ii) If CMS, in consultation with the State agency, determines that the MCO's conduct poses a serious threat to an enrollee's health or safety, the sanction may be made effective earlier than the date of the agency's reconsideration decision under paragraph (c)(1)(ii) of this section.

(g) *CMS's role.* (1) CMS retains the right to independently perform the functions assigned to the State agency under paragraphs (a) through (d) of this section.

(2) At the same time that the agency sends notice to the MCO under paragraph (c)(1)(i) of this section, CMS forwards a copy of the notice to the OIG.

(3) CMS conveys the determination described in paragraph (b) of this section to the OIG for consideration of possible imposition of civil money penalties under section 1903(m)(5)(A) of the Act and part 1003 of this title. In accordance with the provisions of part 1003, the OIG may impose civil money penalties on the MCO in addition to, or in place of, the sanctions that may be imposed under this section.

Subpart J—Conditions for Federal Financial Participation

§ 438.802 Basic requirements.

FFP is available in expenditures for payments under an MCO contract only for the periods during which the contract—

(a) Meets the requirements of this part; and

(b) Is in effect.

§ 438.806 Prior approval.

(a) *Comprehensive risk contracts.* FFP is available under a comprehensive risk contract only if—

(1) The Regional Office has confirmed that the contractor meets the definition of an MCO or is one of the entities described in paragraphs (b)(2) through (b)(5) of § 438.6; and

(2) The contract meets all the requirements of section 1903(m)(2)(A) of the Act, the applicable requirements of section 1932 of the Act, and the implementing regulations in this part.

(b) *MCO contracts.* Prior approval by CMS is a condition for FFP under any MCO contract that extends for less than one full year or that has a value equal to, or greater than, the following threshold amounts:

(1) For 1998, the threshold is $1,000,000.

(2) For subsequent years, the amount is increased by the percentage increase in the consumer price index for all urban consumers.

(c) FFP is not available in an MCO contract that does not have prior approval from CMS under paragraph (b) of this section.

§ 438.808 Exclusion of entities.

(a) *General rule.* FFP is available in payments under MCO contracts only if the State excludes from the contracts any entities described in paragraph (b) of this section.

(b) *Entities that must be excluded.* (1) An entity that could be excluded under section 1128(b)(8) of the Act as being controlled by a sanctioned individual.

(2) An entity that has a substantial contractual relationship as defined in § 431.55(h)(3) of this chapter, either directly or indirectly, with an individual convicted of certain crimes as described in section 1128(b)(8)(B) of the Act.

(3) An entity that employs or contracts, directly or indirectly, for the furnishing of health care, utilization review, medical social work, or administrative services, with one of the following:

(i) Any individual or entity excluded from participation in Federal health care programs under either section 1128 or section 1128A of the Act.

(ii) Any entity that would provide those services through an excluded individual or entity.

§ 438.810 Expenditures for enrollment broker services.

(a) *Terminology.* As used in this section—

Choice counseling means activities such as answering questions and providing information (in an unbiased manner) on available MCO, PIHP or PCCM delivery system options, and advising on what factors to consider when choosing among them and in selecting a primary care provider;

Enrollment activities means activities such as distributing, collecting, and processing enrollment materials and taking enrollments by phone or in person;

Enrollment broker means an individual or entity that performs choice counseling or enrollment activities, or both, and;

Enrollment services means choice counseling, or enrollment activities, or both.

(b) *Conditions that enrollment brokers must meet.* State expenditures for the use of enrollment brokers are considered necessary for the proper and efficient operation of the State plan and thus eligible for FFP only if the broker and its subcontractors meet the following conditions:

(1) *Independence.* The broker and its subcontractors are independent of any MCO, PIHP, PAHP, PCCM, or other health care provider in the State in which they provide enrollment services. A broker or subcontractor is not considered ''independent'' if it—

(i) Is an MCO, PIHP, PAHP, PCCM or other health care provider in the State;

(ii) Is owned or controlled by an MCO, PIHP, PAHP, PCCM, or other health care provider in the State; or

(iii) Owns or controls an MCO, PIHP, PAHP, PCCM or other health care provider in the State.

(2) *Freedom from conflict of interest.* The broker and its subcontractor are free from conflict of interest. A broker or subcontractor is not considered free from conflict of interest if any person who is the owner, employee, or consultant of the broker or subcontractor or has any contract with them—

(i) Has any direct or indirect financial interest in any entity or health care provider that furnishes services in the State in which the broker or subcontractor provides enrollment services;

(ii) Has been excluded from participation under title XVIII or XIX of the Act;

(iii) Has been debarred by any Federal agency; or

(iv) Has been, or is now, subject to civil money penalties under the Act.

(c) *Approval.* The initial contract or memorandum of agreement (MOA) for services performed by the broker has been reviewed and approved by CMS.

§ 438.812 Costs under risk and nonrisk contracts.

(a) Under a risk contract, the total amount the State agency pays for carrying out the contract provisions is a medical assistance cost.

(b) Under a nonrisk contract—

(1) The amount the State agency pays for the furnishing of medical services to eligible recipients is a medical assistance cost; and

(2) The amount the State agency pays for the contractor's performance of other functions is an administrative cost.

PART 440—SERVICES: GENERAL PROVISIONS

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

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

2. In subpart A, a new § 440.168 is added to read as follows:

§ 440.168 Primary care case management services.

(a) Primary care case management services means case management related services that—

(1) Include location, coordination, and monitoring of primary health care services; and

(2) Are provided under a contract between the State and either of the following:

(i) A PCCM who is a physician or may, at State option, be a physician assistant, nurse practitioner, or certified nurse-midwife.

(ii) A physician group practice, or an entity that employs or arranges with physicians to furnish the services.

(b) Primary care case management services may be offered by the State—

(1) As a voluntary option under the State plan; or

(2) On a mandatory basis under section 1932 (a)(1) of the Act or under section 1915(b) or section 1115 waiver authority.

PART 447—PAYMENTS FOR SERVICES

1. The authority citation for part 447 continues to read as follows:

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

2. A new § 447.46 is added to read as follows:

§ 447.46 Timely claims payment by MCOs.

(a) *Basis and scope.* This section implements section 1932(f) of the Act by specifying the rules and exceptions for prompt payment of claims by MCOs.

(b) *Definitions.* ''Claim'' and ''clean claim'' have the meaning given those terms in § 447.45.

(c) *Contract requirements.* (1) *Basic rule.* A contract with an MCO must provide that the organization will meet the requirements of §§ 447.45(d)(2) and (d)(3), and abide by the specifications of §§ 447.45(d)(5) and (d)(6).

(2) *Exception.* The MCO and its providers may, by mutual agreement, establish an alternative payment schedule.

(3) *Alternative schedule.* Any alternative schedule must be stipulated in the contract.

§ 447.53 [Amended]

3. Section 447.53 is amended as follows:

A. In paragraph (b) introductory text, the parenthetical phrase is removed.

B. Paragraph (b)(6) is removed.

C. A new paragraph (e) is added to read as follows:

§ 447.53 Applicability; specification; multiple charges.

* * * * *

(e) No provider may deny services, to an individual who is eligible for the services, on account of the individual's inability to pay the cost sharing.

§ 447.58 [Amended]

4. In § 447.58, ''Except for HMO services subject to the copayment exclusion in § 447.53(b)(6), if'' is removed and ''If'' is added in its place.

5. A new § 447.60 is added to subpart A to read as follows:

§ 447.60 Cost-sharing requirements for services furnished by MCOs.

Contracts with MCOs must provide that any cost-sharing charges the MCO imposes on Medicaid enrollees are in accordance with the requirements set forth in §§ 447.50 and 447.53 through 447.58 for cost-sharing charges imposed by the State agency.

§ 447.361 [Removed]

6. Section 447.361 is removed.

(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.

Dated: May 14, 2002.

Tommy G. Thompson,

Secretary.

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