

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-P]

RIN 0938-AK96

Medicaid Program; Medicaid Managed Care

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the Medicaid regulations published in the **Federal Register** on January 19, 2001 (66 FR 6228) setting forth policies 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. In addition, this proposed rule would expand on existing regulatory beneficiary protections provided to enrollees of prepaid health plans (PHPs) by requiring certain PHPs that provide services on an inpatient basis to meet specified BBA requirements that would not otherwise apply to these entities.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 4 p.m. on October 19, 2001.

ADDRESSES: Mail written comments (one original and three copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-2104-P, P.O. Box 8016, Baltimore, MD 21244-8016.

To ensure that mailed comments are received in time for us to consider them, please allow for possible delays in delivering them.

If you prefer, you may deliver (by hand or courier) your written comments (one original and three copies) to one of

the following addresses: Room 443-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5-16-03, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code CMS-2104-P. For information on viewing public comments see the beginning of the **SUPPLEMENTARY INFORMATION** section.

If you have comments on the information collection requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Information Services, DHES, SSG, Attn: Julie Brown, CMS-2001-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.

FOR FURTHER INFORMATION CONTACT: Part 438, Subparts A and B—Bruce Johnson: (410) 786-0615.

Subpart C—Tim Roe: (410) 786-2006
Subpart D—Ann Page: (410) 786-0083
Subpart F—Tim Roe: (410) 786-2006
Subpart H—Tim Roe: (410) 786-2006
Subpart I—Tim Roe: (410) 786-2006
Subpart J—Bruce Johnson (410) 786-0615

For other amendments—Dierdre Duzor (410) 786-4626

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at 7500 Security Blvd, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view the public comments, phone: (410) 786-7195.

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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 CFR 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" 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 (PHP)."

While the Act was further amended in the 1980's 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 law; (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 State 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.

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. Among other things, section 1932 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 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 eliminated a former statutory requirement that no more than 75 percent of the enrollees in an MCO be Medicaid or Medicare beneficiaries.

Section 4704 created section 1932(b) of the Act to add increased protections for those enrolled in managed care arrangements. These 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 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 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 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 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 allows States the option to provide 6 months of guaranteed eligibility for all individuals enrolled in an MCE.

Section 4710 specifies the effective dates for all the provisions identified in sections 4701 through 4709, 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, setting forth proposed regulations 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 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, we have prepared and are requesting public comment on the proposed rule that is set forth in this notice of proposed rulemaking. In addition, in order to give us the time in the coming months to consider the public comments and take final action on this rulemaking, we have also published in the August 17, 2001 **Federal Register** an interim final rule with comment period that further delays until August 16, 2002, the effective date of the January 2001 final rule with comment period.

We are publishing this new proposed rule to address some of the concerns that were expressed to the Department during our review, as well as to allow

additional opportunity for public comment. In developing this proposed rule, we have been guided by several considerations. First, we gave serious attention to all the concerns that have been communicated to us to date. We have tried to discern when a difference of opinion represented different goals or different methods of achieving the same goals. We believe that 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 have attempted to craft a regulation that will help States to achieve this goal.

Second, we have drafted the provisions of this 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 regulation 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.

Third, 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. That report provides a basis for some of the provisions in this proposed regulation.

The regulations in this proposed rule would mostly be set forth as new provisions in part 438 created in the January 19, 2001 final rule. 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. More detailed discussions of the content of each of the subparts of this proposed rule are found at the beginning of each subpart.

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 BBA, modification of the laws 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, in this proposed rule, we are proposing to require that certain PHPs meet most of the requirements that will 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 regulation 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. Similarly, we currently have two additional technical assistance projects underway. A contract with FACCT will produce in the Fall of 2001 a manual describing valid and reliable tools that State agencies can use to identify children and adults with special health care needs. 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 proposed 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 proposed rule adopts this direction in implementing the new requirements in the BBA, and, as discussed below, extends many of these requirements to certain PHPs.

Section 4710(c) 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 States 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 were in effect.

In the case of section 1115 demonstrations, while the "grandfather" provision in 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,

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 of DHHS 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

This proposed rule would amend the Medicaid regulations setting forth policies to implement provisions of the Balanced Budget Act of 1997 (BBA) that (1) 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; (2) establish new beneficiary protections in areas such as quality assurance, grievance rights, and coverage of emergency services; and (3) 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. In addition, this proposed rule would expand on existing regulatory beneficiary protections provided to enrollees of prepaid health plans (PHPs) by requiring certain PHPs that provide services on an inpatient basis to meet specified BBA requirements that would not otherwise apply to these entities.

Under our proposal, virtually all managed care regulations would be set forth in 42 CFR part 438. Some existing sections from part 434, would be moved to this part. We propose this restructuring to assist the reader in easily accessing all managed care regulations. The proposed new organizational format for part 438 is 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 (§ 438.1)

Section 438.1 of the regulations sets forth the basis and scope of part 438, including the fact that regulations in this part implement sections 1902(a)(4), 1903(m), 1905(t), and 1932 of the Act. Section 438.1 of the regulations also briefly describes these statutory provisions, and sets forth the scope of the applicability of these regulations.

2. Definitions (§ 438.2)

Section 438.2 includes definitions of terms that apply for the purpose of part 438. These definitions reflect revisions in terminology made in section 4701(b) of the BBA. The most significant of these changes is the use of the term Managed Care Organization (MCO) to refer to entities with comprehensive risk contracts that were formerly referred to by the term “health maintenance organization” (HMO). There is a new statutory definition of Medicaid MCO, which builds on the pre-BBA definition of HMO. As was the case for the pre-BBA definition of HMO, absent a statutory exemption, an entity must be found to meet the definition of MCO in order to enter into a Medicaid “comprehensive risk contract” (defined in § 430.5). The new statutory definition defines an MCO as one of several listed types of full risk arrangements (for example, HMOs, a provider sponsored organization, an “M+C organization” that contracts with Medicare) or any other “public or private entity” that complies with advanced directive requirements in section 1902(w) of the Act, and meets a modified version of the same two requirements included in the pre-BBA definition of HMO. The first of these two requirements, involving access to services covered under the contract, is unchanged by the BBA (see section 1903(m)(1)(A)(i) of the Act). The second requirement, involving meeting State-approved solvency standards, has been amended to require (with some exceptions discussed in section 3 below) that the MCO be licensed as an HMO or as a risk bearing entity (see section 1903(m)(1)(A)(ii) of the Act.) Finally, the new statutory definition provides that an entity that is a Federally-qualified HMO under title XIII of the Public Health Service Act is deemed to meet the above access and

solvency requirements (but not the advance directive requirements).

In § 438.2, we essentially have adopted the statutory definition of MCO. Because the managed care entities specifically listed in the revised version of section 1903(m)(1)(A) of the Act all necessarily fall within the category “public or private organization,” our definition refers only to a “public or private entity” that meets the requirements in question. Because Federally qualified HMOs are deemed to meet the access and solvency requirements in sections 1903(m)(1)(A)(i), (m)(1)(A)(ii), and (m)(1)(C) of the Act, we do not apply these requirements to Federally qualified HMOs in our definition of MCO. Finally, we have retained a third requirement from the current regulation implementing the pre-BBA definition of HMO (see § 434.20(c)(1)). This provision requires that the entity be organized primarily for the purpose of providing health care services.

Section 438.2 of the regulations also includes existing definitions of current managed care terms, and the statutory definitions of primary care case management and primary care case manager from the BBA. We have not included the term “managed care entity” in the definitions or the text of the regulation. This term was used in the BBA to include MCOs and PCCMs. However, for purpose of clarity in the proposed rule, we have specified in the text of the regulation whether each specific provision applies to MCOs, PCCMs or both.

While most existing managed care definitions are unchanged, we are proposing to split the current designation of prepaid health plans (PHPs) into two new types of entities. We rely upon the authority in section 1902(a)(4) of the Act to permit States to contract with PHPs and to establish the requirements that these entities must meet. The earliest PHPs in Medicaid managed care programs were predominantly the equivalent of a capitated PCCM. Over the years, States have developed programs using capitated reimbursement for much larger delivery systems, most notably in the area of behavioral health. These contracts may include a portion of the inpatient hospital benefit, as well as physician, outpatient, and some other limited Medicaid services. States have also developed PHPs to deliver transportation services and contracted with dental PHPs to expand access to dental care for the Medicaid population. We have recently reviewed proposals to contract for institutional long-term care

services on a risk basis. Based on these developments, we have concluded that it is no longer appropriate to describe all of these models in the same way or subject them all to the same requirements.

In this proposed rule, we have eliminated the term PHP and replaced it with two types of entities—Prepaid Inpatient Health Plans (PIHPs), and Prepaid Ambulatory Health Plans (PAHPs). “Prepaid inpatient health plan” (PIHP) means an entity that provides medical service on the basis of capitation or other non-State plan payment rates, is responsible for any inpatient hospital or institutional services, and does not have a comprehensive risk contract. “Prepaid ambulatory health plan” (“PAHP”) means an entity that provides medical service on the basis of capitation or other non-State plan payment rates, is not responsible for any inpatient or institutional services, and does not have a comprehensive risk contract.

These two definitions include all entities that were previously defined as PHPs, but make a distinction between (1) those responsible for at least some (but not all) inpatient hospital or institutional care an enrollee receives, as in the case of a large behavioral health plans, and (2) those that are not, such as dental or transportation plans and capitated PCCMs. The requirements that each type of entity must meet are set forth in § 438.8. By making the distinction between these two types of entities, we are able to impose requirements that more accurately reflect the scope of benefits that they contract to provide. We are seeking comments on whether prepaid contracts that include home and community based services should be subject to the additional MCO-like requirements that we have proposed to apply to PIHPs.

The new requirements enacted by the Congress in the BBA apply to managed care arrangements in one or more of three ways. First, section 1903(m)(2)(A)(xi) of the Act requires that MCOs and MCO contracts comply with all applicable requirements in the new section 1932 of the Act enacted by the BBA. Thus, unless the above-discussed “grandfather provision” in section 4710(c) of the BBA applies to the requirement in question, these requirements apply to an MCO whether the MCO is participating in a mandatory managed care enrollment program or is offered as a purely voluntary enrollment option.

Requirements in section 1932 of the Act also apply as conditions for meeting the definition of “primary care case manager” (which incorporates the

definition of “primary care case management contract” requiring compliance with requirements in section 1932 of the Act). Meeting this definition is required in order for a non-MCO to participate as an enrollment option under a mandatory managed care enrollment program under section 1932(a) of the Act. Meeting this definition also makes an entity eligible for automatic re-enrollment under section 1903(m)(2)(H) of the Act, whether enrollment was originally voluntary or mandatory. Finally, meeting this definition permits an entity to offer “primary care case management services” as a State plan service under section 1905(a)(25) of the Act.

Certain requirements in section 1932 of the Act apply only in the context of a mandatory managed care enrollment program under section 1932(a) of the Act. The latter includes specific requirements on comparative information, as found in § 438.10(h); and methods for establishing certain enrollment practices and the default enrollment process, as found in § 438.50.

The terms MCO and PCCM are used in the statute to identify where different requirements apply only to that entity. (As discussed above, the term “managed care entity” is used to describe requirements that apply both to MCOs and PCCMs.) As proposed in § 438.2, an MCO is either a Federally qualified HMO or any other public or private entity that is organized primarily for the purpose of providing health care services, 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 beneficiaries within the area served by the entity, and meets the solvency standards of § 438.116. Thus, in general, HMOs that participate in Medicaid would be considered as MCOs. For purposes of this rule, as described in detail under § 438.8(a), most requirements that would apply to MCOs would also apply to PIHPs. Section 438.8(b) contains requirements that apply to PAHPs.

3. Contract Requirements (§ 438.6)

Proposed § 438.6 contains most of the existing managed care provisions currently found in part 434, revised to reflect changes made by the BBA.

Proposed § 438.6(a) clarifies that the CMS Regional Office must review and approve all MCO, PIHP, and PAHP contracts, including those that, on the basis of their value, are not subject to the prior approval requirement in § 438.806.

Section 438.6(b), like the current § 434.20(a), proposes that State agencies may enter into comprehensive risk contracts only with certain specified entities. In addition to entities meeting the definition of MCO, certain other entities are listed that either are exempt from the requirement in section 1903(m)(1)(A) of the Act that comprehensive risk contractors meet the definition of MCO, or are exempt altogether from the statutory requirements in section 1903(m)(2)(A) of the Act, and from the requirements in this proposed rule.

Proposed § 438.6(c) addresses the computation of capitation payments. We are proposing to delete the upper payment limit requirement for risk contracts in existing § 447.361 and create a new § 438.6(c), *Payments under risk contracts*, which: (1) Does not include a UPL; (2) requires actuarial certification of capitation rates; (3) specifies data elements that must be included in the methodology used to set capitation rates; (4) requires States to consider the costs for individuals with special health care needs or catastrophic claims in developing rates; (5) requires States to provide explanations of risk sharing or incentive methodologies; and (6) imposes special rules, including a limitation on the amount that can be paid under FFP in some of these arrangements.

We believe that the UPL is no longer an effective tool for purposes of judging capitated payment rates. Many States no longer have fee-for-service base year data recent enough to use as a reasonable comparison to the costs of a current capitated managed care system, and the UPL may not account for the cost of all services expected to be delivered under an MCO contract.

In these changes, we are proposing that we move from a review that compares capitation rates in risk contracts to the historical fee-for-service cost of the services under contract for an actuarially equivalent non-enrolled population, to a review of the utilization and cost assumptions and methodology used by the state to set the actual capitation rates. Eliminating the UPL requirement removes what has become a barrier to effective managed care contracting in some areas, and increasingly irrelevant as a regulatory tool. We also believe that this change could result in a more appropriate review of capitation rates by examining how the rates have been established rather than how they compare to an increasingly difficult to establish fee-for-service equivalent.

This change does not affect the rules governing UPLs for other types of

providers or services including the currently applicable provisions in §§ 447.272, 447.304, and 447.321 or those in a final rule published in the **Federal Register** (66 FR 3148) on January 12, 2001 on payments to hospitals, nursing facilities, intermediate care facilities for the mentally retarded, and clinics. Nor will this change affect the UPL for nonrisk contracts in § 447.362, which remains in effect.

As set forth above, FFP is only available for risk contracts to the extent that payments are determined on an actuarially sound basis. Under these provisions, we have determined that where total payments exceed 105 percent of the capitation payments paid under the contract, these payments are no longer actuarially sound. Thus, no FFP would be available for payments resulting from risk corridors or incentive arrangements for amounts that exceed 105 percent of the capitation payments made under the contract. If the risk corridor or incentive arrangement does not apply to all enrollees or services under the contract, the 105 percent limit is based only in that portion of the total capitation payments for the enrollees or services covered by the arrangement. States could make payments under these arrangements with their own funds, but would be precluded from claiming FFP for these payments.

This limitation protects the Federal government against potentially unlimited exposure under risk corridor or bonus arrangements. This is particularly important since the "cost-effectiveness" requirement in section 1915(b) and the "budget neutrality" standard imposed under section 1115(a) demonstrations generally do not contain an outright limit on the Federal share of expenditures under the contract. And, neither of these limits apply to voluntary managed care contracts under section 1915(a) or contracts for mandatory enrollment under section 1932(a)(1)(A) using State plan authority.

Without any upper limit on the amount that can be paid in incentive arrangements or risk sharing mechanisms the potential exists for inefficiency or inappropriate actions by the contractor to maximize funding, resulting in rates that bear no relationship to those certified by actuaries, and that, thus, are no longer "actuarially sound." We have proposed limitations in §§ 438.6(c)(5)(ii) and 438.814 as a workable alternative to the current UPL which meets the following criteria: (1) It provides a clear consistent rule that can be applied to all risk contracts, regardless of the authority

under which the contract operates (waiver or otherwise); (2) it should not discourage the use of any of these arrangements; (3) it explicitly conditions Federal matching on the imposition of these limits under any of these arrangements to prevent any potential abuses; and (4) it can be easily administered. Similarly, proposed § 438.60 also clarifies that a State may not make payments directly to providers for services that are available under its contracts with MCOs, PIHPs, or PAHPs, except where these payments are provided for in Federal statute or regulation. This provision is intended to preclude duplicate or supplemental payments for amounts that should be included in the capitation rate.

Although not part of this proposed rule, we also are planning to revise the policies governing cost effectiveness for section 1915(b) waiver programs. The current regulations at § 431.55, which require waiver programs to be cost effective and efficient and require States to document this cost effectiveness of their waiver programs, will remain unchanged. However, HCFA is modifying the process by which States document this cost effectiveness through re-issuance of State Medicaid Manual provisions and revision of the section 1915(b) Medicaid waiver applications. The revised waiver cost effectiveness test will apply to all waivers under section 1915(b) of the Act, regardless of the payment system, such as capitation or fee-for-service.

Section 438.6(d) includes the enrollment requirements currently in § 434.25. We specify that an MCO, PIHP, PAHP, or PCCM contract must provide for an open enrollment period when 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 specified in the contract. In § 438.6(d)(2), we have added language expressly providing for exceptions to the requirement that enrollment be voluntary.

Section 438.6(e) includes language currently in § 434.20(d) and provides that an MCO contract may cover services not provided under the State plan to enrolled beneficiaries. If enrollment is voluntary, the additional services may, under section 1915(a) of the Act, be provided without regard to statewideness and comparability. If enrollment is mandated under section 1932(a) of the Act, the statute provides that contracts can be carried out without regard to statewideness and comparability requirements. If enrollment is mandated under sections

1915(b) or 1115 of the Act, CMS can waive statewideness and comparability requirements if additional services are offered.

Section 438.6(f) would retain the requirement currently found in § 434.20(e)(1), that contracts comply with the general contract requirements in § 438.6, and has been expanded to specify Federal anti-discrimination statutes with which contracts must comply.

Section 438.6(g) contains the current requirement in § 434.38 that risk contracts must provide the Medicaid agency and the Department of Health and Human Services, including CMS, the right to inspect or audit financial records of the MCO or its subcontractors.

Proposed § 438.6(h) would implement the physician incentive plan requirements in section 1903(m)(2)(A)(x) of the Act, which currently are implemented in existing paragraphs (2) through (4) of § 434.70(a) of the regulations. We propose to expand this requirement to apply to PIHPs and PAHPs, both of which may contract with physicians and put them at financial risk. Section 1903(m)(2)(A)(x) of the Act requires that MCOs comply with the physician incentive plan requirements in section 1876(i)(8) of the Act, which prior to 1999, applied to entities with Medicare risk contracts under section 1876 of the Act. Section 1876(i)(8) of the Act prohibits certain physician incentive payments and requires incentive plans that place physicians at "substantial financial risk" for services they do not provide to conduct enrollee surveys, and provide "adequate and appropriate" stop-loss protection. Section 1876(i)(8) of the Act was implemented in § 417.479, which defines "substantial financial risk" and "adequate and appropriate" stop-loss protection. The current Medicaid physician incentive plan provisions in paragraphs (a)(2) through (a)(4) of § 434.70 reference § 417.479.

On January 1, 1999, however, Medicare risk contractors were required to enter into Medicare+Choice (M+C) contracts under Part C of Title XVIII if they wished to continue to contract with Medicare. The physician incentive rules in part 417 of the regulations that implemented section 1876(i)(8) of the Act no longer apply and will be removed from the Code of Federal Regulations.

Section 1852(j)(4) of the Act, which applies to M+C organizations, contains the same substantive requirements governing physician incentive plans as section 1876(i)(8) of the Act. We have

implemented section 1852(j)(4) in M+C regulations in part 422. While the substantive requirements and standards in section 1852(j)(4) of the Act are identical to those in section 1876(i)(8) of the Act, the regulations in part 422 implementing section 1852(j)(4) of the Act differ from those in part 417 implementing section 1876(i)(8) of the Act in one significant respect. Because the data in question are now available from other sources, we deleted a reporting requirement involving capitation arrangements. (See 63 FR 35002.) Because the regulations in part 417 have not applied to Medicare contracts since 1998, we did not revise the regulations in part 417 to eliminate this reporting requirement.

Even though the Medicaid statute continues to cite section 1876(i)(8) of the Act, proposed § 438.6(g) incorporates the regulations in part 422 that implement nearly identical statutory language, and the same substantive requirements, as set forth in section 1852(j)(4) of the Act.

Section 438.6(i) contains the "advance directive" requirements currently found in § 434.28, which also must be met in order for an entity to qualify as an MCO or PIHP.

Section 438.6(j) would implement the statutory requirement that "HIOs" that began operating on or after January 1, 1986 and are not otherwise exempted by statute, comply with all requirements in section 1903(m)(2)(A) of the Act if they have a comprehensive risk contract, including the requirement that they meet the definition of MCO. This provision would replace the current § 434.44.

Section 438.6(k) specifies additional rules that apply to contracts with primary care case managers. These rules relate to the provision of care and services within reasonable and adequate hours of operation; specification for arrangements or referral to other physicians or practitioners; prohibitions on discrimination in enrollment, disenrollment, or re-enrollment; and provisions on enrollee rights to disenroll.

Section 438.6(l) incorporates terminology currently in § 434.6(a)(ii)(b) on subcontracts. Section 438.6(m) incorporates terminology currently in § 434.29 on choice of health professionals.

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

In this proposed rule, we propose to eliminate the term PHP and replaced it with two types of entities—Prepaid Inpatient Health Plans (PIHPs), and Prepaid Ambulatory Health Plans

(PAHPs). A PIHP is an entity that provides medical services to enrollees, under a contract with the State agency that is not risk comprehensive, but for which payment is made on a prepaid capitation basis or other payment arrangements that do not use State plan payment rates, and in which the entity provides, arranges for, or is otherwise responsible for the provision of, any inpatient hospital or institutional services for its enrollees. Like a PIHP, a PAHP is an entity that provides medical services to enrollees, under a contract with the State agency that is not risk comprehensive, and for which payments are made on the basis of prepaid capitation payments or other payment arrangements that do not use State plan payment rates. However, unlike a PIHP, a PAHP the entity does not provide or arrange for, and is not otherwise responsible for the provision of any inpatient hospital services for its enrollees. All entities that met the definition of PHP under part 434 will meet one of these definitions in § 438.8.

Title XIX does not specifically address State contracts with PHPs (now PIHPs or PAHPs), and thus does not impose requirements on these entities. Instead, we have relied upon section 1902(a)(4) of the Act for the authority to publish regulations governing these entities. This section of the Act provides the Secretary with discretion to specify methods of administration determined to be necessary for proper and efficient operation of State Medicaid programs. Under that authority we are now substituting the terms PIHP and PAHP and proposing to apply specific provisions of this proposed rule to each of these entities.

This change, from the approach taken in the January 19, 2000 final rule, which applied most of these requirements to all PHPs, is warranted for several reasons. First, the scope of services under PHP contracts with States has greatly expanded over the years. The earliest PHPs in Medicaid managed care programs were predominantly capitated PCCMs. States have developed programs using capitated reimbursement for much larger delivery systems, most notably in the area of behavioral health. These contracts may include a portion of the inpatient hospital benefit, as well as physician, outpatient, and some other limited Medicaid services. More than two-thirds of all current PHP contracts are of this type. States have also developed PHPs to deliver transportation services and found that contracting with dental PHPs provides an opportunity to expand access to dental care for the Medicaid population. We have recently reviewed proposals to

contract for institutional long-term care services on a risk basis. Based on these developments, we have concluded that it is no longer appropriate to describe all of these models in the same way or subject them all to the same requirements.

Second, the BBA and this proposed rule contain many significant beneficiary protections that were intended to apply to MCOs and States contracting with MCOs. We believe that these protections are also appropriate for those PHPs that are responsible for a benefit package that closely resembles the risk comprehensive range of services provided by MCOs. However, where PHPs contract to provide a much more limited array of services, such as transportation or dental care, we believe applying the same requirements would not be appropriate. Thus we are making a distinction between these two types of entities based on whether they are responsible for all or some of the inpatient hospital or institutional services needed by their enrollees.

In § 438.8(a), we propose to make PIHPs subject to nearly all of the requirements that apply to MCOs, including: the contract requirements of § 438.6, except for requirements that pertain to HIOs; the information requirements in § 438.10; the provision against provider discrimination in § 438.12; the State responsibility provisions of subpart B, except § 438.50; the enrollee rights and protection provisions in subpart C of this part; the quality assessment and performance improvement requirements in subpart D of this part to the extent that they are applicable to services furnished by the PIHP; the grievance system provisions in subpart F of this part; and the certification and program integrity protection provisions in subpart H of this part.

Under proposed § 438.8(a)(6), the State agency would have to require, at a minimum, through its contract, that the PIHP meet all of the requirements that MCOs must meet relating to minimum performance levels and performance improvement levels that apply to services furnished by the PIHP. The nature of some PIHPs may not allow them to report on performance measures in all of the clinical and non-clinical areas as MCOs can. Also, some PIHPs may not be able to undertake performance projects in the same clinical areas as MCOs can address. The State agency would be required to evaluate the applicability of the MCO performance measures and improvement project areas when establishing the PIHP's contractual

obligations for its quality assessment and performance improvement program.

In proposed § 438.8(b) we would make PAHPs subject to the following requirements: the contract requirements of § 438.6, except for requirements for advance directives and those that pertain to HIOs; designated portions of the information requirements in § 438.10; the provision against provider discrimination in § 438.12; the State responsibility provisions of subpart B, except § 438.50; designated portions of subpart C on enrollee rights and protections; and § 438.206(a) on availability of services.

We have not applied the provisions for sanctions in subpart I to PIHPs or PAHPs (except to the extent that they contract as PCCMs, in which case designated provisions apply). This does not, however, preclude States from applying sanctions to PIHPs and/or PAHPs with which they contract. Similarly, we have not specifically applied the Conditions for FFP in subpart J to PIHPs or PAHPs, since these provisions govern the Federal-State relationship rather than the State-contractor relationship. Nonetheless, provisions governing the availability of FFP to a State may have an impact on the contract a State implements with a PIHP and a PAHP, such as the provisions in § 438.812 governing costs under risk and nonrisk contracts and in § 438.814 governing the limit on payment in excess of capitation rates.

We believe that this two-tiered approach provides the flexibility necessary for innovative contracting by States while applying regulatory requirements that are appropriate to the range of services under the contract. We note that a primary care case manager as defined in section 1905(t)(2) of the Act, could also meet the definition of a PAHP and be subject to the requirements in § 438.8(b). In this case, the primary care case manager would be both a PAHP and a PCCM. This entity would be subject to the requirements in § 438.6(k) and § 438.8(b).

While we are proposing to apply MCO requirements to PIHPs and PAHPs, State agencies would still be free to apply for Federal waiver authority, under sections 1915(b) or 1115 of the Act, to seek relief from some of the provisions. For example, a State agency may request 1915(b) waiver authority for a behavioral health managed care program in which enrollees are mandated to use a single behavioral health PIHP. In this instance, the Secretary has the discretionary authority to waive freedom of choice, under section 1902(a)(23) of the Act, and the right to disenroll in part 438 (for PIHPs and

PAHPs is authorized under section 1902(a)(4) of the Act, and therefore, can be waived) to enable the State agency to establish or continue these programs.

5. Information Requirements (§ 438.10)

Section 438.10(b) contains the basic rule that all enrollment notices and informational and instructional materials relating to enrollment in MCOs, PIHPs, PAHPs, and PCCMs must be provided in a manner and form that are easily understood by Medicaid enrollees and potential enrollees. As a general rule, each State agency, MCO, PIHP, PAHP, PCCM, and enrollment broker must meet the requirements of § 438.10 that pertain to language and format requirements (as specified in § 438.10(c) and (d)). However, a distinction is made within the regulation as to which information needs to be provided to an enrollee or a potential enrollee. We have defined these terms in § 438.10(a). And we have made a distinction between which information needs to be provided to all managed care enrollees and which information needs to be provided only to MCO and PIHP enrollees. Finally, we have identified some information that only has to be made available upon request.

In § 438.10(c) we propose requirements for the languages in which information would have to be made available. We are proposing to require that State agencies establish a methodology for determining the prevalent languages spoken by populations in a geographic area and include provisions in their MCO, PIHP, PAHP, or PCCM contracts to ensure that written materials are available in those specified languages. States have discretion to determine criteria for when a language is "prevalent" for purposes of this requirement, as long as they comply with the requirements of Title VI of the Civil Rights Act of 1964. For technical assistance, States may contact the HHS Office of Civil Rights. Enrollees and potential enrollees must be informed about how to obtain written information published in prevalent languages in that area. Specific methodologies, such as those based upon a consideration of geographic composition, population density, or enrolled population are not imposed by this regulation, as the most appropriate approach to fulfilling this requirement may vary from State to State. However, we are proposing that the State agency, enrollment broker, MCO, PIHP, PAHP, and PCCM be required to have oral interpretation services available free of charge for each enrollee and potential enrollee who has limited English

proficiency, and that enrollees and potential enrollees be informed about how to obtain these services.

In § 438.10(d), we propose to implement the requirement in section 1932(a)(5)(A) of the Act that all written information be provided in an easily understood language and format. Generally, materials should be understandable to enrollees at a fourth-fifth grade reading level, or at another level established by the State agency that adequately reflects the potential population to be enrolled. Materials should use an easily readable typeface (for example, 14 point), frequent headings, and should provide short, simple explanations of key concepts. Technical or legal language should be avoided whenever possible. Use of focus groups and cognitive testing may be beneficial in determining the appropriateness of the information. In addition, in § 438.10(d)(1)(i) and (ii), we propose that enrollment notices as well as informational and instructional materials relating to enrollment in MCOs, PIHPs, PAHPs, and PCCMs take into account the specific needs of enrollees and potential enrollees. This would include furnishing information in alternative formats for the visually impaired (through other media such as, large print, Braille, or audio tapes) and for individuals with limited reading proficiency (through video or audio tapes).

In § 438.10(e) we propose to require the State to provide certain information to potential enrollees. While section 1932(a)(5)(B) requires MCOs and PCCMs to make information available to enrollees and potential enrollees "upon request," we believe it is important to ensure that potential enrollees have certain information prior to enrollment, so they may make an informed choice. It would be unreasonable, however, to require every MCO, PIHP, PAHP or PCCM to provide the relevant information to all potential enrollees. The State agency is the more appropriate entity to do so. Therefore, under authority in section 1902(a)(4) of the Act to provide for necessary and proper methods of administration, we propose in § 438.10(e) that the State (or its contracted representative) be required to provide the information described below to each potential enrollee.

The required information includes general information about the basic features of managed care; which populations are excluded from enrollment, subject to mandatory enrollment, or free to enroll voluntarily in the MCOs, PIHPs, PAHPs and PCCMs; and MCO, PIHP, PAHP and

PCCM responsibilities for coordination of enrollee care. In addition, § 438.10(e)(2)(ii) proposes to require the State to provide at least summary information specific to each MCO, PIHP, and PAHP, and for PCCM programs in the potential enrollee's service area, including benefits covered, cost sharing, service area, network provider information, and benefits covered under the State plan but not available under the contract.

In § 438.10(f), we propose to require MCOs, PIHPs, PAHPs, and PCCMs or States on behalf of their PCCM programs, to provide certain information to their own enrollees. We have proposed this requirement because we do not believe that enrollees can effectively access their benefits if they are not furnished adequate information concerning these fundamental elements as enrollees' rights and responsibilities. Further, it is our belief that it is not sufficient for this information to merely be "available" at designated locations. Therefore, in keeping with the Congress' intent to provide adequate information to actual enrollees, under the authority in section 1902(a)(4), we propose to require these entities to provide basic information that all enrollees should have. In addition, we propose in paragraphs (f)(1) through (f)(5) to require specific timeframes for the provision of specific information, such as disenrollment rights, and changes in providers or operations of the managed care program. Paragraph (f)(2) specifically would require MCOs, PIHPs, PAHPs, PCCMs or the State to notify enrollees annually of their right to request information listed in paragraphs (f) and (g) of this section (as applicable).

In proposed § 438.10(f)(6), we set forth the type of information that, under section 1932(a)(5)(B) of the Act, MCOs and PCCMs must provide to enrollees. We are proposing in § 438.10(f)(6) to require that the information must also be furnished to enrollees of PIHPs and PAHPs. This information must include at least the following:

- Names, locations and telephone numbers of current network providers, including identification of those who speak languages other than English and those who are not accepting new patients. At a minimum, information on the provider networks should include information on primary care physicians, specialists, and hospitals. We also suggest that information be provided regarding ancillary care providers on which enrollees with special health care needs may be dependent for care. If this information is not included, information must be provided to enrollees

explaining how they can obtain this supplemental information. Enrollees making a decision about whether to enroll in a particular MCO, PIHP, PAHP, or PCCM may rely on the provider listing in making their selection, and may assume that they will be able to obtain covered services from any of the providers listed. Therefore, if a provider is not accepting new Medicaid enrollees, this must be clearly indicated, as this provider may not be a choice for new enrollees.

- Any restriction on the enrollee's freedom of choice among network providers. It is essential that the MCO's, PIHP's, PAHP's, or PCCM program's informational materials emphasize any limitations on enrollees' provider selections. If an MCO, PIHP, PAHP, or PCCM program contracts with formal subnetworks, or the entity's arrangement with primary care providers allow for the establishment of informal subnetworks, the informational materials must clearly indicate which providers are available under each subnetwork. The materials must also explain the procedures under which an enrollee may request referral to an affiliated provider not included in the subnetwork.

- Enrollee rights as described in § 438.100.

- Grievance and fair hearing procedures.

- Benefits offered, and the amount, duration, and scope of benefits and services available under the contract. Sufficient detail should be furnished to ensure that beneficiaries receive the services to which they are entitled, such as pharmaceuticals, mental health, and substance abuse services.

- Procedures for obtaining services, including authorization requirements. These procedures must include the procedures for obtaining pharmaceuticals and mental health and substance abuse services, as well as the procedure for obtaining out-of-area coverage.

- The extent to which an enrollee may obtain services from out-of-network providers. For example, enrollees should be notified of their right to obtain family planning services from any Medicaid-participating provider (unless otherwise restricted).

- Provisions for coverage of after-hours, emergency, and post-stabilization services.

- Policies on referrals for specialty care and other services not furnished by the enrollee's primary care provider.

- Cost sharing, if any.

- Any benefits to which they may be entitled under the Medicaid program, but that are not made available to them

through the MCO, PIHP, PAHP, or PCCM. For example, enrollees would have to be provided notice about how to access mental health coverage if it is not a service covered by the MCO, PIHP, PAHP, or PCCM or if the entity provides only limited coverage. This information would have to be provided either directly by the State agency or through the MCO, PIHP, PAHP, or PCCM. The notice would have to provide information on where and how enrollees may access benefits such as mental health coverage not available through the entity. In addition, this notice would be required to include information on how transportation services not covered by the MCO, PIHP, PAHP, or PCCM would be furnished.

While State agencies would be required to develop grievance and appeal processes for enrollees in accordance with subpart F of part 438, this proposed requirement is not meant to imply that State agencies must establish grievance and appeal processes for individual health care providers. However, if these processes exist, information on the processes must be made available to enrollees and potential enrollees in accordance with the requirements of this section.

Proposed § 438.10(g) would require MCOs and PIHPs to provide additional information to their enrollees, based on provisions that apply only to those types of entities. This information must be provided by the MCO or PIHP except where prohibited by the State agency through restrictions on marketing or some other means (in which case the State agency or subcontractor of the State agency must provide the information). MCOs and PIHPs would be required to provide information on grievance, appeal and fair hearing procedures and timeframes in § 438.400. This includes the following:

- The right to a State fair hearing, the method for obtaining a State fair hearing, and the rules that govern representation at the hearing.

- The right to file grievances and appeals.

- The requirements and timeframes for filing a grievance or appeal.

- The availability of assistance in the filing process.

- The toll-free numbers that the enrollee can use to file a grievance or an appeal by phone.

- The fact that, when requested by the enrollee, benefits will continue if the enrollee files an appeal or a request for State fair hearing within the timeframes specified for filing; and that 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.

Further, if the State agency chooses to furnish appeal rights to providers, it must provide MCO and PIHP enrollees information on these appeal rights. We note that while section 1932(a)(5)(A)(ii) of the Act provides for furnishing information on "procedures available to * * * a health care provider to challenge or appeal" an MCO decision, there is no Federal Medicaid requirement that these procedures be provided by MCOs or PIHPs. To the contrary, as discussed below, the requirement in section 1932(b)(4) of the Act that MCOs have grievance procedures refers to rights extended to an enrollee "or a provider on behalf of an enrollee."

MCOs and PIHPs are also required to provide information on advance directives, physician incentive plans, and upon request, information on the structure and operation of the entity as follows:

- Health plans' and health care facilities' licensure, certification, and accreditation status; and
- Information on health professionals, including but not limited to, education and board certification and recertification.
- Other information on accessing services, including physical accessibility and non-English languages spoken
- A description of procedures to control utilization and expenditures
- A summary of the method for compensating physicians.

We are distinguishing between information that must be furnished to all enrollees and information furnished on request because it is our belief that some information is not typically used by enrollees in selecting a provider. By making the information available by request, interested beneficiaries can obtain the information, and MCOs and PIHPs are not required to furnish information that will not be used.

Proposed § 438.10(h) would implement section 1932(a)(5)(C) of the Act, which requires that comparative information be provided by State agencies that implement mandatory managed care programs under the authority in section 1932(a)(1)(A) of the Act. Under proposed § 438.10(h), this information would be provided directly by the State agency, or through the MCO or PCCM at least annually, as well as upon request. The information must be presented in a comparative chart-like form that facilitates comparison among MCOs and PCCMs and must be available in the prevalent languages (as determined by the State) spoken by

populations in the geographic area. It should include the following information for each MCO or PCCM: (1) The service area of the MCO or PCCM; (2) the benefits covered; (3) any cost-sharing imposed by the MCO or PCCM; and (4) to the extent available, quality and performance indicators, including, but not limited to, disenrollment rates, as defined by the State agency and consumer satisfaction. State agencies must specify the meaning of "disenrollment rates" and the voluntary disenrollment from one plan to another plan.

6. Provider Discrimination (§ 438.12)

Proposed § 438.12 would reflect the anti-discrimination provisions in section 1932(b)(7) of the Act. Those provisions state that an MCO must not discriminate with respect to participation, reimbursement, or indemnification as to any provider who is acting within the scope of the provider's license or certification under applicable State law, solely on the basis of the license or certification. Section 1932(b)(7) also states, that this provision does not prohibit an organization from including providers only to the extent necessary to meet the needs of the MCO's enrollees, from establishing different payment rates, or from establishing measures designed to maintain quality and control costs consistent with the responsibilities of the MCO.

Proposed § 438.12 must not be construed as an "any willing provider" provision. We believe that in section 1932(b)(7) of the Act the Congress intended only to ensure that MCOs do not adopt arbitrary policies concerning non-physician providers who, in the past, may have been discriminated against because they do not hold the same licenses and certifications as practicing physicians. Any discriminatory actions may have provided beneficiaries with fewer choices and may have reduced beneficiaries' overall access to quality health care. Accordingly, under proposed § 438.12, MCOs and, under the authority in section 1902(a)(4) of the Act, PIHPs would be required to implement policies for provider participation, reimbursement, and indemnification that are not arbitrary, but rather relate to quality factors such as outcome measures and satisfaction surveys, cost factors, and other legitimate business concerns.

We also propose in § 438.12 that an MCO or PIHP that declines to include individual or groups of providers in its network must give the provider written notice of the reason for its decision.

B. State Responsibilities (Subpart B)

1. State Plan Requirements (§ 438.50)

Proposed § 438.50 would implement section 1932(a)(1)(A) of the Act, which permits State agencies to enroll their Medicaid beneficiaries in an MCO or PCCM on a mandatory basis without a waiver under sections 1915(b) or 1115 of the Act. Under section 1932(a)(1)(A) of the Act and proposed § 438.50, a State agency no longer needs to request, obtain, and seek periodic renewal of CMS waivers to restrict freedom of choice for most Medicaid beneficiaries. Rather, a State agency may amend its Medicaid plan to require these Medicaid beneficiaries to enroll in MCOs or PCCMs, without being out of compliance with the freedom of choice, statewideness, or comparability of services requirements.

We are requiring State agencies to submit a Medicaid State plan amendment to implement the managed care provisions under section 1932(a) of the Act and the implementing regulations at § 438.50. As specified in the current regulations at § 430.16, we must make a decision to approve or disapprove a State agency's request within 90 days of receipt of the State plan amendment, or we may request additional information from the State agency. If we ask for additional information, we must make a decision to approve or disapprove a State plan amendment within 90 days of receipt of the State agency's response to the additional information request. As with other State plan amendments, the effective date provisions specified in the current regulations at §§ 430.20 and 447.256 apply to State plan amendments submitted to implement a section 1932(a) of the Act request. Thus, section 1932(a) State plan amendments may be effective as early as the first day of the quarter in which a State plan amendment is submitted to CMS.

Under proposed § 438.50(b), we identify what the State plan would be required to specify, including the payment method, whether the State contracts on a comprehensive risk basis, and how the State involves the public. Under paragraph (c), State agencies wishing to utilize the authority in § 438.50 would be required to provide assurances of State compliance with all applicable requirements.

Proposed § 438.50(d) reflects the statutory exclusion of the following populations from mandatory managed care enrollment under the State plan option in section 1932(a) of the Act:

- Dual Medicare-Medicaid eligibles.
- Indians who are members of Federally-recognized tribes except when

the MCO or PCCM is either the Indian Health Service or an Indian Health program operated by a tribe or tribal organization under a contract, grant, cooperative agreement, or compact with The Indian Health Service.

- Children (under 19 years of age) who are—
- eligible for Supplemental Security Income benefits under Title XVI of the Act;
- described in section 1902(e)(3) of the Act;
- in foster care or other out-of-home placement;
- receiving foster care or adoption assistance; or
- receiving services through a family-centered, community-based, coordinated care system receiving grant funds under section 501(a)(1)(D) of the Act.

While State agencies are prohibited from enrolling the above groups under the State plan option, a State agency may permit voluntary enrollment of these individuals in a program authorized under section 1932(a) of the Act or use a section 1915(b) waiver or section 1115 demonstration authority to mandate enrollment for these individuals in a managed care system. Under section 1915(b) or section 1115 authority, a State agency would be required to demonstrate how the individuals' special needs and circumstances would be met under the managed care arrangements. There is a growing body of State experience and best practices regarding enrollment of these groups. We will use this knowledge when evaluating whether a particular State's waiver or demonstration request demonstrates that their program will adequately address the needs and complexities of these groups, that set them apart from the groups that can be mandatorily enrolled without a waiver.

The requirements in paragraph (e) reflect the requirements in section 1932(a)(4)(C) on enrollment priorities. For beneficiaries enrolled under the State plan option under section 1932(a)(1) of the Act, the State agency must establish a method whereby individuals already enrolled with an MCO or PCCM must be given priority to continue that enrollment where the MCO or PCCM does not have the capacity to enroll all individuals seeking enrollment under the program.

Proposed § 438.50(f) reflects the provisions in section 1932(a)(4)(D) of the Act, which stipulate that in applying the default assignment provision under section 1932(a)(1) programs, State agencies are required to establish an

enrollment process that takes into consideration a beneficiary's existing relationships with providers and providers' traditional service to Medicaid beneficiaries. If enrollment based on the foregoing considerations is not possible, States must utilize an assignment process that equitably distributes enrollees among qualified, available MCOs or PCCMs.

Except when State agencies have a fee-for-service experience or prior MCO or PCCM enrollment data regarding an individual, it may be difficult to establish a provider and individual relationship for default assignment purposes. We recommend that State agencies ask potential enrollees in this situation for the names of providers from whom they receive services and whether they would wish to continue this relationship. When the beneficiary identifies a provider who is participating and has additional capacity, this information should be used in determining the individual's assignment. In this instance, the State agency makes the assignment to any MCO or PCCM in which that provider participates.

We propose under § 438.50(f)(3) that existing provider-individual relationships be defined as the provider who was the main source of care for the beneficiary in the last year. This can be established through State records of previous MCO or PCCM enrollment or fee-for-service experience, or through contact with the beneficiary. Under proposed § 438.50(f)(4), we describe providers as traditionally serving Medicaid beneficiaries if the provider has experience in dealing with the Medicaid population. If the State agency has no recent claims history, cannot get a response from the beneficiary, or the named provider does not participate, the State agency must give consideration to traditional providers. If no traditional providers are available, remaining individuals are to be equitably distributed among qualified MCOs and PCCMs with adequate capacity.

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

Subject to certain exceptions, under section 1932(a)(3) of the Act, a State agency that requires Medicaid beneficiaries to enroll in an MCO or PCCM must offer to its beneficiaries a choice of at least two MCOs or PCCMs. This is consistent with the longstanding requirement under section 1915(b) waivers that beneficiaries have at least two options. This requirement derived from the fact that the right to disenroll provided in section 1903(m)(2)(A)(vi) of

the Act could not be waived under section 1915(b) of the Act. Thus, in the case of a comprehensive risk contract subject to section 1903(m) of the Act (formerly HMO contracts, now MCO contracts), a beneficiary has always had the right to disenroll to another option. Section 1932(a)(3) of the Act reflects this existing mandatory managed care policy, and applies to primary care case managers under section 1905(t) of the Act as well. Therefore, a State agency could comply with this provision by offering a choice of two practitioners for a primary care case management system as long as each practitioner is a separate primary care provider. We also propose to extend this requirement to PIHPs and PAHPs.

Section 1932(a)(3) of the Act provides two exceptions to the general choice of coverage requirement in section 1932(a)(3)(A) of the Act. First, under section 1932(a)(3)(B) of the Act, in rural areas, a State agency may restrict choice of coverage to a single MCO, PIHP, PAHP, or PCCM if certain conditions are met. In those situations, the State agency must allow the beneficiary to choose from at least two physicians or case managers (to the extent that at least two physicians or case managers are available to furnish care and services in the area), and the State agency must allow the beneficiary to obtain assistance from any other provider outside the network in appropriate circumstances, as established by the State agency under CMS regulations.

Since a State agency may elect to implement this rural exception, the BBA requires us to promulgate regulations under which State agencies can establish the "appropriate circumstances" under which an individual will be permitted to obtain care from any provider. In § 438.52(b)(2), we propose the following as appropriate circumstances under which a State agency must permit beneficiaries to seek out-of-plan treatment: (1) When a service or type of provider is not available within the MCO, PIHP, PAHP, or PCCM network; (2) for up to 60 days, when a provider that is not part of the MCO, PIHP, PAHP, or PCCM network, has an existing relationship with the beneficiary, is the beneficiary's main source of care, and has not accepted an offer to participate in the network; (3) when the only plan or provider available to the beneficiary does not, because of moral or religious objections, furnish the service the enrollee seeks; or (4) when the beneficiary's primary care provider determines that there is unnecessary risk to the beneficiary to receive separately a related service not

available in the network. We also propose that State agencies have the discretion to determine additional circumstances that warrant out-of-network treatment. The State agency must ensure that enrollees are informed of the appropriate circumstances for out-of-plan treatment. We invite comments and additional suggestions in this area.

For purposes of the rural area exception in section 1932(a)(3)(B) of the Act, we propose in paragraph (b)(3) to define "rural area" as any area not meeting the Medicare definition of "urban area" at § 412.62(f)(1)(ii). Under this definition, any area that is part of a Metropolitan Statistical Area cannot be considered "rural" for the purposes of this exception. Areas designated as Metropolitan Areas, Primary Metropolitan Statistical Areas, or Consolidated Metropolitan Statistical Areas are all considered to be urban. Therefore, they are ineligible for this exception.

In the case of certain HIOs (specifically, pre-1986 HIOs or the county-operated HIOs in California that are exempt from section 1903(m) of the Act), the choice requirement in section 1932(a)(3)(A) of the Act is deemed to be met if a choice of at least two providers within the entity is provided.

Finally, we propose in paragraph (d) that when there is a rural or HIO exception to choice, any limitation to change between primary care providers may be no more restrictive than the limitations on disenrollment under § 438.56(c).

Section 1932(a)(4)(A)(i) of the Act expressly permits individuals to disenroll at any time with cause. Under section 1932(a)(4)(A)(ii), enrollees must be permitted to disenroll without cause during the initial 90 days of enrollment with an MCO or PCCM, and at least once every 12 months thereafter. If read to apply in all circumstances, this requirement would be inconsistent with allowing only one MCO or PCCM option, such as under the rural area and HIO exceptions provided under sections 1932(a)(3)(B) and (C) of the Act. We believe that in authorizing mandatory enrollment in a single entity under these exceptions, while imposing as a condition the right to choose among individual providers within the entity, the Congress was providing for an implicit exception to the general rule under section 1932(a)(4) of the Act in these cases. Under these exceptions, therefore, we propose that the requirements in section 1932(a)(4)(A) of the Act are deemed satisfied by providing that beneficiaries can disenroll to a different primary care

physician or case manager. Thus, individuals may disenroll from their current primary care provider, but must continue as an enrollee in the MCO or PCCM system. This would make it unnecessary for a State agency to operate a parallel fee-for-service system for those individuals who disenroll. We note that this "exception" to the ordinary operation of the requirement in section 1932(a)(4) of the Act would also be incorporated in section 1903(m)(2)(A)(vi) of the Act, which cannot be waived under a section 1915(b) waiver program. Thus, under our proposed rule, a State agency could offer a single MCO or multi-provider PCCM in a rural area under a section 1915(b) waiver, as long as the requirements in § 438.52(c) are satisfied. (The issue of section 1903(m)(2)(A)(vi) of the Act does not arise for the HIOs addressed in § 438.52(d), because they are exempt from section 1903(m) requirements.)

3. Enrollment and Disenrollment: Requirements and Limitations (§ 438.56)

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 mandatory programs under section 1932(a)(1)(A) of the Act, these requirements are also incorporated under section 1903(m)(2)(A) of the Act for MCOs and section 1905(t) of the Act for PCCMs. Thus, these new requirements also apply to voluntary programs, and, unless the "grandfather provision" in section 4710(c) of the BBA applies or an exception is authorized by CMS under section 1115(a)(2) in the case of a demonstration project, to mandatory programs under section 1915(b) or section 1115.

Under section 1932(a)(4)(A) of the Act, enrolled beneficiaries may terminate or change their enrollment for cause at any time, unless the beneficiary is enrolled in a single MCO or PCCM in a rural area as described earlier in regards to § 438.52(b). Beneficiaries must also be permitted to disenroll without cause from an MCO or PCCM within the first 90 days of the initial enrollment period of up to 12 months, and annually thereafter. We propose in § 438.56 that these enrollment provisions would apply to all PIHPs and PAHPs as well. Thus, the provisions apply to virtually all Medicaid managed care entities and programs.

We propose to replace § 434.27, which required HMO and PHP contracts to specify when they could request beneficiary disenrollment, with proposed § 438.56(b). The new requirement specifies the conditions

under which an MCO, PIHP, PAHP, or PCCM may request beneficiary disenrollment. These conditions are consistent with Medicare+Choice requirements.

The right of an enrollee to disenroll without cause (paragraph (c)(2)) during the first 90 days of enrollment, from a particular MCO, PIHP, PAHP, or PCCM and at least annually thereafter, replaces the pre-BBA version of section 1903(m)(2)(A)(vi) of the Act, which provided enrollees with the right to disenroll without cause at any time, or in the case of Federally qualified HMOs and certain other entities, at least every 6 months.

Under the pre-BBA version of section 1903(m)(2)(A)(vi) of the Act, a 12-month lock-in was possible only under a section 1115 demonstration, since section 1115(a)(2) authority was required in order to exempt an HMO from the requirement in that version of section 1903(m)(2)(A)(vi) of the Act. The BBA permitted 12-month lock-ins without demonstration authority, and even in the case of a voluntary program.

In addition to extending the maximum enrollment period from 6 months to 12 months and allowing for a 90-day, without-cause disenrollment period, section 1932(a)(4) of the Act—

- Applies this lengthened enrollment period to all MCOs and PCCMs, rather than a specific type of HMO;
- Requires that beneficiaries be notified of their ability to disenroll or change plans during an enrollment period that occurs at least every 12 months, and at least 60 days before the start of each enrollment period; and
- Eliminates all previous statutory provisions on enrollment and termination of enrollment.

Under proposed § 438.56(c), the above provisions apply to enrollment and disenrollment in MCOs, PIHPs, PAHPs, and PCCMs, regardless of authority, with the exception of (1) waiver or demonstration projects "grandfathered" under section 4710(c) of the BBA, and (2) States that have been granted an exception from these rules under section 1115, or, for PIHPs and PAHPs, under section 1915(b) of the Act.

We note that the language in section 1932(a)(4)(A)(ii) of the Act specifies that the 90-day period to disenroll without cause is to begin on the date the individual "receives notice of such enrollment * * *" However, we recognize that a literal application of this starting date could make this provision extremely difficult for State agencies to administer, and therefore propose in § 438.56(c)(2)(i) that the 90 days will begin when enrollment is

effective or notice is sent, whichever is later.

We provide that the 90-day period for disenrollment without cause applies only when an individual first enrolls with a particular MCO, PIHP, PAHP, or PCCM. The language in section 1932(a)(4) of the Act regarding the 90-day period for disenrollment without cause expressly provides for a 90-day period that begins with enrollment with the entity in which the beneficiary is enrolled. Thus, beneficiaries are entitled to a 90-day "without cause" period for disenrollment any time they enroll in a new MCO, PIHP, PAHP, or PCCM.

Section 1932(a)(4) of the Act provides for a notice of termination rights under which an enrollee must be informed of his or her ability to terminate or change enrollment at least 60 days before the start of each enrollment period. This 60-day period gives individuals the opportunity to change MCO, PIHP, PAHP, or PCCM effective with the start of their initial enrollment period with a particular MCO, PIHP, PAHP, or PCCM. If they choose to remain in the same plan, they have had their opportunity for disenrollment without cause and declined it. However, enrollees who change plans, would have an opportunity to try out the new MCO, PIHP, PAHP, or PCCM and determine whether they wish to remain enrolled through the enrollment period. This interpretation is consistent with the statutory language, that refers to a 90-day period beginning with the date of enrollment with "the entity," and is also consistent with what we believe to be the intent of this provision. We believe that this provision was designed to provide a beneficiary with a period of time to try out an MCO, PIHP, PAHP, or PCCM and see whether it is right for him or her. A beneficiary who has already had a 90-day period with a particular MCO, PIHP, PAHP, or PCCM does not need another one in order to try out that entity. The only exceptions provided are when a beneficiary is automatically re-enrolled under paragraph (g) and missed the annual enrollment opportunity, and when a State imposes intermediate sanctions specified in proposed § 438.702(a)(3).

Proposed § 438.56(d) sets forth procedures for disenrollment. The enrollee may submit a disenrollment request orally or in writing to the State agency. In § 438.56(d)(1)(ii), we propose that the MCO, PIHP, PAHP, or PCCM may approve the request for disenrollment if the State agency permits this.

We propose to describe cause for disenrollment in paragraph (d)(2) to include circumstances in which the

beneficiary moves out of the MCO, PIHP's, PAHP's, or PCCM's service area; cases in which the plan does not cover, because of moral or religious objections, a service the enrollee seeks; and for other reasons determined by the State, such as for homeless individuals or migrant workers.

In paragraph (d)(3) and (d)(4), we propose that the disenrollment request be processed within the timeframe specified in paragraph (e), or the request be deemed approved. In paragraph (d)(5), we permit the State agency to require that the enrollee seek redress in the MCO's, PIHP's, PAHP's, or PCCM's grievance system before making a determination on the request.

In paragraph (e), we propose to establish the timeframe for processing all disenrollment requests. The effective date of an approved disenrollment would have to be no later than the first day of the second month in which the request was filed. If a determination is not made within that timeframe, it would be considered approved.

In accordance with section 1932(a)(4)(B) of the Act, we propose, in § 438.56(f), a requirement for States that restrict disenrollment to notify enrollees 60 days before the start of each enrollment period, and ensure access to the State fair hearing process if disenrollment for cause is denied.

Section 1932(a)(4), of the Act requires State agencies to permit disenrollment without cause at least every 12 months after the individual's enrollment with an MCO or PCCM. State agencies may fulfill this requirement by having an annual open season for all MCO or PCCM enrollees or establishing an open enrollment opportunity for each individual based on the individual's date of enrollment. Through this regulation, we would apply these provisions to PIHPs and PAHPs as well.

Section 438.56(g) incorporates section 4732(c) of Pub. L. 101-508, effective November 5, 1990, as well as the provision set forth in section 4702(b)(1) of the BBA, to allow State agencies to provide in their State plans and contracts with MCOs and PCCMs for the automatic re-enrollment of beneficiaries who become disenrolled from the MCO or PCCM solely by virtue of becoming temporarily (for months or less) ineligible for Medicaid.

4. Conflict of Interest Safeguards (§ 438.58)

Under section 1932(d)(3) of the Act, State agencies cannot enter into contracts with any MCO, unless the State agency has in effect conflict-of-interest safeguards with respect to its officers and employees, and local

officers and employees who have responsibilities relating to contracts with these MCOs, or to the default enrollment process. These safeguards must be at least as effective as the Federal safeguards provided under section 27 of the Office of Federal Procurement Policy Act (41 U.S.C. 423). This provision applies to contracts entered into or renewed by October 1, 1997 and signed by both parties.

The Federal Procurement Policy Act specifies prohibitions for former and current employees from entering into any type of communications with individuals or third parties to unduly influence their decisions. These provisions include the following:

- Prohibited conduct by competing contractors.
- Prohibited conduct by procurement officials.
- Refusal to engage in discussion with competing contractors.
- Disclosure to unauthorized persons.
- Certification and enforcement matters.

These requirements are designed to ensure that there is no undue influence or preference given to an MCO because a State employee has an interest in that MCO and to require State agencies to have stringent safeguards over individuals for the proper and efficient administration of a State Plan.

Before section 1932(d)(3) of the Act was added by section 4207 of the BBA, section 1902(a)(4)(C) of the Act provided that Medicaid State and local officers or employees, former officers or employees, and partners of former officers or employees were prohibited from committing any act that is prohibited by Section 207 or 208 of title 18 of the United States Code. Section 207 or 208 of title 18, prohibits former and current employees from entering into communications to influence on behalf of any other persons.

In proposed § 438.58, we would extend these provisions to PIHPs and PAHPs as well, under our authority under section 1902(a)(4) of the Act.

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

We are proposing to redesignate existing § 434.57 as § 438.60, and to clarify that this section prohibits payments to providers for services available under an MCO, PIHP, or PAHP contract. The only exceptions to this prohibition are for payments specifically authorized by Federal statute or regulation.

6. Continued Service to Beneficiaries (§ 438.62)

We propose to redesignate § 434.59 as § 438.62 with appropriate changes in terminology.

7. Monitoring Procedures (§ 438.66)

We propose to redesignate § 434.63 as § 438.66 with non-substantive revisions and appropriate changes in terminology.

C. Enrollee Rights and Protections (Subpart C)

1. Enrollee Rights (§ 438.100)

We are proposing requirements to ensure that each contract with an MCO or PIHP have written policies regarding enrollee rights and that MCOs, PIHPs, PAHPs, and PCCMs ensure compliance with Federal and State laws affecting the rights of enrollees. Under this proposed rule, as set forth in proposed § 438.100, each enrollee would have the right to receive information in accordance with proposed § 438.10; be treated with respect and consideration for enrollee dignity and privacy; receive information on available treatment options or alternative courses of care; participate in decision-making regarding his or her health care; and be free from any form of restraint or seclusion used as a means of coercion, discipline, convenience, or retaliation. In addition, each enrollee of an MCO or PIHP would have the right to obtain a second opinion from a qualified health care provider in accordance with proposed § 438.206(b), and to access his or her medical records and request that they be amended or corrected.

We are proposing 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. Further, under proposed § 438.100, the MCO, PIHP, PAHP, and PCCM would have to comply with any other Federal and State law pertaining to enrollee rights. These requirements extend to an individual acting on behalf of someone who is unable to exercise his or her rights.

In proposed § 438.100(d), we would require that States ensure that MCOs, PIHPs, PAHPs, and PCCMs and their subcontractors comply with Federal and State laws affecting the rights of enrollees. Federal laws affecting the rights of enrollees include, but are not limited to: Title VI of the Civil Rights Act of 1964 as implemented by

regulations at 45 CFR part 484; 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.

2. Enrollee-Provider Communications (§ 438.102)

Medicaid beneficiaries have historically been entitled to receive from their health care providers the full range of medical advice and counseling that is appropriate for their condition. The BBA expanded upon this basic right by expressly precluding an MCO from establishing restrictions that interfere with enrollee-practitioner communications. Under proposed § 438.102, which expands this right to PIHPs and PAHPs, a health care professional who is acting within his or her scope of practice, must be permitted to freely advise a patient about his or her health status and discuss appropriate medical care or treatment for that condition or disease regardless of whether the care or treatment is covered under the contract with the MCO, PIHP, or PAHP. A health care professional means a physician, 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.

While the new provision precludes MCOs, PIHPs, and PAHPs from interfering with enrollee-practitioner communications, it does not require MCOs, PIHPs and PAHPs to provide reimbursement for, or provide coverage of counseling or referral services for specific services, if the MCO, PIHP, or PAHP objects to the service on moral or religious grounds. Please note, however, that the State agency remains responsible for ensuring access to all covered services. In these cases, the MCO, PIHP, or PAHP must inform beneficiaries in writing of its policies before and during enrollment. If the MCO, PIHP, or PAHP changes its policies with regard to a specific counseling or referral service, the organization must provide written notification to enrollees within 90 days of the change. However, this timeframe, while sufficient to meet the statutory requirement related to changes in counseling or referral services, is overridden by the provision at proposed

§ 438.10(e)(1)(ii) that requires the MCO and PIHP to furnish the information at least 30 days before the effective date of the policy.

3. Marketing Activities (§ 438.104)

Terminology. We currently require each MCO, under § 434.36, to specify in its contract a methodology for assuring that marketing plans, procedures, and materials are accurate and do not mislead, confuse, or defraud either recipients or the Medicaid agency. Section 1932(d)(2) of the Act, established by section 4707(a) of the BBA, further strengthened consumer protections and prohibits fraud and abuse by restricting marketing activities by MCOs and PCCMs. Section 1932(d)(2) of the Act requires that marketing materials be distributed to the entire service area covered under contract, prohibits "cold-call" marketing, and requires that marketing materials not be distributed without the prior approval of the State agency. We propose to implement these BBA provisions and prohibit certain other marketing practices, under proposed § 438.104. We also propose to extend the requirements to PIHPs and PAHPs.

For the purposes of this regulation, we propose in § 438.104(a) to define marketing materials as materials produced in any medium, by or on behalf of an MCO, PIHP, PAHP, or PCCM, used to communicate with individuals who are not its enrollees and that can reasonably be interpreted as intended to influence the individuals to enroll in that particular MCO, PIHP, PAHP, or PCCM.

Required Marketing Activities. In § 438.104(b)(1)(i) and (ii), we propose to reflect the requirements in section 1932(d)(2)(B) of the Act that MCOs and PCCMs must: (1) Obtain State approval before distributing marketing materials; and (2) distribute marketing materials to the entire service area in which they have contracts under sections 1903(m) or 1903(t)(3) of the Act. According to the last sentence in section 1932(d)(2)(A)(i) of the Act this, prior approval requirement was to take effect on a date specified by the Secretary in consultation with the State agency. Following this consultation, this requirement became effective on July 1, 1998. In § 438.104(b)(1)(iii), we propose to include the requirement in section 1932(d)(2)(D) of the Act that MCOs and PCCMs that comply with the information requirements set forth in § 438.10 to ensure that each Medicaid beneficiary receives accurate oral and written information in order that the individual can make an informed decision whether or not to enroll.

Prohibited Marketing Activities. In § 438.104(b)(1)(iv), we propose to include the prohibition in section 1932(d)(2) of the Act on the MCO, PCCM, or any agent attempting to influence enrollment with the MCO or PCCM in conjunction with the sale of any other insurance. We interpret this to mean that MCOs and PCCMs may not entice a Medicaid beneficiary to join the MCO or PCCM by offering the sale of any other type of insurance as a bonus for enrollment. However, we invite comment on this provision since no legislative history is available to help determine if this interpretation is accurate.

In § 438.104(b)(1)(v) we propose to include the prohibition in section 1932(d)(2)(E) of the Act barring an MCO or PCCM, directly or indirectly, from conducting door-to-door, telephonic, or other "cold-call" marketing of enrollment. MCOs, PCCMs, and their employees are prohibited from conducting these marketing practices either by themselves (directly) or by using an agent, affiliated provider, or contractor (indirectly). This provision does not prohibit MCOs and PCCMs from engaging in other State approved activities, such as marketing at health fairs, procuring billboards, bus signs, or other broadcast advertising materials, and contacting in person, Medicaid beneficiaries who request further information about the entity. However, it is the prerogative of the State agency to further limit marketing practices beyond those prohibited or required by Federal statute. Cold-call marketing is defined in proposed § 438.104(a) as any unsolicited personal contact with a potential enrollee by an employee, affiliated provider or contractor of the entity for the purpose of influencing enrollment with that entity. This would include those activities as a physician or other member of the medical staff or salesperson or other managed care entity, employee, or independent contractor approaching a beneficiary in order to influence the Medicaid beneficiaries decision to enroll with a particular plan.

In addition, we propose in § 438.104(b)(2) to implement the provision in section 1932(d)(2)(A)(i)(II) of the Act on the distribution by MCOs, PCCMs, or any agents, of marketing materials that contain false or materially misleading information by requiring that MCO and PCCM contracts specify the methods by which compliance with this requirement is assured. Examples of misleading marketing information would be an assertion that the beneficiary must enroll with the MCO or PCCM to get Medicaid benefits, or that

the MCO or PCCM is recommended or endorsed by us.

Consultation in State Agency Approval of Marketing Materials. In § 438.104(c) we propose to specify the requirement in section 1932(d)(2)(A)(ii) of the Act that State agencies provide for consultation with a Medical Care Advisory Committee (MAC) in the process of reviewing and approving marketing materials. Currently, MAC is described in the regulations at § 431.12. The current MCAC must include Board-certified physicians and other representatives of the health professions who are familiar with the medical needs of low-income population groups and with the resources available and required for their care; members of consumers' groups that include Medicaid recipients and consumer organizations such as labor unions, cooperatives, consumer sponsored prepaid group practice plans, and others; and the Director of the Public Welfare Department or the Public Health Department, whichever does not head the Medicaid agency. State agencies do not have to use the current MCAC but can establish a new MCAC for consultation in reviewing and approving marketing material. If a new MCAC is established, it must be composed of similar membership to that described above and in § 431.12.

4. Liability for Payment (§ 438.106)

In § 438.106, we propose to specify the requirement in section 1932(b)(6) of the Act that MCOs protect Medicaid beneficiaries from being held responsible for payment liabilities incurred by the MCO or by a health care provider with a contractual, referral, or other arrangement with the MCO. For example, under the regulation, if the MCO, PIHP, or PAHP were to become bankrupt, the Medicaid enrollee would not have to assume responsibility for costs that the MCO, PIHP, or PAHP was responsible for covering, nor any of the debts of the providers affiliated with the MCO, PIHP, or PAHP. In addition, if the MCO, PIHP, or PAHP fails to receive payment from the State agency, or if a provider fails to receive payment from the State agency or the MCO, PIHP, or PAHP, the Medicaid enrollee cannot be held responsible for these payments. The Medicaid enrollee cannot be held responsible for payments to a provider in excess of the amount that he or she would have owed if the MCO, PIHP, or PAHP had directly provided the service.

5. Cost Sharing (§ 438.108)

Proposed § 438.108 would require compliance with the restrictions on cost-sharing in §§ 447.50 through

447.60. We note that section 4708(b) of the BBA amended sections 1916(a)(2)(D) and 1916(b)(2)(D) of the Act to eliminate the prohibition that existed prior to the BBA on the imposition cost-sharing by MCOs. Copayments for services provided by MCOs, PIHPs, and PAHP, may now be imposed in the same manner as copayments are applied under fee-for-service, as discussed in §§ 447.50 through 447.60.

Accordingly, State agencies must use their fee-for-service payment rates to serve as the basis for determining copayments that can be assigned for managed care services. State agencies would be allowed to impose copayment requirements to the same extent that they are allowed to impose copayment requirements on Medicaid beneficiaries not enrolled in MCOs, PIHPs, and PAHPs. For example, State agencies would have the option of establishing a standard copayment amount for managed care services that is determined by applying the maximum copayment amounts specified at § 447.54 as applied to the State agency's fee-for-service payment for that service.

In addition, any beneficiary groups excluded by statute from having to pay copayments under fee-for-service would continue to be excluded from any copayment responsibility for managed care services. These beneficiary groups include children, pregnant women, and institutionalized beneficiaries. Also prohibited are copayments for emergency services and family planning services.

We also propose in § 447.53(e) that 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. This language closely tracks the statutory language in section 1916(e) of the Act. This proposed provision applies to services furnished by either an MCO or under fee-for-service.

6. Emergency and Post-Stabilization Services (§ 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 condition under certain circumstances. 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 interpret 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 of a PCCM) that pays for hospital services generally, must pay for the cost of emergency services obtained by Medicaid enrollees. We interpret coverage in the PCCM context to mean that the PCCM must allow direct access to emergency services without prior authorization. We apply 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, 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 § 438.114(c)(2), we propose to provide 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.

The BBA further stipulates that emergency services must be covered without regard to prior authorization or the emergency care provider's contractual relationship with the organization. These provisions collectively enable a Medicaid enrollee 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 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 provide 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 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 clarifies financial responsibility. Proposed § 438.114(d)(1) provides 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) provides 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) provides 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 to coverage of "post-stabilization" services after they have been "stabilized" (that is, they no longer have an emergency medical condition) 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 M+C post-stabilization requirements referenced by section 1932(b)(2)(A)(ii) of the Act are set forth in proposed § 438.114(e), which references § 422.113(c) of the M+C 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, or under the circumstances described in paragraph § 422.113(c)(2)(iii), to improve or resolve the enrollee's condition.

The above emergency provisions are consistent with most of the emergency services provisions in the M+C regulations.

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.

7. Solvency Standards (§ 438.116)

Section 4706 of the BBA amended section 1903(m)(1) of the Act by providing additional requirements for the solvency standards that an MCO must meet. Previously, MCOs had to make adequate provision against the risk of insolvency to the satisfaction of the State agency, and provide that enrolled Medicaid beneficiaries were not held liable for the debts of the MCO in the case of insolvency. Now, under the BBA, unless they meet one of the exceptions noted below, MCOs must either meet the same solvency standards that the State agency establishes for its private HMOs, or otherwise be licensed or certified by the State agency as a risk bearing entity. By meeting these standards, these MCOs are considered to have met the general solvency standards. However, this provision does not apply to MCOs that do not provide inpatient and physician services, are public entities, have solvency guaranteed by the State agency, or are Federally qualified health centers (FQHCs) or are controlled by an FQHC that meets the solvency standards already established for these centers by the State agency. For further clarification, the term "control" (for an MCO being controlled by an FQHC) means the possession, whether direct or indirect, of the power to direct or cause the direction of the management and policies of the MCO through membership, board representation, or an ownership interest equal to or greater than 50.1 percent. These MCOs must still meet the general requirement that MCOs have to make adequate provision against the risk of insolvency to the satisfaction of the State agency and provide that Medicaid beneficiaries enrolled will not be held liable for the debts of the MCO in the case of its insolvency.

In accordance with our authority under section 1902(a)(4), we have extended the new solvency requirements in section 1903(m)(1)(A) to PIHPs and PAHPs, as the risks to enrollees from an insolvency apply equally in these settings.

D. Quality Assessment and Performance Improvement (Subpart D)

1. Background

Before the passage of the BBA, Medicaid statute and regulations included a number of disparate and incremental provisions addressing quality. The statute focused specifically on services furnished by HMOs under 1903(m) of the Act. Section 1902(a)(30)(C) of the Act required State agencies to conduct on an annual basis, an independent, external review of the quality of services furnished under each State contract with an HMO.

Medicaid regulations contained several provisions that related to quality. Specifically, the regulations required HMOs to have an internal quality assurance plan that met limited requirements (§ 434.34); required the State to conduct periodic medical audits of HMOs to ensure that each organization furnished quality and accessible care to all Medicaid enrollees (§ 434.53); provided that contracts include provisions that identify the population covered under the contract, and to specify the amount, duration, and scope of medical services to be provided (§ 434.6(a)), required the State to obtain proof from its contractor of its ability to provide services under the contract efficiently, effectively, and economically (§ 434.50(b)), and proof that the contractor furnished the health services required by the enrolled recipients as promptly as is appropriate, meeting the State agency's quality standards (§ 434.52). The State agency and HHS were given discretion in the regulations to evaluate through inspection or other means, the quality, appropriateness, and timeliness of services performed under the contract (§ 434.6(a)(6)).

Other requirements that related to the quality of services included grievance procedures for beneficiaries enrolled in HMOs (§ 434.32), emergency medical services (§ 434.30), enrollee choice of health professional (§ 434.29), other State monitoring procedures (§ 434.63), and use of sanctions for HMO failure to provide medically necessary services resulting in an adverse effect on the enrollee.

In addition to the above, Medicaid statute included several indirect assurances related to quality, such as a requirement that States contract with HMOs that met certain enrollment composition requirements (specifically, at least 25 percent of a health plan's enrollment was to consist of persons not covered by Medicare or Medicaid), solvency standards for HMOs serving Medicaid beneficiaries, and a

requirement that the State ensure that access to and quality of services provided under managed care are at least comparable to those provided under the fee-for-service program. For the latter, neither the statute nor the regulation specified the specific methods or standards to support the access and quality assurances.

As illustrated above, a number of the statutory and regulatory requirements before 1997 were duplicative (for example, periodic audits of managed care plans by State agencies and external reviews of HMOs from an agent of the State) or otherwise failed to allow for improvements in technology of measuring and improving quality (for example, use of performance measures and consumer surveys). As a consequence, it was unclear to many stakeholders how the various statutory and regulatory requirements worked together to effectively and efficiently ensure, and improve where appropriate, the quality of care delivered under managed care arrangements.

2. Overview

Under section 1932(c)(1)(A) of the Act, as added by section 4705(a) of the BBA, each State that elects to furnish services to Medicaid beneficiaries through an MCO must develop and implement a quality assessment and performance improvement strategy that includes access standards, other measures, monitoring procedures, and periodic review. This statutory arrangement applies regardless of whether the managed care arrangement is mandatory or voluntary. Further, this strategy must be "consistent with standards" that we establish in regulations (section 1932(c)(1)(B) of the Act).

Proposed subpart D of part 438 contains our proposed standards, developed in accordance with the statute. The proposed standards, discussed later in greater detail, would require a State's strategy to include various access standards, structure and operation standards, and measurement and improvement standards. Once developed, each State would be required to review the strategy to ensure its overall effectiveness in achieving its desired results.

Many of the requirements in this subpart would be imposed on States. States in turn would impose these requirements on MCOs. As previously discussed, we have proposed to add PIHPs as entities subject to this subpart under our authority at section 1902(a)(4) of the Act.

Proposed Provisions of Subpart D**3. Scope (§ 438.200)**

This section sets forth the scope of Subpart D.

4. State Responsibilities (§ 438.202)

This section sets forth the State responsibilities in implementing its quality strategy. Specifically, proposed § 438.202 would require that each State contracting with an MCO or PIHP do the following:

- Have a written strategy for assessing and improving the quality of managed care services provided by the MCO and PIHP.

- Have a means for obtaining input of recipients and other stakeholders in the development of the strategy, including making the strategy available for public comment before adopting it as final.

- Ensure compliance with standards established by the State.

- Conduct periodic reviews to evaluate the effectiveness of the strategy and update the strategy, periodically, as needed.

- Submit a copy of the initial strategy to CMS as well as a revised strategy when significant changes are made.

Additionally, regular reports on the implementation and effectiveness of the strategy would have to be submitted to us, consistent with the State's periodic reviews.

5. Elements of State Quality Strategies (§ 438.204)

This section sets forth the minimum elements of a State's quality strategy. We propose that these elements include the following:

- MCO and PIHP contract provisions that incorporate the standards in this subpart.

- Procedures for accessing the quality and appropriateness of care and services furnished to all Medicaid enrollees under the MCO and PIHP contracts, including individuals with special health care needs. We suggest states reference the November 6, 2000 Report to the Congress entities safeguards for individuals with special health care needs enrolled in Medicaid managed care to determine what populations to consider when determining individuals with special health care needs. We also propose that the State strategy include procedures that identify the race, ethnicity, and primary language spoken of each Medicaid enrollee. We would require the latter information to be provided to the MCO and PIHP at the time of enrollment.

- Continuous monitoring and evaluation of MCO and PIHP compliance with the standards.

- Performance measures and levels, identified and developed by CMS in consultation with States and other relevant stakeholders.

- Arranging for annual, external independent reviews of quality outcomes and timeliness of, and access to, the services covered under the contract.

- Appropriate use of intermediate sanctions that, at a minimum, meet the requirements of subpart I of this part.

- An information system that supports initial and ongoing operation and review of the State's quality strategy.

- 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.

In the development of the proposed rule, some stakeholders expressed concern over any provision that would require States to identify to MCOs and PIHPs the race, ethnicity, and primary language spoken by MCO and PIHP enrollees. Some stakeholders expressed concern that the requirement for ethnicity would require States to change their information systems. They questioned whether the value of requiring this information was worth the cost. In response to these concerns, we believe that most States are currently collecting and reporting data on race and ethnicity and, thus, should not have to expend significant costs for systems changes. Based on this current practice, we believe that States should not be unduly burdened by this provision of the proposed rule. We invite comments on this issue.

We have included as an element of States quality strategies that they must include "performance measures and levels, certified and developed by CMS in consultation with States and other relevant stakeholders." We propose this requirement because of the increasing interest in comparable information across health plans and States on their performance in serving Medicaid enrollees. We invite public comment on this proposal, including what would be an effective means to provide State and other stakeholder input into the development of these measures.

Access standards. The following sections are proposed in accordance with statutory authority that requires State agencies that contract with MCOs under section 1903(m) of the Act to develop a quality assessment and improvement strategy that includes standards for access to care so that all covered services are available in a manner that ensures continuity of care, adequate primary care, and specialized

services capacity (section 1932(c)(1)(A) of the Act, as added by section 4704 of the BBA).

6. Availability of Services (§ 438.206)

- *Basic rule.* Paragraph (a) of this section sets forth the basic requirement for this section, which would require the State to ensure, through its contracts, that all covered services are available and accessible to enrollees.

- *Delivery Network.* Paragraph (b) of this section would require the State to ensure the following:

—Each MCO and PIHP 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. (Each MCO and PIHP would have to consider the anticipated enrollment in the MCO or PIHP, the expected utilization of services, considering enrollee characteristics and health care needs, the number and types (in terms of training, experience, and specialization) of providers required to furnish the contracted services, the numbers of network providers who are not accepting new Medicaid patients, and 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 enrollee with disabilities.)

—The MCO or PIHP 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 preventative health care services.

—The MCO or PIHP provides for a second opinion from a qualified health care professional within the network, or arranges for the enrollee to obtain one outside of the network, at no cost to the enrollee.

—If the network is unable to provide necessary medical services, covered under the contract, to a particular enrollee, the MCO or PIHP adequately and timely covers these services out of network for the enrollee, for as long as the MCO or PIHP is unable to provide them.

—The MCO or PIHP requires the 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 are furnished within the network.

—The MCO or PIHP demonstrates that its providers are credentialed as required by § 438.214.

• *Furnishing of services.* Paragraph (c) of this section would require States to ensure that MCOs and PIHPs meet requirements addressing the following:

—Timely access to services.

Specifically, MCOs and PIHPs would have to meet and require their providers to: meet State-established standards for timely access to care, that would take into account the urgency of need for services; 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; make services available 24 hours a day, 7 days a week, when medically necessary; establish mechanisms to ensure compliance; monitor continuously to determine compliance; and take corrective action if there is a failure to comply.

—Cultural considerations. In addition to timely access standards, we believe that it is important for MCOs and PIHPs to address cultural considerations. Therefore, we are proposing in paragraph (c)(2) of this section that each MCO and PIHP 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.

7. Assurances of Adequate Capacity and Services (§ 438.207)

Apart from the statutory provisions addressing the State's quality strategy, and the need to develop access standards under that strategy, the statute specifically requires MCOs to provide to the State agency and the Secretary adequate assurances that it has the capacity to serve the expected enrollment in its service area (section 1932(b)(5) of the Act, as added by section 4704(a) of the BBA). The statute provides that the adequate assurances must be provided in a time and manner determined by the Secretary, and must demonstrate that each MCO offers an appropriate range of services and a sufficient number, mix, and geographic distribution of providers of services.

The requirements in this section are proposed in accordance with section 1932(b)(5) of the Act, described earlier. In order to avoid confusion between proposed § 438.206 and § 438.207, we would clarify that proposed § 438.207 would address procedural requirements for submitting assurances of adequate capacity and services, while proposed § 438.206 would address substantive

standards relating to the availability of services. Both sections are related in the sense that we are requiring MCOs and PIHPs to submit documentation to the State (which in turn will submit assurances to CMS) addressing how the MCO or PIHP has met the access standards proposed under § 438.206. We believe this fulfills the intent of Congress that MCOs submit assurances of adequate capacity and services, in a form and manner determined by the Secretary. As previously discussed, we added PIHPs as entities subject to this subpart under our authority at 1902(a)(4) of the Act.

• *Basic Rule.* Section 438.207(a) sets forth the basic provision of this section. It would require the State to ensure, through its contracts, that each MCO and each PIHP provides assurances to the State 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.

• *Nature of assurances.* Paragraph (b) of this section would require each MCO and each PIHP to submit documentation to the State, in a format specified by the State and acceptable to CMS, to demonstrate that it complies with the following requirements:

—Offers an appropriate range of services, including preventive services, primary care services and specialty services that is adequate for the anticipated number of enrollees for the service area.

—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.

• *Timing of documentation.* Paragraph (c) would require each MCO and PIHP to submit the documentation described in paragraph (b) of this section as specifies by the State, and specifically—

—At the time it enters into a contract with the State.

—At any time there has been a significant change (as defined by the State) in the MCO's or PIHP's operations that would affect adequate capacity and services. These include changes in the MCO or PIHP services, benefits, geographic service area or payments, and enrollment of a new population in the MCO or PIHP.

• *State review and submission to CMS.* Paragraph (d) would require the State, after it reviews the documentation submitted by the MCO or PIHP, to certify to CMS that the MCO or PIHP has complied with the State's requirements for availability of services, as set forth in § 438.206.

• *CMS's right to inspect documentation.* Paragraph (e) would ensure that the State makes available to CMS, upon request, all documentation collected by the State from the MCO or PIHP.

8. Coordination and Continuity of Care (§ 438.208)

Basic Requirement. Paragraph (a) of this section sets forth the basic requirement of this proposed section. We would require the State to ensure, through its contracts, that MCOs and PIHPs, except as otherwise specified in this section, meet the provisions outlined in this section. This paragraph also acknowledges two exceptions: one for PIHPs and another for MCOs that serve dually eligible enrollees. It would permit a State to determine, based on the scope of the PIHP's services, and the way the State has organized the delivery of managed care services, whether a PIHP is required to perform the screenings and assessments specified in paragraph (c) or required to meet the primary care requirements of paragraph (e)(1). The second exception would permit the State to determine to what extent an MCO that serves enrollees who are also enrolled in a Medicare+Choice plan and receive Medicare benefits, must meet the screening and assessment, referral and treatment plan, and primary care and coordination requirements of paragraphs (c), (d) and (e)(1) of this section, respectively.

We believe that the paragraphs of this section should apply to PIHPs to the extent they are applicable to the services furnished by the PIHP. Because some PIHPs provide services to the most vulnerable Medicaid enrollees, many of whom have been diagnosed with chronic conditions or who are determined to have long term care needs, it is important that those PIHPs have mechanisms for timely screening and assessment of enrollees requiring special attention. We acknowledge, however, that the State might design a system that involves PIHPs for which the screening and assessment function is performed by an acute care MCO and imposing a similar requirement on the PIHP would be duplicative (that is, a carve-out program for mental health services in which the enrollee was referred by the MCO contracted to provide physical health services). Likewise, some of the requirements of this section might be duplicative for an MCO that serves dual eligible enrollees who are also enrolled in a Medicare+Choice plan and receive Medicare benefits. Accordingly, we drafted an exception that would permit

a State to determine the application of these requirements to the MCOs, based on the services the MCO is contracted to furnish. We invite comments in this area.

State Responsibility To Identify Certain Enrollees with Special Health Care Needs. This paragraph would require the State implement a mechanism to identify to its enrollment broker, if applicable prior to enrollment, and the MCO and PIHP, upon enrollment, individuals with special health care needs, as specified by the state. This requirement is proposed to facilitate the early identification and assessment of enrollees with special health care needs. Although we do not define in regulation the term "special health care needs," our Report to the Congress entitled, "*Safeguards for Individuals with Special Health Care Needs Enrolled in Medicaid Managed Care*" (November 6, 2000), identified certain groups of individuals at risk of having special health care needs. We encourage States to consider those groups as they establish their own definitions. We invite comment in this area.

Screening and Assessment. This paragraph sets forth the requirement that the State (either through its own staff or its enrollment broker), or at the State's discretion, each MCO or PIHP (through appropriate health care professionals) must ensure a best effort is made to meet the following standards:

The proposed requirements of this section permit States some discretion to use their own staff or an enrollment broker to conduct screening and assessment functions of individuals enrolling in MCOs or PIHPs. It also permits States to require MCOs or PIHPs, as appropriate, to perform the screening and assessment functions through appropriate health care professionals. We acknowledge that 100 percent compliance may not be achieved in the case of individuals who refuse to undergo a screening or assessment, or for those the MCO or PIHP has tried to contact on multiple occasions but has been unable to reach. In those cases the MCO or PIHP, through appropriate health care professionals, should ensure that this information is documented in the enrollee's medical records explaining why the screening or assessment was not performed.

Treatment plans. This paragraph proposes that the State ensures that each MCO and PIHP has a mechanism in place for enrollees determined through an assessment to have ongoing special conditions that require a course of

treatment or regular care monitoring as follows:

- The enrollee may directly access a specialist (for example, through a standing referral or an approved number of visits) as is appropriate for the enrollee's condition and identified needs.

- A treatment plan, if required by the MCO or PIHP, is developed by a specialist in consultation with the enrollee's primary care provider; is developed with enrollee participation; is approved by the MCO or PIHP in a timely manner, if an approval is required; and is in accordance with the State's quality assurance and utilization review standards. We envision that for children with special healthcare needs, enrollee participation would also encompass participation by the family.

During the development of this proposed rule, some stakeholders expressed concern that our requirements not be overly prescriptive and burdensome with respect to screening, assessment, and treatment plans. We believe the proposed rules set forth minimum requirements that are critical to the success of managed care for persons with special health care needs. We further believe that some level of prescription is necessary to ensure that enrollees with ongoing special conditions who are undergoing a course of treatment or requiring care coordination from specialist can do so without having to receive a referral from their primary care provider for each specialist visit or treatment. We invite public comments in this area. Further treatment plans should be updated when these are changes in the enrollee's condition, including changes in developmental status and needs.

- *Primary care and coordination program.* This paragraph would require each MCO and each PIHP to implement a coordination program that meets State requirements and achieves the following:

- Ensures 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.
- Coordinates the services the MCO or PIHP furnishes to the enrollee with the services the enrollee receives from any other MCOs and PIHPs.
- Shares with other MCOs and PIHPs serving the enrollee the results of its screenings and assessments of the enrollee so that those activities need not be duplicated.
- Ensures that in the process of coordinating care, each enrollee's

privacy is protected consistent with privacy rules at 45 CFR 160 and 164.

9. Coverage and Authorization of Services (§ 438.210)

- *Coverage.* This paragraph sets forth proposed basic coverage requirements. We are proposing that each contract with an MCO or PIHP do the following:
 - Identify, define, and specify each service that the MCO or PIHP is required to offer.

- Require that the MCO or PIHP make available the services it is required to furnish in no less than the amount, duration, and scope that are specified in the State plan and that are sufficient to reasonably be expected to achieve the purpose for which the services are furnished.

- Provide that the MCO or PIHP may not arbitrarily deny or reduce the amount, duration, or scope of a required service solely because of the diagnosis, type of illness, or condition (although they may place appropriate limits on services on the basis of criteria such as medical necessity or utilization control, provided the services furnished can reasonably be expected to achieve their purpose).

- Specify what constitutes "medically necessary services" in a manner that is no more restrictive than the State Medicaid program as indicated in State statutes and regulations, the State Plan, and other State policy and procedures, and addresses the extent to which the MCO or PIHP is responsible for covering services related to the prevention, diagnosis, and treatment of health impairments, the ability to achieve age-appropriate growth and development, and the ability to attain, maintain, or regain functional capacity.

- *Processing of requests.* In this paragraph, we are proposing that, for the processing of requests for initial and continuing authorizations of services, each contract must require the following:

- The MCO or PIHP and its subcontractors have in place, and follow, written policies and procedures.
- 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. For the review criteria, we propose that MCOs and PIHPs have in effect mechanisms to ensure the consistent application of the review criteria for authorization decision;

and consult with requesting providers when appropriate.

- *Notice of adverse action.* In this paragraph, we are proposing that each contract be required to provide for the MCO or PIHP to notify the requesting provider, and give the enrollee written notice of any decision by the MCO or PIHP to deny a service authorization request, or a decision to authorize a service in an amount, duration, or scope that is less than requested. We specify that the notice must meet the requirements of § 438.404, except that the notice to the provider need not be in writing.

- *Timeframe for decisions.* In this paragraph, we are proposing that each MCO or PIHP contract provide for the following decisions and notices for standard authorization decisions and expedited authorization decisions. For standard authorization decisions, the MCO or PIHP would 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 the enrollee, or the provider, requests an extension or the MCO or PIHP justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest). For cases in which a provider indicates, or the MCO or PIHP 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 or PIHP would be required to 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. We propose that the MCO or PIHP be permitted to extend the 3 working days time period by up to 14 calendar days if the enrollee requests an extension, or if the MCO or PIHP justifies that a need for additional information is in the enrollee's interest.

- *Compensation for utilization management activities.* This paragraph would require each contract to provide that 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. The following sections are proposed in accordance with statutory authority that requires State agencies that contract

with MCOs under section 1903(m) of the Act to develop a quality assessment and improvement strategy that includes examination of other aspects of care and service directly related to the improvement of quality of care (Section 1932(c)(1)(A) of the Act, as added by section 4704 of the BBA).

10. Provider Selection (§ 438.214)

- *General rules.* This paragraph sets forth the proposed rules for this section. The State would be required to ensure, through its contracts, that MCOs and PIHPs implement written policies and procedures for the selection and retention of providers and that those policies and procedures include, at a minimum, the requirements outlined in the following paragraphs.

- *Credentialing and recredentialing requirements.* In this paragraph, we propose that each MCO and PIHP would have to follow a documented process for credentialing and recredentialing of providers who have signed contracts or participation agreements with the MCO or the PIHP.

- *Nondiscrimination.* In this paragraph, we would require the MCO and PIHP provider selection policies and procedures to be consistent with the antidiscrimination requirements at § 438.12 and to not discriminate against particular providers that serve high risk populations or specialize in conditions that require costly treatment.

- *Excluded providers.* This proposed paragraph would provide that MCOs or PIHPs 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.

- *State requirements.* In this paragraph, we are proposing that MCOs and PIHPs comply with any additional requirements established by the State.

11. Enrollee Information (§ 438.218)

In this section, we propose to incorporate the information requirements under § 438.10 as part of the State's quality strategy.

12. Confidentiality (§ 438.224)

This section sets forth the requirement that States must ensure MCOs and PIHPs meet privacy requirements at Subpart F of part 431 of this chapter and 45 CFR 160 and 164.

13. Enrollment and Disenrollment (§ 438.226)

In this section, we propose to incorporate the enrollment and disenrollment requirements in other parts of this rule as part of the State's quality assessment and improvement

strategy. We would require the State to ensure that each MCO and PIHP contract complies with the enrollment and disenrollment requirements and limitations set forth in § 438.56.

14. Grievance Systems (§ 438.228)

In this section, we propose to incorporate the requirements for a grievance system as part of the State's quality assessment and improvement strategy. Thus, we would require the State to 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. We also require that 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.

15. Subcontractual Relationships and Delegation (§ 438.230)

In this section, we address subcontracting and delegation. We would require the State to ensure, through its contracts, that each MCO and PIHP oversees and is accountable for any functions and responsibilities that it delegates to any subcontractor, and meets specific conditions. The specific conditions require the following:

- Before any delegation, each MCO and PIHP evaluates the prospective subcontractor's ability to perform the activities to be delegated.
- There 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.
- The MCO or PIHP 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.

- If any MCO or PIHP identifies deficiencies or areas for improvement, the MCO and the subcontractor take corrective action.

Measurement and Improvement Standards. The following sections are proposed pursuant to statutory authority that requires State agencies that contract with MCOs under section 1903(m) of the Act 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 (section 1932(c)(1)(A) of the Act, as added by section 4704 of the BBA).

16. Practice Guidelines (§ 438.236)

This section addresses the adoption, dissemination, and application of practice guidelines. We propose that each MCO and PIHP adopts 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 propose that MCOs and PIHPs disseminate the guidelines to all affected providers and, upon request, to enrollees and potential enrollees. Finally, we specify that decisions with respect to utilization management, enrollee education, coverage of services, and other areas to which the guidelines apply are consistent with the guidelines.

17. Quality Assessment and Performance Improvement Program (§ 438.240)

- *General rules.* This paragraph sets forth the proposed general requirements of this section. We would require the State to ensure, through its contracts, that each MCO and PIHP has an ongoing quality assessment and performance improvement program for the services it furnishes to its enrollees. In addition, we specify 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.

- *Basic elements of an MCO and PIHP quality assessment and performance improvement programs.* In this paragraph, we propose the basic elements of an MCO and PIHP quality assessment and improvement program. We propose that, at a minimum, the State must require that each MCO and PIHP do the following:

- Conduct performance improvement projects as described in paragraph (d) of this section.
- Have in effect mechanisms to detect both underutilization and overutilization of services.
- Have in effect mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs.

We specify that the performance improvement projects would have to achieve, through ongoing measurements

and intervention, demonstrable and sustained improvement in significant aspects of clinical care and non-clinical care areas that can be expected to have a favorable effect on health outcomes and enrollee satisfaction.

- *Performance measurement and improvement.* In this paragraph, we propose that each MCO and PIHP annually measure its performance, using standard measures required by the State consistent with the requirements of § 438.204(c), and report its performance to the State.

- *Performance improvement projects.* In this paragraph, we propose the following:

- Each MCO and PIHP would be required to have an ongoing program of performance improvement projects that focuses on clinical and non-clinical areas.

- Each MCO and PIHP must report the status and results of each project to the State as requested.

We envision States will establish quality indicators that are objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research, and capable of measuring outcomes such as changes in health status, functional status, and enrollee satisfaction, or valid proxies of these outcomes. Further, performance improvement projects must use objective quality indicators, the implementation of system interventions to achieve improvement in quality, evaluation of the effectiveness of the interventions, and planning and initiation of activities for increasing or sustaining improvement.

Finally, we specify that 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.

In the development of this proposed rule, some stakeholders expressed concern that we not mandate the number, type, or quantity of quality improvement studies a State requires the MCO to undertake. Stakeholders expressed concern that targets for improvement vary greatly from State to State, and region to region within a State. Thus, a national consensus would be difficult to achieve. Further, stakeholders also expressed concern that we not set minimum levels for performance measures, noting that by setting them at a level that all plans could reasonably achieve, we might lower performance in the aggregate.

Moreover, our actions might undercut a State's negotiating position. We are sympathetic to many of the above concerns, and have considered them in the development of this proposed rule. However, as the art of quality improvement and measurement advances, we believe that we should have the ability to specify standardized measures and topics for improvement projects. We preserve this right in regulation and clarify that, in exercising this right, we will consult with States and other stakeholders to achieve consensus to the greatest extent possible. We invite public comments in this area.

- *Program review by the State.* In this paragraph, we propose requirements for the State's review of the MCO and PIHP quality assessment and improvement program. We would require the State to review, at least annually, the impact and effectiveness of each MCO's and PIHP's quality assessment and performance improvement program. We also would require the State's review to address the MCO's and PIHP's performance on the standard measures on which it is required to report, and the results of the each MCO's and PIHP's performance improvement projects. Finally, we specify that 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.

18. Health Information Systems (§ 438.242)

This section proposes requirements for health information systems. We generally would require the State to ensure, through its contracts, that the MCO and PIHP maintains a health information system that collects, analyzes, integrates, and reports data and can achieve the objectives of this subpart. We specify that the system should provide information on areas including, but not limited to, utilization, grievances, and disenrollments for other than loss of Medicaid eligibility. At a minimum, the MCO and PIHP would be required to do the following:

- 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.
- Ensure that data received from providers is accurate and complete.
- Make all collected data available to the State, and upon request to CMS, as required in this subpart. In ensuring that the data from providers is accurate and complete, we specify that the MCO and PIHP must have mechanisms to verify

the accuracy and timeliness of reported data, screen the data for completeness, logic, and consistency, and collect service information in standardized formats to the extent feasible and appropriate.

E. Subpart E

We are proposing to reserve Subpart E.

F. Grievance Systems (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 or payment by the MCO).

In this subpart, we propose 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 define terms, describe what constitutes a notice of action, and address how grievances and appeals must be handled, including timeframes for taking action. We include a process for expedited resolution of appeals in specific circumstances; address the requirement for continuation of benefits; and lay out the requirements relating to record keeping, monitoring and effectuation of reversed appeal resolutions.

1. Statutory Basis and Definitions (§ 438.400)

Definitions of terms used in proposed subpart F are found in proposed § 438.400 and would 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.

Governing body means the MCO's or PIHP's Board of Directors, or a designated committee of its senior management.

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.

2. General Requirements (Proposed § 438.402)

Proposed § 438.402 would require that each MCO and PIHP must 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) would specify that an enrollee may file a grievance or an MCO or PIHP level appeal, and may request a State fair hearing. In addition, a provider, acting on behalf of an enrollee and with the enrollee's written consent may file an appeal. However, the provider cannot file a grievance or request a State fair hearing on behalf of the enrollee.

Under § 438.402(b)(2), we propose timeframes within which the enrollee or provider may file an appeal. Our intent is to mirror the filing timeframes for the State fair hearing, that is, a reasonable amount of time up to 90 days. In addition, we have incorporated the longstanding policy at section 2901.3 of the 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 requires 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. Within this timeframe, the enrollee or the provider 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 specify the manner in which enrollees may file grievances, and enrollees or the provider may file appeals. For grievances, the enrollee may file either orally or in writing either to the State or

with the MCO or PIHP, as determined by the State. 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. While enrollees may start the appeal clock with an oral request, they must follow it with a written request as a written appeal best documents the issue being appealed. In expedited situations, this proposed rule provides that the enrollee is not required to place the appeal in writing.

3. Notice of Action (§ 438.404)

We are proposing that the notice MCOs and PIHPs would be required to provide to enrollees under proposed § 438.404 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 propose that the notice must meet the language and format requirements of proposed § 438.10(c) and (d) of this chapter to ensure ease of understanding. The notice would be required to include the elements that are listed in proposed § 438.404, 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 specify 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 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 propose that notice be given at the time of any action affecting the claim. Proposed § 438.404(c)(3) and (c)(4) requires 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 where the service authorization decision is not reached within specified timeframes, we propose at § 438.404(c)(5) that notice be mailed on the date that the timeframe expires. Finally, for expedited service authorization decisions, notice must be given within the timeframes specified in proposed § 438.210(e).

4. Handling of Grievances and Appeals (§ 438.406)

Section 438.406 proposes 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), to give enrollees any reasonable assistance. We would also require that MCOs and PIHPs make interpreter services available to enrollees, as well as, 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 do 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) specifies 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 enrollee 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.

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

In § 438.408(a) we propose to require that 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. In addition, this section proposes that the State must establish timeframes for disposition of grievances and resolution of appeals, but that they may not exceed the specific timeframes proposed in this section.

While we are proposing timeframes to resolve appeals, we realize that 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. We believe that uniform timeframes, across payers, are desirable in that this will make the process more understandable to enrollees and ease the burden on health plans of administering the internal appeals system. Therefore, our intent, in this proposed rule, is to consider a patient's bill of rights when enacted by the Congress.

Under proposed § 438.408(b), we would establish the specific timeframes for disposition of grievances and resolution of appeals. For 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, we propose at § 438.408(b)(2) that the State establish a timeframe that is no longer than 45 days from the day the MCO or PIHP receives the appeal. However, we would allow this timeframe to be extended. Under proposed § 438.408(c) we specify 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) would provide a maximum timeframe for expedited resolution of appeals and notice to affected parties. We propose that the State establish a timeframe that is 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 health 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 propose 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 do propose some parameters for the extension process. Under proposed § 438.408(c)(2), if the MCO or PIHP grants themselves an extension, they would be required to notify the enrollee in writing of the reason for the delay. In § 438.408(d), we propose, that the State must establish the method MCOs and PIHPs will use to notify an enrollee of the disposition of a grievance. Under proposed § 438.408(e), we specify 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) we outline the requirements for State fair hearings. We propose that 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 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.

6. Expedited Resolution of Appeals. (§ 438.410)

In proposed § 438.410 we specify that each MCO and PIHP must 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 would be required to ensure that punitive action is neither threatened nor taken against a provider who requests an expedited resolution or supports an enrollee's appeal.

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

7. Record Keeping and Reporting Requirements (§ 438.416)

Proposed § 438.416 would require 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.

8. Continuation of Benefits While the MCO or PIHP Appeal and the State Fair Hearing are Pending (§ 438.420)

In § 438.420, we propose 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 extension of benefits.

We specify 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 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 physician or affect benefits not originally authorized. We expect that the MCO will neither take nor threaten to take any punitive action against a physician who requests continuation of benefits or supports an enrollee's request for continuation of benefits.

If the MCO or PIHP continues or reinstates the enrollee's benefits while the appeal is pending, according to 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 office 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 propose 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).

We considered but rejected an option that would have required MCOs to automatically forward appeals they reject to the State fair hearing process for external review, as is currently the case in Medicare. Under this option, continuation of benefits could have also automatically occurred with the forwarding of the request. We have rejected this as well. We determined that this option would have been too burdensome and in many cases would result in forwarding unnecessary paperwork to the State fair hearing office.

9. Effectuation of Reversed Appeal Resolutions (§ 438.424)

In § 438.424 we propose 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.

G. Subpart G

We are proposing to reserve Subpart G.

H. Certifications and Program Integrity Protections (Subpart H)

Subpart H contains provisions pertaining to plan certification of data, information, and material and general contract provisions.

Sections 1902(a)(4) and (a)(19) of the Act establish methods of administration that are necessary for the proper and efficient operation of the plan and ensure that care and services will be provided in a manner consistent with the best interest of the recipient and to preserve the integrity of the Medicaid program.

In this proposed rule, we are requiring MCOs and PIHPs to certify the accuracy, completeness, and truthfulness of any data, including but not limited to, enrollment information, encounter data, data upon which payment is based, and other information required by the State, that may be submitted to determine the basis for payment from a State agency. The certification must be made by the MCO's or PIHP's Chief Executive Officer, Chief Operating Officer, or their delegate. Each MCO and PIHP must certify that it is in substantial compliance with the contract and provide additional certification as required by the State. Consistent with the Medicare+Choice provisions, we propose to require that the certifications be based on best knowledge, information, and belief.

We are also requiring, consistent with Medicare+Choice, that any entity seeking to contract as an MCO or PIHP must have administrative and management arrangements or procedures, including a mandatory compliance plan, designed to guard against fraud and abuse. We specify in § 438.608 what those arrangements must include.

I. 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 States establish intermediate sanctions that the State may impose on an MCO that commits one of six specified offenses: (1) Failing substantially to provide medically necessary services; (2) imposing premiums or charges in excess of those permitted; (3) discriminating among enrollees based on health status or requirements for health care services; (4) misrepresenting or falsifying information; (5) failing to comply with physician incentive plan requirements; and (6) distributing marketing materials that have not been approved or that contain false or materially misleading information. In the case of the violation related to marketing materials (number 6), the statute imposes sanctions against PCCMs as well as MCOs. Proposed § 438.700 contains the above provisions from section 1932(e)(1) of the Act.

In section 1932(e)(2) of the Act, the Congress provided specific sanction

authority under which States may impose civil money penalties in specified amounts for specified violations, take over temporary control of an MCO, suspend enrollment or payment for new enrollees, or authorize enrollees to disenroll without cause. These provisions are reflected in proposed § 438.702(a). Given the extraordinary nature of the sanction of taking over management of an MCO, we propose in § 438.706 that this sanction be imposed only in the case of "continued egregious behavior," in situations in which there is "substantial risk" to enrollee health, or when the sanction is "necessary to ensure the health of enrollees." We also want to clarify that States have the right and authority to terminate an MCO's contract before temporary management would have to be imposed. We recognize the burden associated with this sanction and realize that most States would rather terminate a contract before having to impose temporary management. We believe we have written the proposed rule to allow this flexibility.

We have not applied the sanction provisions to PIHPs and PAHPs because we do not believe that the statutory authority on which PIHPs and PAHPs are based (section 1902(a)(4) of the Act) provides authority to publish 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.

Although these sanctions are referenced in section 1932(e)(1) of the Act as sanctions to be imposed on MCOs, and on PCCMs only in the case of marketing violations, section 1932(e)(2)(C) of the Act refers to a "managed care entity," while paragraphs (D) and (E) that follow refer to "the entity" and provide for suspension of enrollment or suspension of payment after the date the Secretary notifies "the entity" of a determination that it has violated "section 1903(m) or * * * section [1932]." While only an MCO could violate section 1903(m) of the Act, a PCCM could violate requirements of section 1932 of the Act that apply to MCOs and PCCMs generally or to PCCMs specifically. In proposed § 438.700(d), we interpret the foregoing language to mean that the sanctions in sections 1932(e)(2)(D) and (E) of the Act are available in the case of a PCCM that violates "any requirement" in section 1932 of the Act. The general intermediate sanction authority in paragraphs (D) and (E) of section 1932(e)(2) of the Act is reflected in proposed § 438.700(d) for MCOs. In light of the foregoing interpretation,

paragraphs (a)(4) and (a)(5) of proposed § 438.702 can be applied to MCOs or PCCMs rather than MCOs only, even though the only "determinations" that apply to PCCMs are terminations under proposed § 438.700(c) (marketing violations) or the general violations of section 1932 of the Act that are addressed in proposed § 438.700(d).

Section 1932(e)(3) of the Act requires that, for MCOs with chronic violations, the State impose temporary management and allow disenrollment without cause. This provision is implemented in proposed § 438.706.

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 authority is implemented in proposed § 438.708. Under section 1932(e)(4)(B) of the Act, before terminating a contract, the State is required to provide a hearing. Proposed § 438.710 sets forth this hearing requirement as well as procedures for the hearing. Under section 1932(e)(4)(C) of the Act, enrollees must be notified of their right to disenroll immediately without cause in the case of any enrollee subject to a termination hearing. Proposed § 438.722 reflects this provision.

Section 1932(e)(5) of the Act contains a general requirement that States provide "notice" and "such other due process protections as the State may provide" in the case of sanctions other than terminations, which are governed by section 1932(e)(4)(B) of the Act. Section 1932(e)(5) of the Act also provides that "a State may not provide a managed care entity with a . . . hearing before imposing the sanction" of temporary management. Proposed § 438.706(c) reflects this statutory language.

In proposed § 438.724, we propose that States be required to notify CMS whenever they impose or lift a sanction.

The new sanction authority in section 1932(e) of the Act represents the first time that the Congress has granted Medicaid sanction authority directly to State agencies. Under section 1903(m)(5) of the Act, which the Congress has left in place, CMS has 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. In proposed § 438.730, we retain the existing regulations implementing section 1903(m)(5) of the Act, which is currently in § 434.67.

J. Conditions for Federal Financial Participation (Subpart J)

In subpart J, we propose to include both existing and new regulations pertaining to State eligibility for FFP in payments under managed care contracts. Absent a statutory exemption from its provisions, section 1903(m)(2)(A) of the Act conditions Federal matching in payments under a comprehensive risk contract on compliance with the requirements in section 1903(m)(2)(A) of the Act. The requirements of this section of the Act include an entity meeting the definition of MCO, payment on an actuarially sound basis, prior approval by CMS of the contract, physician incentive requirements, and the new disenrollment rights under section 1932(a)(4) of the Act, which are incorporated under section 1903(m)(2)(A)(vi) of the Act. Most significantly, section 1903(m)(2)(A)(xi) of the Act conditions Federal matching in comprehensive risk contracts on the contract's and the MCO's compliance with applicable requirements in section 1932 of the Act. This includes the MCO's role in complying with the State quality strategy proposed under subpart D, the beneficiary protections in subpart C, and the grievance requirements in subpart F. All of the requirements in this part that apply to MCOs implement either section 1903(m) or section 1932 of the Act. Thus, Federal matching in MCO contracts is conditioned on compliance with these requirements.

1. Basic Requirements (§ 438.802)

We propose in § 438.802 that FFP is available in expenditures for payments under an MCO contract only for periods during which the contract meets the requirements of part 438 and is in effect. We also propose that FFP is available only when the MCO and its subcontractors are in substantial compliance with the physician incentive plan requirements and the requirements of the MCO contract.

2. Prior Approval (§ 438.806)

Section 4708(a) of the BBA amended section 1903(m)(2)(A)(iii) of the Act to require the Secretary's prior approval for all MCO contracts involving expenditures in excess of \$1,000,000 for 1998. For subsequent years, the threshold amount for MCO contracts will be increased by the percentage increase as determined by the consumer price index for all urban consumers.

Before the amendments made by section 4708 (a) of the BBA, section 1903 (m)(2)(A)(iii) of the Act required that the Secretary must provide prior

approval for all HMO contracts involving expenditures in excess of \$100,000. There was no reference in statute or regulations made for monetary increases of the threshold amount in future years.

3. Exclusion of Entities (§ 438.808)

We propose to redesignate existing § 434.80 as 438.808 to describe entities that must be excluded.

4. Expenditures for Enrollment Broker Services (§ 438.810)

Proposed § 438.810 would implement section 1903(b)(4) of the Act, added by section 4707(b) of the BBA, which provides for limitations on FFP in payments to enrollment brokers. Prior to this provision, there was no reference or provisions in current law or regulations specifically pertaining to enrollment brokers and their expenditures. This provision clarifies that States' expenditures for enrollment brokers are considered necessary for the proper administration of the State Plan, but only if the broker is independent of any managed care entity or health care provider that provides services in the same State in which the broker is conducting enrollment activities. No owner, employee, board member, or person who has a contract with the broker may have financial interest in that entity or provider, nor may the individual have been debarred by any Federal agency or subject to civil penalties under the Act or be excluded from participation under title XVIII or XIX of the Act. An enrollment broker would not meet the test for independence if it is an MCO, PIHP, PAHP, PCCM or other health care provider, or owns, or is owned by an MCO, PIHP, PAHP, PCCM, or other health care provider in the State in which the broker operates. This would include county eligibility employees performing enrollment activities when the county also provides health care services.

In addition, under our proposed rule, State agencies would be required to submit to CMS all initial enrollment broker contracts or Memoranda of Agreement (MOA) for approval. Contracts being renewed with the same contractor would not be subject to approval. We are proposing to impose this requirement under our authority under section 1902(a)(4) of the Act to provide for necessary and proper methods of administration. We believe that it is important that all parties know whether an enrollment broker arrangement meets the requirements for FFP. We accordingly believe that it is "necessary and proper" for the State

agency to obtain approval of broker arrangements. CMS will review contracts or MOAs to ensure that they meet the requirements for FFP.

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

Proposed § 438.812 contains the rules on Federal matching rates for medical services and administrative costs under risk and non-risk contracts currently set forth in §§ 434.74 and 434.75.

6. Limit on Payments in Excess of Capitation Rates (§ 483.814)

As discussed earlier in this preamble in regards to proposed § 438.6(c), we propose in § 438.814 that FFP is not available in expenditures for payments under risk corridors or incentive payments in excess of 105 percent of the aggregate capitation payments made under proposed § 438.6(c). We are concerned that without any upper limit on the amount that can be paid in incentive arrangements or risk-sharing mechanisms, the potential exists for inefficiency or inappropriate actions by the contractor to maximize funding. This funding maximization may result in payments that bear no relationship to the rates certified by actuaries and that are no longer "actuarially sound."

K. Amendments and Revisions to Parts 400, 430, 431, 434, 435, 440, and 447

1. Revisions to Part 400

We propose at § 400.203 to add the following definitions. We propose specifying that PCCM stands for primary care case manager and PCP stands for primary care physician. We believe it is important to include these definitions early in the regulation text, as these are commonly used terms that are used in numerous subparts.

We also propose to revise the definition of provider to mean either of the following: (1) For the fee-for-service program, any individual or entity furnishing Medicaid services under an agreement with the State Medicaid agency; and (2) for managed care programs, 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 this definition is sufficiently broad to allow State flexibility in designation of its providers.

2. Revisions to Part 430

We propose to add a new § 430.5, containing two definitions that currently appear in part 434 or elsewhere. We propose to revise the definition of contractor to eliminate listed examples and apply it more

broadly to any contractor that meets the current introductory clause. The definition, as proposed, would specify that a contractor means any entity that contracts with the State agency, under the State plan and 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.

We also propose to include a definition of representative. This term will have the meaning given by each State consistent with its laws, regulations, and policies. We believe that this definition will allow flexibility in determining who can serve as a Medicaid beneficiary's representative and will not place any restrictions on State definitions currently in use.

3. Revisions to Part 431

We propose conforming amendments to part 431 to reflect changes in terminology and other new provisions enacted in the BBA. As discussed in section II.B.5. of this preamble, we also have made conforming changes to the fair hearing regulations in part 431, subpart E, to reflect the MCO grievance and appeals requirements in part 438 subpart F.

4. Revisions to Part 434

As discussed earlier, we propose to revise part 434 to remove provisions relating to managed care, which we have moved to part 438.

5. Revisions to Part 435

Technical and Conforming Changes. We propose conforming amendments to part 435 to reflect changes in terminology and other new provisions enacted in the BBA. As discussed above, in section II.B.5. of this preamble, we also have made conforming changes to the fair hearing regulations in subpart E of part 435 to reflect the grievance and appeals provisions in subpart F of part 438. In addition, we propose to implement BBA changes to the rules on guaranteed eligibility.

Guaranteed Eligibility (§§ 435.212 and 435.326). Prior to the enactment on August 5, 1997 of section 4709 of the BBA, section 1902(e)(2) of the Act provided that State agencies, at their option, could provide for a minimum enrollment period, during which a Medicaid individual enrolled in a Federally qualified HMO or one of certain other specified entities retains eligibility for Medicaid services the HMO provides even if the enrollee otherwise loses Medicaid eligibility. Even though this provision was enacted in 1983, since that time only a few State agencies have opted to implement this

provision. One factor we believe that has kept State agencies from making greater use of this provision is the requirement that it was limited only to those individuals who were enrolled in Federally qualified HMOs and other entities that are not prevalent in all States.

Section 4709 of the BBA expands section 1902(e)(2)(A) of the Act to include individuals enrolled in MCOs and primary care case management systems. This expansion greatly increases the number of individuals who will be potentially eligible for the guaranteed eligibility provision.

Specifically, section 4709 expands the State's option to guarantee up to 6 months of eligibility in two ways: (1) it expands the types of MCOs or PCCMs whose members may have guaranteed eligibility in that it now includes anyone who is enrolled with a Medicaid MCO as defined in section 1903(m)(1)(A) of the Act, and (2) it expands the option to include those individuals enrolled with a primary care case manager as defined in section 1905(t) of the Act. The provision also describes that when Medicaid benefits are furnished under the guaranteed eligibility provisions, the benefits include only those provided by the MCO or by or through the case manager. This provision applies to the 50 States and the District of Columbia.

We note that section 1902(e)(2) limits the "guaranteed" benefits provided for under its authority to benefits provided to the individual as an enrollee of the MCO, or by or through the case manager for primary care case management enrollees. For primary care case management arrangements, we have interpreted that the guaranteed benefits provided under this provision extend to services that do not require case-by-case authorization of the case manager, such as emergency services, dental, or OB/GYN services received by an enrollee. The scope of the blanket authorization can be defined by the State agency. An example of a blanket authorization would be one that allows Medicaid beneficiaries to access emergency room or dental services without the need to consult a case manager.

6. Revisions to Part 440: Primary Care Case Management Services (§ 440.168)

Section 4702 of the BBA adds primary care case management 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 new section defines primary care case management services, identifies who may provide them, and sets forth requirements for contracts between

primary care case managers and the State agency. Before to the BBA, State agencies were permitted to implement a primary care case management system only through a freedom of choice waiver under section 1915(b)(1) of the Act or through a section 1115 waiver authority. This provision was set forth in order to allow State agencies more flexibility in providing quality services to Medicaid beneficiaries through an arrangement that has proven to be cost effective for the Medicaid program. We are proposing to add § 440.168—Primary Care Case Management Services. This new section will define primary care case management services and identify who may provide them.

Primary care case management services means case management related services that include the locating, coordinating, and monitoring of health care services provided by a primary care case management provider under contract with the State agency as set forth in § 438.6(k). This includes the authority for a primary care case management provider to deny services that are not medically necessary to require preauthorization of services.

A primary care case manager is a physician, physician group practice, or an entity employing or having other arrangements with physicians to provide primary care case management services under contract with the State agency. At the State's option, nurse practitioners, certified nurse midwives, and physician assistants may also qualify as primary care case management providers.

Primary care for the purpose of this provision includes all health care services and laboratory services customarily provided by or through a general practitioner, family medicine physician, internal medicine physician, obstetrician/gynecologist, or pediatrician in accordance with State licensure and certification laws and regulations.

7. Revisions to Part 447

Technical and Conforming Changes. We propose to make technical and conforming changes reflecting changes in terminology and other revisions made by the BBA.

Timely Claims Payment by Managed Care Organizations (§ 447.46). The purpose of this new section of the regulations is to implement section 4708(c) of the BBA, which added section 1932(f) to the Act. Under this provision, contracts, under section 1903(m) of the Act, with managed care organizations must provide that payment to affiliated 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. To be consistent with section 1902(a)(37)(A) of the Act, the Medicaid MCO's contract must ensure 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 furnished 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. However, the MCO and health care providers have the flexibility to establish an alternative payment schedule that is mutually agreed upon. If an alternative payment schedule is established, it should also be described in the managed care organization's contract, so that providers are ensured payment under the procedures agreed to.

We also made conforming changes to §§ 447.53 through 447.60.

III. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-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 an information collection should be approved by OMB, 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 3 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 25,731,040 beneficiaries enrolled in these plans (some beneficiaries are enrolled in more than one plan) in 48 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) would modify the rules governing payments to MCOs, PIHPs and PAHPs by doing the following: (1) Eliminates the upper limit (UPL) requirements; (2) requires actuarial certification of capitation rates; (3) specifies data elements that must be included in the methodology used to set capitation rates; (4) requires States to consider the costs for individuals with chronic illness, disability, ongoing health care needs, or catastrophic claims in developing rates; (5) requires States to provide explanations of risk sharing or incentive methodologies; and (6) imposes special rules, including a limitation on the amount that can be paid under FFP in some of these arrangements.

2. Burden

We believe that the burden of providing additional information to support the actuarial soundness of a State's capitation rates will be offset by the elimination of the UPL requirement. States will no longer be required to extract FFS data and manipulate the data by trending and other adjustments in order to establish a FFS equivalent for purposes of comparison to capitation rates. We invite comment on this burden assumption.

B. Section 438.8 Provisions That Apply To PIHPs and PAHPs

Section 438.8(a) Contract Requirements

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, while physician incentive plan requirements apply to both PIHPs and 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 PIHPs to provide written information to enrollees of their rights under this provision and the PIHP's policies for the implementation of those rights. We project 8 hours for each of the 123 PIHPs 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. The total time for this would be 210,984 hours.

Under the physician incentive plan provision, PIHPs and PAHPs, like MCOs, will be required to provide descriptive information to States and us 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.

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) that contained the original regulatory provisions on physician incentive plans for Medicare and Medicaid HMOs. Based on those assumptions, we believe no more than one third 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 52 PIHPs and PAHPs the total burden would be 5,200 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 one fourth 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 113 hours. Altogether, we estimate 5,313 hours of burden through imposition of this requirement on PIHPs and PAHPs.

C. Section 438.10 Information requirements

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

1. Requirement

In summary, § 438.10 requires that each State or 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 notify enrollees and potential enrollees, and require each MCO, PIHP, and PAHP and PCCM to notify its enrollees and potential enrollees that oral interpretation and written information are available in languages other than English and how to access those services. The basic information listed in paragraph (e) of this section must be provided to each potential enrollee by the State, MCO, or PIHP. The information listed paragraph (f) must be furnished to enrollees by the MCO or PIHP within a reasonable time after it receives from the State notice of the beneficiary's enrollment. The MCO or PIHP must notify enrollees annually of their right to disenroll and receive the information listed in paragraph (f)(6) and, if applicable, paragraph (g). The information that must be provided includes the following:

2. Information for Potential Enrollees

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.

Information specific to each MCO and PIHP 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.

3. Information for Enrollees

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.

Information Required for MCOs, PIHPs, PAHPs, and PCCMs

- Names, locations, and telephone numbers of current network providers, including information at least on primary care physicians, specialists, and hospitals, and identification of providers that are not accepting new patients.
- Any restrictions on the enrollee's freedom of choice among network providers.
- Enrollee rights as specified in § 438.100.
- Kinds of benefits, and amount, duration, and scope of benefits available under the contract.
- Procedures for obtaining benefits, including authorization requirements.
- The extent to which, and how, enrollees may obtain benefits, including family planning services, from out-of-network providers.
- The extent to which, and how, after-hours and emergency coverage are provided.
- The rules for emergency and post-stabilization services, as set forth in § 438.114.
- Additional information that is available upon request, and how to request that information.
- Cost sharing, if any.
- 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, and cost sharing, and how transportation is provided. The State must furnish information about how and where to obtain the service.

Additional Information Required of MCOs and PIHPs

- Grievance, appeal, and fair hearing procedures and timeframes, as provided in § 438.400 through § 438.424, in a State-approved or State-developed description.

- Advance directives, as set forth in § 438.6(I)(2).
- Physician incentive plans as set forth in § 438.70(a)(4).

• Additional information that is available upon request, including information on the structure and operations of the MCO or PIHP.

Burden. We believe the burden placed on States, MCOs, PIHPs, PAHPs, and PCCMs and enrollment brokers as a result of this requirement 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 to modify existing information materials to conform with the requirement above. We further estimate that there are approximately 533 MCOs, PIHPs, PAHPs, and PCCMs equating to an initial modification burden of approximately 6,396 hours. After the initial modification, we estimate that it will take MCOs, PIHPs, PAHPs, and PCCMs 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 PCCMs 5 minutes 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 will take 5 minutes for MCO, PIHPs, PAHPs, and PCCM 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 MCO, PIHPs, PAHP, and PCCMs if delegated this responsibility by the State, of 214,425 hours.

Section 438.10(h)

1. Requirement

In summary, § 438.10(h) states that if a 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

We believe that the additional burden on States (that is, burden 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 4 hours each to create the comparative chart. Currently 9 States per year have approved manage care under the State Plan Option, for a total annual burden of approximately 36 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 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 40 hours per State to develop the process for involving the public for a total burden of 1,960 hours (48 States and D.C.). We

estimate that ensuring ongoing public involvement will take another 20 hours per State annually for a total annual burden of 980 hours.

F. Section 438.56 Disenrollment: Requirements and Limitations

Section 438.56(b)

1. Requirement

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 a 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; and

(3) Specify the methods by which the MCO, PIHP, PAHP, or PCCM ensures the agency that it does not request disenrollment for reasons other than those permitted under the contract.

2. Burden

The burden of submitting this supporting documentation when MCOs, PIHPs and PAHPs, or PCCMs request disenrollment of beneficiaries would be 2 hours per request. We calculate that approximately one-tenth of one percent of enrollees (25,731) would be affected, or 48 per MCO, PIHP, PAHP, or PCCM annually. The total burden would be 51,462 hours, or approximately 97 hours per MCO, PIHP, PAHP, or PCCM.

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.

Section 438.56(d)(3)

1. Requirement

When MCOs, PIHP, PAHP, or PCCMs are processing disenrollment requests and do not act to approve them, they must submit written notice to the State and then the State takes action. When a State is acting on a for-cause disenrollment request, they may request written information from the MCO, PIHP, PAHP, or PCCM to determine the outcome. In addition, if the MCO, PIHP, PAHP, or PCCM approves the disenrollment for cause, it must give the enrollee and the State agency written notice of its determination.

2. Burden

We believe that the burden associated with this requirement is the time taken for MCOs, PIHPs and PAHPs, or PCCMs to submit written notice to the State and beneficiaries.

Of the 1,286,552 affected enrollees, we calculate that one-fifth (257,310) will not be approved. If each notice takes 15 minutes to produce, the total burden would be 64,328 hours. Of the 257,310 enrollees not approved, we calculate that three-fourths (192,983) will involve the State requesting information from the MCO, PIHP, PAHP, or PCCM justifying the denial. At 1 hour per request, the total burden on MCOs, PIHPs, PAHPs, or PCCMs would be 192,983 hours.

We estimate that the MCOs, PIHPs, PAHPs, and PCCMs will need to produce notices for the remaining four-fifths of enrollees whose disenrollment (1,029,240) is approved. As this notice will probably be a short form letter, with attachments as necessary, we believe that it will take ten minutes per request to send out the notices, for an annual burden of 171,540 hours.

G. Section 438.102 Enrollee-Provider Communications

1. Requirement

Section 438.102(c) states that the general rule in paragraph (b) of this section does not require the MCOs and PIHPs to cover, furnish, or pay for a particular counseling or referral service if the MCO or PIHPs 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 for any particular service.

2. Burden

The above information collection requirement is subject to the PRA. However, we believe the burden associated with these requirements is captured in the general information requirements in § 438.10.

H. Section 438.114 Emergency Services

1. Requirement

Section 438.114(b) states that at the time of enrollment and at least annually thereafter, each MCO, PIHP, PAHP, and State (for a PCCM) must provide, in clear, accurate, and standardized form, information that, at a minimum, describes or explains (1) What constitutes an emergency, with reference to the definitions in paragraph (a) of this section, (2) the appropriate use of emergency services, (3) the process and procedures for obtaining emergency services, including use of the 911 telephone system or its local equivalent, (4) the locations of emergency settings and other locations at which MCO, PIHP, or PAHP physicians and hospitals provide emergency services and post-stabilization care covered under the contract, and (5) the fact that prior authorization is not required.

2. Burden

The following information collection requirement is subject to the PRA. However, we believe the burden associated with these requirements is captured in the general information requirements in § 438.10.

I. 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 at least every 3 years. Each State must also submit to us 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 us 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 us 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 1640 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 us 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 least every 3 years for a total annual burden of 546 hours.

J. Section 438.204 Elements of State Quality Strategies

1. Requirement

In this proposed rule we require at § 438.204(b)(1)(iii) 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 2 hours of programming for each of the 41 jurisdictions for a total of 82 hours.

K. Section 438.207 Assurances of Adequate Capacity and Services

1. Requirement

Section 438.207(b) requires that each MCO and PIHP must submit documentation to the State, in a format specified by the State and acceptable to us, 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 least annually, and specifically at the time the MCO or PIHP 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 or PIHP's operations that would affect adequate capacity and services.

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

2. Burden

We believe that MCOs and PIHPs 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 and PIHPs is the length of time required for MCOs and PIHPs to compile this information in the format specified by the State agency, and the length of time for the MCOs and PIHPs to mail the information to the State and to us. We estimate that it will take each MCO and PIHP approximately 20 hours to compile the information necessary to meet this requirement, for a total of 20 hours multiplied by 462 MCOs and PIHPs, or approximately 9,240 hours. In addition, we estimate that it will take MCOs and PIHPs 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 462 MCOs and PIHPs, or approximately 39 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 MCOs 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 and PIHP for a total estimated burden of 18,480 hours.

L. 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, in § 438.240(d)(1) States are to ensure that each MCO and PIHP must 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 project to the State as requested.

2. Burden

This regulation would require 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 have these programs. 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.

For the requirements for an ongoing program performance improvement projects in § 438.240(d), we estimate that, in any given year, each MCO and PIHP will complete two projects, and will have 4 others underway. We further expect that States will request the status and results of each MCOs and PIHPs 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.

M. 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 methods as may be specified by the State.

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.

N. 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 for expedited service authorization decisions) must be followed by a written request.

2. Burden

We estimate that approximately 1 percent of 19 million MCO and PIHP enrollees (190,000) annually will file a grievance with their MCO or PIHP and that approximately .5 percent (95,000) 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 95,000 hours.

O. 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 (950,000) of the approximately 19 million MCO and PIHP enrollees will receive one notice of intended action per year from their MCO or PIHP (approximately 17 hours per MCO or PIHP) for a total burden of approximately 7917 hours.

P. 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.

Q. Section 438.408 Resolution and Notification: Grievances and Appeals

1. Requirement

In summary, § 438.408 states that for grievances filed in writing, 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 requests 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.

R. Section 438.410 Expedited Resolution of Grievances

Paragraph (c)

1. Requirement

Paragraph (c), Action following denial of a request for expected 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.

S. Section 438.416 Record Keeping and Reporting Requirements

1. Requirement

Section 438.416 paragraphs (a) and (c) state that each MCO and PIHP must 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).

T. Section 438.604 Data That Must Be Certified

1. Requirement

Each MCO and PIHP must certify that it is in substantial compliance with its contract. Certification is required, as provided in § 438.606, for all documents specified by the State.

2. Burden

While the requirement for MCOs and PIHP to certify its compliance with its contract and for all documents required by the State, the burden associated with these requirements is captured during the submission of the information. Therefore, we are assigning 1 token hour of burden for this requirement. Submission of the certified information and data occurs when the MCO or PIHP requests payment from the State according to the terms of its contract. There is no burden assigned to the submission as it is not required by this regulation, but rather by terms of the MCO's or PIHP's contract with the State.

U. 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 requirements are not subject to the P.A. They are exempt under 5 CFR 1320.4(a) because they occur 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.

V. 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 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.

W. Section 438.724

1. Requirement

Section 438.724 requires that the State give our 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.

X. 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 us for review and approval prior to the effective date of services required by the contract or MOA.

2. Burden

The burden associated with this requirement is the length of time for a State to mail each contract to us for review. We estimate 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 proposed rule to OMB for its review of the information collection requirements described above. These requirements are not effective until they have been approved by OMB.

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The following table summarizes the collection of information burden as discussed above.

**NUMBER OF BURDEN HOURS
(BASED ON 2000 ENROLLMENT REPORT)**

REQUIREMENT	STATE	PLAN	ENROLLEE
§438.8 Provisions that apply to PIHPs and PAHPs ~ written information on enrollee rights ~ information to State and CMS on financial risk		216,287 210,984 5,313	
§438.10 Information requirements (for potential enrollees and enrollees including information on benefits, the basic features of managed care, and information on enrollees' right to request information) 438.10(e)(f)(g)(h) ~ modify existing materials ~ annual update of materials ~ mail information to potential enrollees ~ mail annual information to enrollees ~ mail requested material to potential enrollees ~ create comparative chart 438.10(h) Total information requirement burden hours	2,430,214 65,000 2,144,253* 6,500 214,425* 36 2,438,742	8,528 6,396 2,132	
§438.12 Provider discrimination prohibited		4,960	
§438.50(b) State plan information	2,940		
§438.56 Disenrollment: Requirements and limitations 438.56(b) ~ submit documentation to State for disenrollment request 438.56(d)(1) ~ enrollee written request for disenrollment 438.56(d)(3) ~ notice of disapproval of disenrollment request 438.56(d)(3) ~ MCO information to State justifying the denial 438.56(d)(3) ~ notice to beneficiary of disenrollment approval Total disenrollment requirement burden hours		480,313 51,462 64,328 192,983 171,540 533,919	53,606 53,606
§438.202 State responsibilities (written strategy for assessing and improving quality)	3,950		
§438.204 Elements of State quality strategies	82		
§438.207 Assurances of adequate capacity and services		27,759	
§438.240 Quality assessment and performance improvement program; Performance improvement projects		13,860	
§438.402 General requirements (of the grievance system)			95,000
§438.404 Notice of action (associated with the grievance system)		7,917	
§438.416 Record keeping and reporting requirements (associated with the grievance system)		1,583	
§438.604 Data that must be certified		1	
§438.722 Disenrollment of enrollees during MCO termination hearing	46,206		
§438.724 Notice of intent (to impose or lift a sanction)	18		
§438.810 Expenditures for enrollment broker services	3		
Burden hours by category	2,483,413	761,217	148,606
Total Burden Hours	3,393,236		

* State may delegate these requirements to the MCO, PIHP, PAHP, or PCCM as applicable.

IV. Regulatory Impact

A. Introduction

We have examined the impacts of this proposed rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when 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). This rule meets the criteria of being economically significant because the impact would be over \$100 million.

The RFA requires agencies to analyze options for regulatory relief of small entities. This rule implements Medicaid managed care provisions as directed by BBA. The statute does not permit significant alternatives to these regulatory provisions; however, we invite comments on alternatives to provisions of this proposed rule that would reduce burden on small entities.

This proposed rule primarily impacts beneficiaries, State agencies, enrollment brokers, MCOs, PIHPs, PAHPs, and PCCMs. Small entities include small business in the health care sector with receipts of less than \$5 million to \$25 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. We estimate that in 2000 there were 339 MCOs, 123 PIHPs, 34 PAHPs, and 37 PCCMs. We believe that only a few of these entities qualify as small entities.

Specifically, we believe that the 37 PCCM systems are likely to be small entities, as are approximately 12 of the PAHPs. We believe that the 10 PAHPs that are at risk for ambulatory medical services only are likely to be small businesses, as are two dental PAHPs. We believe that the remaining PAHPs and all the MCOs and PIHPs have annual receipts from Medicaid contacts and other business interests in excess of \$25 million.

We do not believe that the impact of the new provisions of this proposed regulation are great on the small entities that we have identified. The most significant requirement relates to providing information to enrollees. Specifically, PCCMs and PAHPs 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. We do not believe that PCCMs or PAHPs provide much written material to enrollees. In fact, in the proposed regulation, we place the responsibility on States, rather than PCCMs and PAHPs, to provide information to potential enrollees. The regulation does provide that the State may require the PCCM or PAHP to provide additional information to enrollees, at their request, concerning the grievance procedures available to enrollees. However, the State may take responsibility for this rather than require that it be done by the PCCM or PAHP. In either case, we believe that States will prepare this information so that the only burden on PCCMs and PAHPs would be to distribute the information when it is requested by an enrollee.

The regulation would require managed care entities, including PCCMs and PAHPs, to make oral interpretation services available to each potential enrollee or enrollee requesting them. We do not have information on which to base an estimate of the burden of this requirement. We invite comment on the burden of this provision and cost data to help us develop estimates.

PCCMs and PAHPs also 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 PCCM or PAHP. However, as all enrollees will have an annual opportunity to disenroll, we believe that the number of disenrollment requests for cause will be small. In addition, PCCMs and PAHPs must submit marketing material to the State for review and approval and must cover and pay for emergency services based on the prudent layperson standard (this only applies to PCCMs if they have a risk contract). We believe that only the two dental PAHPs are likely to produce marketing material and that only the 10 PAHPs with a risk contract will be subject to the emergency services provision.

PAHPs must meet two other requirements. First they may not discriminate against providers seeking to participate in the plan. This requirement imposes no burden. Second, they must meet solvency standards to ensure that Medicaid enrollees will not be responsible for any debt should the entity become insolvent. We believe that this imposes

little burden in addition to normal business requirements for entities assuming risk.

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 603 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 proposed rule would 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. The impact on individual hospitals would vary according to each hospital's current and future contractual relationships with MCOs and PIHPs. Furthermore, the impact would also vary according to each hospital's current procedures and level of compliance with existing statute and regulation pertaining to Medicaid managed care. For these reasons, this proposed rule is not expected to have a significant impact on the operations of a substantial number of hospitals.

The Unfunded Mandates Reform Act of 1995 requires that agencies prepare an assessment of anticipated costs and benefits before proposing 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 rule does not impose any mandates on State, local, or tribal governments, or the private sector that would result in an annual expenditure of \$110 million or more.

B. Summary of the Proposed Rule

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

- Eliminating the requirement that no more than 75 percent of enrollees in an MCO or PHP be Medicaid or Medicare enrollees.

- 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 and PIHPs 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 from \$100,000 to \$1 million.

- Permitting cost sharing for managed care enrollees under the same circumstances as permitted in fee-for-service.

- Expanding the managed care population for which States can provide 6 months of guaranteed eligibility.

- Revising the rules for setting capitation rates.

It would be 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 original proposed regulation published on September 29, 1998 the **Federal Register** (63 FR 52022). Because this new proposed regulation 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 proposed regulation. However, the 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. While the study's focus is limited to selected provisions of the

previously proposed regulation, and some of the details of the provisions in this proposed rule differ from the earlier proposed rule, nevertheless, we believe that the overall cost conclusions are relevant to this proposed 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 effect 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.

According to the MCOs included in the Lewin study, many of the proposed provisions 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 proposed 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 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 fourth and subsequent years (ongoing performance measurement).

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 proposed regulatory requirements, they would 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 would 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 proposed rule would be beneficial to Medicaid beneficiaries, MCOs, PIHPs, PAHPs, PCCMs, States, and us. Many of the BBA Medicaid managed care requirements merely codify 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 would be affected by this proposed Medicaid regulation but in varying degrees. Much of the burden would be on MCOs, PIHPs, PAHPs, and PCCMs contracting with States, but this would also vary by existing and continuing relationships between State agencies and MCOs, PIHPs, PAHPs, and PCCMs. This regulation is intended to provide States flexibility and minimize the compliance cost to States, MCOs, PIHPs, PAHPs, and PCCMs to the extent possible consistent with the detailed BBA requirements. We believe the proposed provisions would 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, and PIHPs would 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.

C. State Options to Use Managed Care Managed Care Organizations

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 would still be required to include certain exempted populations in mandatory managed care programs, notably SSI populations,

Indians, and groups of children with special needs. Federal review would be limited to a one-time State plan amendment approval, while States would no longer need to request waiver renewals every 2 years for section 1915(b) of the Act and 5 years for section 1115 of the Act waivers. State agencies may include "exempted" populations as voluntary enrollees in State plan managed care programs. Currently, nine 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 would not alter the standards of care practiced by MCOs and health care providers and, therefore, would 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 would eliminate the need for States to go through the waiver renewal process. Likewise, we would benefit from a reduced administrative burden if fewer waiver applications and renewals are requested. However, we believe the overall reduction in burden to both States and to Medicare would be small in relation to the overall administrative requirements of the Medicaid program.

D. Elimination of 75/5 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 would broaden the number of MCOs, PIHPs, and PAHPs available to States for contracting, leading to more choice for beneficiaries.

E. 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 have not specified 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 proposed regulation. This belief is supported by recent State surveys, 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 would require uniform procedures across MCOs and PIHPs, and would require MCOs and PIHPs to change their procedures to conform to the regulation, the requirements of the proposed regulation would not impose additional requirements on MCOs and PIHPs over what is currently in place.

In the Collection of Information section of this preamble, we assigned 7,917 burden hours to MCOs and PIHPs for the notice requirements of the grievance system, and 1583 hours for the record keeping requirements and summary reports to be prepared by MCOs and PIHPs and submitted to the States. This results in 9,500 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 \$155,230.

F. Provision of Information

In mandatory managed care programs, we have required 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. 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 would

represent different degrees of difficulty and expense.

The information requirements for MCOs and PCCMs in the proposed regulation are required under the BBA. In this proposed regulation, however, we extend requirements to PIHPs and PAHPs. We welcome examples of the current experience of PIHPs and PAHPs in providing information to enrollees. This would assist us in more accurately estimating the impact of these provisions.

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 9 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 a 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 would 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 9 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 4 hours to create a chart, or 36 hours for 9 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 \$614.

G. 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 and PIHPs. 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 and PIHP contracts. This may be perceived as a burden to MCOs and PIHPs, and for States that have not been required to formally certify that an MCO or PIHP meets the States' capacity and service requirements. However, certification to us would ensure an important beneficiary protection while imposing only a minor burden on States to issue a certification to us.

Quantifying the additional burden on States, MCOs, or PIHPs as a result of implementing this regulation is not feasible for several reasons. First, we do not have State-specific data on the types of detailed information States currently require of their MCOs and PIHPs to assure adequate capacity and services. Second, we do not have State-specific information on the manner in which State agencies collect and evaluate documentation in this area. Rather, 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 would determine and specify both the detail and type of documentation to be submitted by the MCO or PIHP to assure adequate capacity and services and the type of certification to be submitted to us. 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, State agencies, and us, Medicaid beneficiaries would 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 or PIHP to complete this requirement. For the 462 MCOs and PIHPs, this requirement would take 9,240 hours to complete annually.

H. 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, marketing, and information standards; (3) procedures for monitoring and evaluating the quality and appropriateness of care and service to enrollees; and (4) regular and periodic examinations of the scope and content of the State's quality strategy.

The provisions of this regulation propose 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 would have implications for State Medicaid agencies that would be responsible for monitoring for compliance with the new requirements, we believe that a number of recent statutory, regulatory, and private sector developments would enable State Medicaid agencies to more easily monitor for compliance than in the past at potentially less cost to the State. First, the BBA included provisions addressing how States are to fulfill the statutory requirement for an annual, external quality review (EQR) of each Medicaid-contracting MCO and PIHP. (These provisions are addressed in a separate rule). Prior to the BBA, 75 percent Federal financial participation in the cost of these activities was available to States only if the State used a narrowly defined list of entities to perform the quality review. The BBA opened up the possibility for use of a much wider array of entities to perform this function. Further, in our proposed rule to implement these EQR provisions published in the **Federal Register** on December 1, 1999 (64 FR 67223), we specified that the 75 percent Federal match would be available to EQR

organizations that performed activities necessary for monitoring compliance with these BBA quality requirements for MCOs and PIHPs. The BBA also provided that States could exercise an option whereby MCOs that were accredited by a private accrediting organization under certain conditions could be determined to meet certain quality requirements specified in this rule, thereby avoiding costs to the State of directly monitoring for compliance with these requirements. In response to this, private accrediting organizations such as the National Committee for Quality Assurance have developed Medicaid accreditation product lines.

In addition, 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 proposed 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 would 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 would present administrative challenges for some State agencies, MCOs, and PIHPs. However, States have significant latitude in how these requirements would be implemented. Acknowledging that there likely would 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 would outweigh the costs of implementing and maintaining these processes over time.

I. Administration

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

2. 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 would 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 proposed provision would not affect a significant number of plans or States.

J. 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 would 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 would be necessary on the part of MCOs or PIHPs. 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 would take advantage of this option or of the net costs or savings that would result.

K. 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 would 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 2001	FY 2002	FY 2003	FY 2004	FY 2005
Federal	55	80	115	165	230
State	45	60	90	125	175

COST OF 6-MONTH GUARANTEED ELIGIBILITY OPTION—Continued

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

	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005
Total	100	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 would have access to increased continuity of care, which should result in better health care management and improved clinical outcomes.

L. Financial Impact of Revised Rules for Setting Capitation Payments

This rule proposes to replace 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 proposed 438.6(c). In general, we would not expect a major budget impact from the use of these proposed 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 would retain the authority to look behind rates that appear questionable and disapprove any that did not comply with the proposed rate setting requirements.

M. Costs to States and Providers of Provisions Assigned Burden Hours

The preceding section on Collection of Information Requirements 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 42,342,191. 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 \$21,171,095. 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 \$10.5 million annually.

For MCOs, PIHPs, PAHPs, and PCCMs, we estimate that the Collection and Information Requirements will take 761,217 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 \$12.5 million.

N. Administrative Costs

This proposed regulation would require 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 would add some administrative burden and costs to States. The amount of additional administrative cost would 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 would be adopting similar requirements on their own in the future absent this proposed regulation.

The proposed regulation would also increase 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.

O. Alternatives Considered

We considered allowing the January 19, 2001 final rule with comment to become effective as published, after the two 60-day delays in effective date for Department review. However, the serious concerns raised by some key stakeholders, especially regarding changes made to the final rule that had not been included in the proposed rule, led us to decide to develop a new proposed rule.

P. Conclusion

This BBA managed care proposed regulation would affect States, MCOs, PIHPs, PAHPs, PCCMs, providers, beneficiaries, and us in different ways. The initial investments that are needed by State agencies and MCOs, PIHPs, PAHPs, and PCCMs would result in improved and more consistent standards for the delivery of health care to Medicaid beneficiaries. Greater consumer safeguards would result from new quality improvement and protection provisions. Consequently, long term savings would derive 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.

Q. Federalism

Under Executive Order 13132, we are required to adhere to certain criteria regarding Federalism in developing regulations. We have determined that this proposed rule would not significantly affect States rights, roles, and responsibilities. This regulation, when published in final, would supersede 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 proposes to implement those BBA provisions in accordance with the Administrative Procedure Act. This rule also proposes to eliminate 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 propose to 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 proposed regulation. In 1997–1998, when we were developing the original proposed rule, 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 proposed 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 300 individuals and organizations. Most of the commenters had substantial comments

that addressed many provisions of the regulation.

Following publication of the final rule on January 19, 2001, the new Administration delayed the effective date of the rule to provide it an opportunity to conduct its own review of the regulation. Following the announcement of the delay, we received additional comments from the APHSA, individual States, provider organizations, and advocates for beneficiaries. We considered those comments when developing this proposed rule. To provide an opportunity for comment by the public, we are now soliciting comments on this proposed rule. We will consider and respond to all comments received in the preamble to the final rule.

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

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.

42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs-

health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

For the reasons set forth in the preamble, 42 CFR Chapter IV is proposed to be 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 and 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).

§ 431.51 [Amended]

2. In § 431.51, the following changes are made:

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) *Statutory basis.* * * *

(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.

* * * * *

§ 431.55 [Amended]

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 hearing if the State agency takes action 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” after the third semicolon are removed and periods are inserted in their place, and a new paragraph (a)(5) is 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.

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 files an MCO or PIHP appeal.

(ii) The date the enrollee files a request for State fair hearing.

(2) As expeditiously as the enrollee’s health condition requires, but no later than 72 hours 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(c)(2) 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) As expeditiously as the enrollee’s health condition requires, but no later than 72 hours 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).

§ 434.1 [Amended]

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.

Subpart C [Removed]

5. Subpart C, consisting of §§ 434.20 through 434.38, is removed and reserved.

Subpart D [Amended]

6. In subpart D, §§ 434.42 and 434.44 are removed.

Subpart E [Removed]

7. Subpart E, consisting of §§ 434.50 through 434.67, is removed and reserved.

§ 434.70 [Revised]

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—

(1) The State fails to meet the State plan requirements of this part; or

(2) Either party substantially fails to carry out the terms of the contract.

§§ 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. In § 435.212, the following changes are made.

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**

Sec.

438.1 Basis and scope.

438.2 Definitions.

438.6 Contract requirements.

438.8 Provisions that apply to PIHPs and PAHPs.

438.10 Information requirements.

438.12 Provider discrimination prohibited.

Subpart B—State Responsibilities

438.50 State Plan requirements.

438.52 Choice of MCOs, PIHPs, PAHPs, and PCCMs.

438.56 Disenrollment: Requirements and limitations

438.58 Conflict of interest safeguards.

438.60 Limit on payment to other providers.

438.62 Continued services to recipients.

438.66 Monitoring procedures.

Subpart C—Enrollee Rights and Protections

438.100 Enrollee rights.

438.102 Provider-enrollee communications.

438.104 Marketing activities.

438.106 Liability for payment.

438.108 Cost sharing.

438.114 Emergency and post-stabilization services.

438.116 Solvency standards.

Subpart D—Quality Assessment and Performance Improvement

438.200 Scope.

438.202 State responsibilities.

438.204 Elements of State quality strategies.

Access Standards

438.206 Availability of services.

438.207 Assurances of adequate capacity and services.

438.208 Coordination and continuity of care.

438.210 Coverage and authorization of services.

Structure and Operation Standards

438.214 Provider selection.

438.218 Enrollee information.

438.224 Confidentiality.

438.226 Enrollment and disenrollment.

438.228 Grievance systems.

438.230 Subcontractual relationships and delegation.

Measurement and Improvement Standards

438.236 Practice guidelines.

438.240 Quality assessment and performance improvement program.

438.242 Health information systems.

Subpart E—[Reserved]**Subpart F—Grievance System**

438.400 Statutory basis and definitions.

438.402 General requirements.

438.404 Notice of action.

438.406 Handling of grievances and appeals.

438.408 Resolution and notification: Grievances and appeals.

438.410 Expedited resolution of appeals.

438.414 Information about the grievance system to providers and subcontractors.

438.416 Recordkeeping and reporting requirements.

438.420 Continuation of benefits while the MCO or PIHP appeal and the State Fair Hearing are pending.

438.424 Effectuation of reversed appeal resolutions.

Subpart G—[Reserved]**Subpart H—Certifications and Program Integrity**

438.600 Statutory basis.

438.602 Basic rule.

438.604 Data that must be certified.

438.606 Source, content, and timing of certification.

438.608 Program integrity requirements.

Subpart I—Sanctions

438.700 Basis for imposition of sanctions.

438.702 Types of intermediate sanctions.

438.704 Amounts of civil money penalties.

438.706 Special rules for temporary management.

438.708 Termination of an MCO or PCCM contract.

438.710 Due process: Notice of sanction and pre-termination hearing.

438.722 Disenrollment during termination hearing process.

438.724 Notice to CMS.

438.726 State plan requirement.

438.730 Sanction by CMS: Special rules for MCOs with risk contracts.

Subpart J—Conditions for Federal Financial Participation

438.802 Basic requirements.

438.806 Prior approval.

438.808 Exclusion of entities.

438.810 Expenditures for enrollment broker services.

438.812 Costs under risk and nonrisk contracts.

438.814 Limit on payments in excess of capitation rates.

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 and 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 insuring organization (HIO) means an entity that in exchange for capitation payments, covers services for recipients—

- (1) Through payments to, or arrangements with, providers; and
- (2) Under a risk contract with the State.

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 one of 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.

(2) *Basic requirements.* (i) All capitation rates paid 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 inflation, an 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 based only upon services covered under the State plan and to be provided under the contract to Medicaid-eligible individuals.

(iii) Its 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 (other than risk corridors) must be computed on an actuarially sound basis.

(ii) If risk corridors or incentive arrangements result in payments that exceed the approved capitation rates, the FFP limitation of § 438.814 applies.

(iii) 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) Designed to include withholds or other payment penalties if the contractor does not perform the specified activities or does not meet the specified targets;

(D) Made available to both public and private contractors;

(E) Not conditioned on intergovernmental transfer agreements; and

(F) Necessary for the specified activities and targets.

(d) *Enrollment discrimination prohibited.* Contracts with MCOs, PIHPs and 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.

(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, 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) The MCO or PIHP must provide adult enrollees with written information on advance directives policies, and include a description of applicable State law.

(3) 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.

(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 in the MCO 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 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 apply to PAHPs, PAHP contracts, and States for PAHPs.

(1) The contract requirements of § 438.6, except for requirements for advance directives and those that pertain to HIOs.

(2) Designated 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 except § 438.50.

(5) Designated portions of subpart C on enrollee rights and protections.

(6) Section 438.206(a) on availability of services.

§ 438.10 Information requirements.

(a) *Terminology.* As used in this section, the following terms have the indicated meanings:

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 in a MCO, PIHP, PAHP, or PCCM.

Enrollee means a Medicaid recipient who is currently enrolled in an MCO, PIHP, PAHP, or PCCM in a given managed care program.

(b) *Basic rule.* 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.

(c) *Language.* The State must:

(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) Provide 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 the 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;

(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; and

(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 furnish information about where and how to obtain the service.

(f) *General Information for all enrollees of MCOs, PIHPs, PAHPs, and PCCMs.* Information must be made available to MCO, PIHP, PAHP, and PCCM enrollees as follows:

(1) The State must notify all enrollees of their disenrollment rights at least annually, and 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 (g) of this section if applicable) 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 (g) of this section if applicable) 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 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 paragraph (f)(6) of this section, at least 30 days before the intended effective date of the change.

(5) The MCO, PIHP, and where 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 following information must also be provided to all enrollees:

(i) Names, locations, 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.

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

(iii) Enrollee rights and responsibilities, 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)(i).

(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 post-stabilization 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 post-stabilization 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 post-stabilization 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 furnish information about 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(e), MCOs and PIHPs 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:

(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) Physician incentive plans as set forth in § 434.70(a)(4) of this chapter.

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

(h) *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 (g)(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 to all potential enrollees—

(i) At least once a year; and

(ii) 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 (d) of this section. However, all of the information in this paragraph is subject to the timeframe and format requirements of

paragraph (g)(2) of this section, and includes the following for each contracting MCO or PCCM:

- (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, but not limited to, disenrollment rates as defined by the State, and 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 provides for requiring 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;

(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, 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 a 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 where 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 the 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 paragraphs (e)(1) and (e)(2) 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 where these payments are provided for in title XIX of the Act or in 42 CFR.

§ 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:

(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 each 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(e).)

(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.

(3) An enrollee of an MCO or a PIHP also has the right to—

(i) Be furnished health care services in accordance with §§ 438.206 through 438.210.

(ii) Obtain a second opinion from an appropriately qualified health care professional in accordance with § 438.206(b)(3).

(iii) Request and receive a copy of his or her medical records, and to request that they be amended or corrected, as specified in 45 CFR part 164.

(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) *Health care professional defined.* As used in this subpart, "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.

(b) *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 non-treatment.

(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 (c) 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 (b)(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.

(c) *Information requirements: MCO, PIHP, and PAHP responsibility.* (1) An MCO, PIHP, or PAHP that elects the option provided in paragraph (b)(3) 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 (b)(3) of this section, the overriding rule in § 438.10(f)(4) requires the 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(d) and (e), 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 (b)(3) of this section.

(d) *Information requirements: State responsibility.* For each service excluded by an MCO, PIHP, or PAHP under paragraph (b)(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)(E).

(e) *Sanction.* An MCO that violates the prohibition of paragraph (b)(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 other 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 post-stabilization services.

(a) *Definitions.* As used in this section—

Emergency medical condition has the meaning given the term in § 422.113(b) of this chapter.

Emergency services has the meaning given the term in § 422.113(b) of this chapter.

Post-stabilization care services has the meaning given the term in § 422.113(c) of this chapter.

(b) *Coverage and payment: General rule.* The following entities are responsible for coverage and payment of emergency services and post-stabilization 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 (c) of this section—

(i) Must cover and pay for emergency services regardless of whether the entity 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 (b)(1)(i)(A), (B), and (C) of the definition of emergency medical condition in § 422.113 of this chapter.

(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 (c) 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 process any claim because it does not contain the primary care provider's authorization number.

(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 (c) of this section as responsible for coverage and payment.

(e) *Coverage and payment: Post-stabilization care services.* Post-stabilization 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 and PIHPs. It also establishes standards that States, MCOs and PIHPs must meet.

§ 438.202 State responsibilities.

Each State contracting with an MCO or PIHP must—

(a) Have a written strategy for assessing and improving the quality of managed care services offered by all MCOs and PIHPs;

(b) Provide for the input of recipients and other stakeholders in the development of the strategy, including making the strategy available for public comment before adopting it in final;

(c) Ensure compliance with standards established by the State, consistent with this subpart; and

(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, including 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) Continuously monitor and evaluate the MCO and PIHP compliance with the standards.

(c) Performance measures and levels 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) 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 covered services are available and accessible to enrollees.

(b) *Delivery network.* The State must ensure, through its contracts, that each MCO, and each PIHP consistent with the scope of PIHP'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 and PIHP must consider the following:

(i) The anticipated Medicaid enrollment.

(ii) The expected utilization of services, considering Medicaid enrollee characteristics and health care needs.

(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 medical services, covered under the contract, to a particular enrollee, the MCO or PIHP must adequately and timely cover these services out of network for the enrollee, for as long as the MCO or PIHP 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 and PIHP contract complies with the requirements of this paragraph.

(1) *Timely access.* Each MCO and each PIHP must—

(i) Meet and require its providers to meet State standards for timely access to care and services, taking into account the urgency of 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 available 24 hours a day, 7 days a week, when medically necessary.

(iv) Establish mechanisms to ensure compliance.

(v) Monitor continuously to determine compliance.

(vi) Take corrective action if there is a failure to comply.

(2) *Cultural considerations.* Each MCO and each PIHP 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 and each PIHP gives assurances to the

State 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 assurances.* Each MCO and each PIHP must submit documentation to the State, in a format specified by the State and acceptable to CMS, to demonstrate that it complies with the following requirements:

(1) Offers an appropriate range of services, including preventive services, primary care services 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 and each PIHP must submit the documentation described in paragraph (b) of this section as specified by the State, and specifically—

(1) At the time it enters into a contract with the State; and

(2) At any time there has been a significant change (as defined by the State) in the MCO's or PIHP's operations that would affect adequate capacity and services, including—

(i) Changes in MCO or PIHP services, benefits, geographic service area or payments; or

(ii) Enrollment of a new population in the MCO or PIHP.

(d) *State review and submission to CMS.* After the State reviews the documentation submitted by the MCO or PIHP, the State must certify to CMS that the MCO or PIHP 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 or PIHP.

§ 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 and PIHPs complies with the requirements of this section.

(2) *PIHP exception.* For PIHPs, 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 is required—

(i) To implement mechanisms for the screenings and assessments specified in paragraphs (c) of this section; and

(ii) To meet the primary care requirement of paragraph (e)(1) of this section.

(3) *Exception for MCOs that serve dually eligible enrollees.* (i) For an MCO that serves enrollees who are also enrolled in a Medicare+Choice plan and also receive Medicare benefits, the State determines to what extent that an MCO must meet the screening and assessment, referral and treatment plan and primary care and coordination provisions of paragraphs (c), (d), and (e)(1) of this section.

(ii) The State bases its determination on the services it requires the MCO to furnish to dually eligible enrollees.

(b) *State responsibility to identify certain enrollees with special health care needs.* The State must implement mechanisms to identify to its enrollment broker, if applicable prior to enrollment, and the MCO and PIHP, upon enrollment, individuals with special health care needs, as specified by the State.

(c) *Screening and assessment.* The State (either through its own staff or its enrollment broker) or at the State's discretion each MCO or PIHP (through appropriate health care professionals) must implement mechanisms for the identification and assessment of persons with special health care needs as defined by the State. These mechanisms should be identified in the State's quality improvement strategy in § 438.202.

(d) *Referrals and treatment plans.* The state must ensure that each MCO and PIHP has a mechanism in place for enrollees determined to have ongoing special conditions that require a course of treatment or regular care monitoring that:

(1) The enrollee may directly access a specialist (for example, through a standing referral or an approved number of visits) as is appropriate for the enrollee's condition and identified needs.

(2) A treatment plan, if required by the MCO or PIHP is developed by the specialist in consultation with the enrollee's primary care provider, and

(i) Is developed with enrollee participation.

(ii) Is approved by the MCO or PIHP in a timely manner, if this approval is required,

(iii) Is in accordance with the State's quality assurance and utilization review standards.

(e) *Primary care and coordination program.* Each MCO and each PIHP must implement a coordination program that meets State requirements and achieves the following:

(1) Ensures 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) Coordinates the services the MCO or PIHP furnishes to the enrollee with the services the enrollee receives from any other MCOs and PIHPs;

(3) Shares with other MCOs and PIHPs serving the enrollee the results of its screenings and assessments of the enrollee so that those activities need not be duplicated.

(4) Ensures that in the process of coordinating care, each enrollee's privacy is protected consistent with the confidentiality requirements in 45 CFR parts 160 and 164.

§ 438.210 Coverage and authorization of services.

(a) *Coverage.* Each contract with an MCO or PIHP must:

(1) Identify, define, and specify each service that the MCO or PIHP is required to offer.

(2) Require that the MCO or PIHP make available the services it is required to furnish in no less than the amount, duration, and scope that are specified in the State plan and are sufficient to reasonably be expected to achieve the purpose for which the services are furnished.

(3) Provide that the MCO or PIHP—

(i) May not arbitrarily deny or reduce the amount, duration, or scope of a required service solely because of the diagnosis, type of illness, or condition; and

(ii) May place appropriate limits on a service—

(A) On the basis of criteria 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)(2) of this section; and

(4) Specify what constitutes "medically necessary services" in a manner that—

(i) Is no more restrictive than 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 or PIHP 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) *Processing of requests.* For the processing of requests for initial and continuing authorizations of services, each contract must require—

(1) That the MCO or PIHP and its subcontractors have in place, and follow, written policies and procedures.

(2) That the MCO or PIHP—

(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 or PIHP to notify the requesting provider, and give the enrollee written notice of any decision by the MCO or PIHP to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested. 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 or PIHP 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 or the PIHP 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 or PIHP 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 or PIHP 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 or PIHP may extend the 3 working days time period by up to 14 calendar days if the enrollee requests an extension, or if the MCO or PIHP 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(g), 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 and PIHP 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.

(b) *Credentialing and recredentialing requirements.* Each MCO and PIHP must follow a documented process for credentialing and recredentialing of providers who have signed contracts or participation agreements with the MCO or the PIHP.

(c) *Nondiscrimination.* MCO and PIHP provider selection policies and procedures, consistent with § 438.12, do not discriminate against particular providers that serve high risk populations or specialize in conditions that require costly treatment.

(d) *Excluded providers.* MCOs or PIHPs 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 and PIHP 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 and PIHP establishes and implements procedures consistent with confidentiality requirements in 45 CFR parts 160 and 164.

§ 438.226 Enrollment and disenrollment.

The State must ensure that each MCO and PIHP 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 and PIHP—

(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 and PIHP 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 or PIHP 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 or PIHP identifies deficiencies or areas for improvement, the MCO 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 PIHP meets the requirements of this section.

(b) *Adoption of practice guidelines.* Each MCO and PIHP 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 or PIHP's enrollees;

(3) Are adopted in consultation with contracting health care professionals; and

(4) Are reviewed and updated periodically as appropriate.

(c) *Dissemination of guidelines.* Each MCO and PIHP 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 standardized quality 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 achieve, through ongoing measurements and intervention, demonstrable and sustained improvement in significant aspects of clinical care and non-clinical care areas that are expected to have a favorable effect on health outcomes and enrollee satisfaction;

(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.

(c) *Performance measurement and improvement.* Each MCO and PIHP must annually measure its performance, using standard measures required by the State, consistent with the requirements of § 438.204(c), and report its performance to the State.

(d) *Performance improvement projects.* (1) MCOs and PIHPs must have an ongoing program of performance improvement projects that focus on clinical and non-clinical 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. 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 the 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 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—

(1) In the case of an MCO or PIHP or any of its providers—

(i) The denial or limited authorization of a requested service, including the type or level of service;

(ii) The reduction, suspension, or termination of a previously authorized service;

(iii) The denial, in whole or in part, of payment for a service;

(iv) 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; or

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

Governing body means the MCO's or PIHP's Board of Directors, or a designated committee of its senior management.

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 not file a grievance or request a State fair hearing.

(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) of this chapter 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)

(4) If the MCO or PIHP extends the timeframe in accordance with § 438.210(d), 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(e).

§ 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 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 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 (d) 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 expedited resolution, the MCO or PIHP must also 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.

(c) *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; and

(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) 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 Record keeping 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) The expiration of the timeframe specified by the State (in accordance with § 438.402(b)(2)) and communicated in 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 period covered by the 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) 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.

(3) A State Fair Hearing Office issues a hearing decision adverse to the enrollee.

(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 Provisions

§ 438.600 Statutory basis.

This subpart is based on sections 1902(a)(4) and 1902(a)(19) 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.

§ 438.602 Basic rule.

As a condition for contracting and for receiving payment under the Medicaid managed care program, an MCO or PIHP must comply with the certification and program integrity requirements of this section.

§ 438.604 Data that must be certified.

(a) *Data certifications.* When State payments to the 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 includes, but is not limited to, enrollment information, encounter data, and other information required by the State and contained in contracts, proposals, and related documents.

(b) *Certification of substantial compliance with contract.* Regardless of whether payment is based on data, each MCO and PIHP must certify that it is in substantial compliance with its contract.

(c) *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 MCO or PIHP must require that one of the following certify the data the MCO or PIHP submits to the State:

(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 data.

(2) That the MCO or PIHP is in substantial compliance with its contract.

(3) To the accuracy, completeness and truthfulness of documents specified by the State.

(c) *Timing of certification.* The MCO or PIHP must submit the certification concurrently with the certified data or, in the case of compliance with the terms of the contract, when requesting payment.

§ 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 of 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.

Subpart I—Sanctions

§ 438.700 Basis for imposition of sanctions.

(a) Each State that contracts with a 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's determination may be based on findings from onsite survey, enrollee or other complaints, financial status, or any other source.

(b) A 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 MCO or a PCCM distributes 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 MCO violates any of the requirements in section 1903(m) of the Act and implementing regulations, or a MCO or a PCCM violates any of the requirements of section 1932 of the Act and implementing regulations. (For these violations, only the sanctions specified in § 438.702(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 as provided in § 438.706. (The State may not impose this sanction on a PCCM.)

(3) Granting enrollees the right to terminate enrollment without cause. (The State must notify 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 specific amount of, a 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 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 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;

(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).

(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.* Before imposing any of the alternative 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.

(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.

The State plan must provide for the State to monitor for violations that involve the actions and failures to act specified in this part and to implement the provisions of this part.

§ 438.730 Sanction by CMS: Special rules for MCOs with risk contracts.

(a) *Basis for sanction.* (1) A State agency may recommend that CMS impose the denial of payment sanction on an MCO with a comprehensive risk contract if the MCO acts or fails to act as specified in § 438.700(b)(1) through (b)(6).

(2) The State agency's recommendation becomes CMS's recommendation unless CMS rejects it within 15 days of receipt.

(b) *Notice of sanction.* If CMS accepts the recommendation, the State agency and CMS take the following actions:

(1) The State agency—

(i) Gives the MCO written notice of the proposed sanction;

(ii) Allows the MCO 15 days from date of receipt of 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;

(iii) May extend the initial 15-day period for an additional 15 days if, before the end of the initial period, the MCO submits a written request that includes a credible explanation of why it needs additional time; and

(iv) May not grant an extension if CMS determines that the MCO's conduct poses a threat to an enrollee's health or safety.

(2) CMS conveys the determination 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 in addition to, or in place of, the sanctions that may be imposed under this section.

(c) *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; and

(ii) Gives the MCO a concise written decision setting forth the factual and legal basis for the decision.

(2) The State agency decision under paragraph (c)(1) of this section, forwarded to CMS, becomes CMS's decision unless CMS reverses or modifies the decision within 15 days from date of receipt.

(3) If CMS reverses or modifies the State agency decision, the agency sends the MCO a copy of CMS's decision.

(d) *Effective date of sanction.* (1) If the MCO does not seek reconsideration, a sanction is effective 15 days after the date of the notice of sanction under paragraph (b) of this section.

(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, CMS may make the sanction effective earlier than the date of CMS's reconsideration decision under paragraph (c) of this section.

(e) *CMS's role.* CMS retains the right to independently perform the functions assigned to the State agency 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 following conditions are met:

(a) The contract—

(1) Meets the requirements of this part; and

(2) Is in effect.

(b) The MCO and its subcontractors are in substantial compliance with the physician incentive plan requirements set forth in §§ 422.208 and 422.210 of this chapter.

(c) The MCO and the State are in substantial compliance with the requirements of the MCO contract and of this part.

§ 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 MCO or is one of the entities described in paragraphs (a)(2) through (a)(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's 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; and

Enrollment broker means an individual or entity that performs choice counseling or enrollment activities, or both.

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.

§ 438.814 Limit on payments in excess of capitation rates.

FFP is not available for payments pursuant to risk corridors or incentive arrangements that exceed 105 percent of that portion of the aggregate amount of approved capitation payments attributable to the enrollees or services covered by the risk corridor or incentive arrangement.

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 regular State plan program; 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) Any alternative schedule must be stipulated in the contract.

§ 447.53 [Amended]

3. In § 447.53, the following changes are made:

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 inserted 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]

Section 447.361 is removed.

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

Dated: August 1, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Approved: August 10, 2001.

Tommy G. Thompson,

Secretary.

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