DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

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

[HCFA–2001–P]

RIN 0938–AI70

Medicaid Program; Medicaid Managed Care

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the Medicaid regulations to allow the States greater flexibility by giving them the option to require Medicaid recipients to enroll in managed care entities without obtaining waivers. These revisions, which are authorized by the Balanced Budget Act of 1997, would establish new beneficiary protections in areas such as quality assurance, grievance rights, and coverage of emergency services. They would 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. They would also permit State agencies to amend their State plans to require enrollment in managed care organizations subject to certain conditions, including limits on whose enrollment can be mandated, and a requirement for beneficiary choice. In addition, this rule would extend most of these new requirements to prepaid health plans.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on November 30, 1998.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–2001–P, P.O. Box 7517, Baltimore, MD 21207–0517.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses: Room 413–G Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT: Subparts A and B—Michael Fiore (410) 786–0623; Subpart C—Kristin McGinn (410) 786–4581; Subpart E—Ann Page (410) 786–0083; Nicole Martin (410) 786–1068; Subpart F—Nicole Martin (410) 786–1068; Brenda Jackson (816) 426–3406; Subpart H—Tim Roe (410) 786–2006; Subpart I—Tim Roe (410) 786–2006; Subpart J—Michael Fiore (410) 786–0623.

SUPPLEMENTARY INFORMATION: Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code 2CFA–2001–P. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

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I. Introduction

Title XIX of the Social Security Act (the Act) established the Medicaid program, under which matching Federal funds are provided to State agencies to pay for coverage of health care services to low-income pregnant women, families and aged, blind, and disabled individuals. The Medicaid program is administered by States according to Federal statutory and regulatory requirements, under the aegis of a ''State plan'' that must be approved by the Health Care Financing Administration (HCFA). At the program's inception, most health coverage under the Medicaid program was provided by reimbursing health care providers on a fee-for-service basis for services furnished to Medicaid beneficiaries.

Note: The term ''beneficiaries'' is used throughout the preamble to refer to individuals eligible for and receiving Medicaid benefits. The term ''recipients'' is used in the text of the regulation and is synonymous to ''beneficiary''.

Increasingly, however, State agencies have provided Medicaid coverage through managed care contracts, under which a health maintenance organization (HMO) or other similar entity is paid a fixed monthly capitation payment for each beneficiary enrolled with the entity for health coverage. Enrolled beneficiaries are required to receive the majority of health care services through the managed care entity. In most States, enrollment in such managed care arrangements is currently mandatory for at least certain categories of beneficiaries. Prior to the enactment of the Balanced Budget Act of 1997 (BBA), States agencies were required to obtain a waiver of a statutory ''freedom of choice requirement'' in order to operate such mandatory managed care programs, as discussed below. No such waiver was required for arrangements involving voluntary enrollment in managed care.

Chapter One of the Medicaid provisions (Subtitle H) of the BBA significantly strengthens Medicaid managed care programs by modifying prior law to: (1) reflect the more widespread use of managed care by State agencies to serve Medicaid beneficiaries; (2) build on the increased expertise acquired by HCFA and the State agencies in the administration of managed care programs; (3) incorporate the knowledge that has been learned from Medicaid, Medicare and private sector managed care programs and their oversight organizations; and (4) provide a framework that will allow HCFA and State agencies to continue to incorporate further advances in the oversight of managed care, particularly as it pertains to the protection of beneficiaries and the quality of care delivered to Medicaid enrollees. This proposed rule would implement most of the provisions of that chapter (that is, sections 4701 through 4710). It addresses BBA provisions that reduce the need for State agencies to obtain waivers to implement certain managed care programs; eliminate enrollment composition requirements for managed care contracts; increase beneficiary protections for enrollees in Medicaid

managed care entities; improve quality assurance; establish solvency standards; protect against fraud and abuse; permit a period of guaranteed eligibility for Medicaid beneficiaries; and improve certain administrative features of State managed care programs.

The development of this regulation has been guided by knowledge shared with us by a number of constituencies and experts over the past decade. We have addressed the issues identified by advocates regarding the rights of Medicaid beneficiaries, particularly vulnerable populations, and how they can be protected as State agencies increasingly replace fee-for-service Medicaid delivery systems with managed care programs. In doing so, we have been guided by the Consumers Bill of Rights and Responsibilities (CBRR) issued in November 1997, by the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry. A Presidential directive ordered the Medicaid program to comply, to the extent permitted by law, with the recommendations in the CBRR. As a result, when writing this regulation, we incorporated the CBRR recommendations whenever authorized by law.

The knowledge and experience that State agencies have shared with us has also influenced the content of this proposed rule. Numerous State agencies have used waivers of Title XIX requirements authorized under section 1115 of the Act referred to as ''1115 waivers'' to implement research and demonstration projects to test innovative managed care programs. As part of our approval of a State agency waiver program, an evaluation of the effectiveness of these interventions is required. Many of these demonstrations have addressed the effectiveness of different approaches to Medicaid managed care programs. We have also incorporated knowledge learned from ''freedom of choice'' waivers authorized under section 1915(b) of the Act that also allows State agencies to waive limited provisions of the Act in order to implement managed care programs, consistent with State-specific design features. These waiver applications are also evaluated based on their impact on access to services, quality of care, and cost effectiveness. Our experiences with State agencies in overseeing both these types of waiver programs have influenced the development of this regulation. It should be noted here that, even with the implementation of BBA, State agencies still retain the option of applying for Federal waiver authority under sections 1915(b) and 1115 of the Act.

In the last decade, private sector group purchasers, quality oversight organizations, the managed care industry, and quality improvement experts have greatly advanced our knowledge base of how managed care can be made more effective in serving consumers, through research, program evaluations, and tests of new administrative, payment, and healthcare delivery systems. We have attempted to incorporate the knowledge shared by these organizations, along with literature evaluating managed care, to develop the specifications for State Medicaid managed care purchasing programs and expect to continue work with these organizations and the State agencies.

Several principles also guided the development of this proposed rule. First, when there was not clear evidence that one single approach to operationalizing statutory language was more effective than other approaches, we attempted to provide State agencies with sufficient flexibility to continue to be innovative in the development and improvement of their State Medicaid managed care programs. We deviated from this principle when there was not a clear need for State flexibility or when there was a potential to develop Medicaid regulatory language that is the same as the language used in the Medicare+Choice (M+C) rule published on June 26, 1998 at 63 FR 34967. That rule implements Medicare managed care provisions in the BBA, many of which are similar to the Medicaid provisions implemented in this proposed rule. Consistency between the Medicare and the Medicaid programs was intended to reduce the demand on the managed care industry to comply with multiple, different sets of standards. Second, this proposed rule was developed with a clear emphasis on consumer protections and an increased focus on quality in managed care. Third, the regulations were written to support State agencies in their role as ''health care purchasers,'' in addition to their role as ''health care regulators.'' State agencies, like group purchasers in the private sector, are continuing to seek better value for their health care dollars, when ''value'' means the best possible combination of both quality and price. Relevant subparts of this proposed rule attempt to provide State agencies with the tools needed to become better purchasers.

Finally, with respect to quality-related provisions, we opted to take a more conservative approach and not impose greater regulatory burden, without a strong evidence base. If commenters believe that additional or stronger requirements are needed, we ask that comments include, if possible, the evidence base in support of any such proposed modifications.

This proposed rule would create a new part of the Code of Federal Regulations (Part 438). All new managed care regulations created under the authority of the BBA, other sections of existing Medicaid regulations pertaining to managed care, and appropriate cross references will appear in this new part. By creating this new part, we are attempting to help users of the regulations to better comprehend 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.

II. Background

A. Statutory Basis

Section 4701 of the BBA creates 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) of the Act to require that contracts and managed care organizations (MCOs) comply with applicable requirements in the new section. Among other things, section 1932 of the Act permits State agencies to require most groups of Medicaid beneficiaries to enroll in managed care arrangements without section 1915(b) or section 1115 waiver authority. Under the law prior to 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 of the Act also defines the term ''managed care entity'' (MCE) to include MCOs and primary care case managers; establishes new requirements for managed care enrollment and choice of coverage; and requires MCEs and State agencies to provide specified information to enrollees and potential enrollees.

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

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

Section 4704 of the BBA creates section 1932(b) of the Act to add

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

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

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

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

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

Section 4709 of the BBA allows State agencies the option to provide 6 months of guaranteed eligibility for all individuals enrolled in an MCE.

Section 4710 of the BBA specifies the effective dates for all the provisions identified in sections 4701 through 4709.

B. 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, however, 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 ''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, The Omnibus Budget Reconciliation Act of 1981 (OBRA 1981) required that Medicaid enrollees be allowed to voluntarily disenroll without cause from HMOs, but 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 subsequent to OBRA 1981 and the Tax Equity and Fiscal Responsibility Act of 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 programs in 1981, by 1997 this number had increased to over 15 million. Over 50 percent of the entire Medicaid population now receive at least some services through a health plan 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 managed care organizations. A 1997 GAO 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 such 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 and any one of other services specified in section 1903(m)(2)(A) of the Act, or for any three of the non-inpatient services specified therein. 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) of the Act, either because they provided less than comprehensive services or because they were specifically exempted by the Congress from complying with requirements under section 1903(m) of the Act. These entities were called ''prepaid health plans,'' or ''PHPs.''

The regulatory requirements we applied to PHPs were not as stringent as those under section 1903(m) of the Act in many areas. 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 requirement under section 1903(m) of the Act that beneficiaries have the right to disenroll without cause at any time, and beneficiaries enrolled in the PHPs could have their ability to disenroll restricted under section 1915(b) waiver authority, when the right to disenroll required under section 1903(m) of the Act 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 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 most current PHPs meet most of the requirements that will apply to MCOs.

Concurrent with the increasing need for stronger Medicaid managed care programs has been the development of improved tools, techniques, and strategies for delivering and monitoring 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,'' that 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, HCFA, working in collaboration with the National Committee for Quality Assurance (NCQA) and the American Public Human Services Association, produced a Medicaid version of 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 modified for use by State Medicaid agencies. NCQA, under contract with HCFA, also developed ''Health Care Quality Improvement Studies in Managed Care Settings: Design and Assessment—A Guide for State Medicaid Agencies.'' In 1997, the Agency for Health Care Policy and Research (AHCPR) 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.

These and multiple other tools 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 of the Act 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 of the Act requirements could result in a disallowance of Federal financial participation (FFP) in contract payments. In the latter two cases, if the State agency fails to meet conditions for the section 1932 of the Act exception to the freedom-of-choice requirement in section 1902(a)(23) of the Act, or has its section 1915(b) waiver non-renewed 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) of the Act, 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 in 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, extending these requirements to PHPs.

Section 4710(c) of the BBA provides for a limited exemption from the BBA requirements in sections 4701 through 4710 for approved waiver programs under the authority of section 1115 or 1915(b) of the Act. Specifically, none of the provisions contained in sections 4701 through 4710 of the BBA will affect the terms and conditions of any approved waiver under section 1115 or 1915(b) of the Act, because the waiver was in effect on the date of the enactment of the BBA (that is, August 5, 1997.)

In general, any provision of a State's approved section 1115 or 1915(b) waiver program (which was approved or effective as of August 5, 1997) that is 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 HCFA, would not be affected by the BBA provisions, even if it differs from the BBA managed care requirements. As long as the BBA provisions are addressed in the State's approved waiver materials, no determination needs to be made as to whether the State's policy or procedures meet or exceed the BBA requirements. If the BBA provisions are not addressed, then the State agency must meet the BBA requirements, except as specified below for newly submitted or amended waivers.

The exemption from the BBA requirements will apply to all States' section 1915(b) waiver programs until the date that the waiver authority approved or in effect as of August 5, 1997 expires. As of the date of any section 1915(b) waiver renewal or any temporary extension of that authority granted after August 5, 1997, the State agency will be required to comply with all BBA requirements that are in effect.

Exemptions from the BBA managed care provisions will apply to those section 1115 demonstration waivers approved or in effect as of August 5, 1997, which may be extended for up to 3 years under the authority of section 4757 of the BBA. These waiver extensions are specifically limited to the Medicaid section 1115 comprehensive statewide health care reform demonstrations, which must be approved under the same terms and conditions that applied before the extension. Therefore, any exemptions from the BBA requirements to which these programs are entitled may continue during the period of the extended waiver authority.

For newly submitted or amended section 1115 waivers, the Secretary of DHHS retains the discretionary authority to waive the BBA managed care provisions. Generally, waivers are granted allowing State agencies 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 will apply effective with the BBA enactment unless a State agency can demonstrate that a waiver program beneficiary protection or quality standard would equal or exceed what the BBA requires.

III. Provisions of the Proposed Rule

Under our proposal, virtually all managed care regulations would be set forth in 42 CFR part 438. This new part would integrate existing sections from part 434. 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 Protections
Subpart D—[Reserved]
Subpart E—Quality Assessment and Performance Improvement
Subpart F—Grievance Systems
Subpart G—(Reserved)
Subpart H—Certifications and Program Integrity Protections
Subpart I—Sanctions
Subpart J—Conditions for FFP

The basis and purpose of the provisions of this proposed rule are described below.

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 authority in 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.

2. Definitions (§ 438.2)

Section 438.2 includes definitions of terms that apply for 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 with respect to 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, discussed below in section III. C.). The new statutory definition defines an MCO as one of several listed types of full risk arrangements (for example, HMOs, a provider sponsored organization, a ''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), (c) 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), (A)(ii), and (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 ''managed care entity'' (MCE), primary care case management, and primary care case manager. While most existing managed care definitions are unchanged, we are proposing to revise the definition of PHP to exclude from the current definition entities that have comprehensive risk contracts, but have been exempted by the Congress from the requirements in section 1903(m) of the Act. We are making this change in light of our decision in proposed § 438.8 (discussed below) to apply most of section 1903(m) MCO requirements to PHPs. In cases in which the Congress has explicitly directed that particular entities, which we currently treat as PHPs, be exempt from the requirements in section 1903(m) of the Act, we did not believe it would be appropriate to apply section 1903(m) requirements to such entities by regulation. The entities that the Congress has determined should be exempted from section 1903(m) requirements even if they have comprehensive risk contracts include the entities described in section 1903(m)(2)(B) of the Act. Also exempt from section 1903(m) requirements are certain ''health insuring organizations'' (''HIOs'') that the Congress has expressly exempted from the requirements in section 1903(m) of the Act, that is, HIOs that began operating before 1986 and certain county-operated HIOs in California. Our revised definition of PHP would have the effect of giving entities described in section 1903(m)(2)(B) of the Act the same status as HMOS that were exempted by the Congress from section 1903(m) of the Act. Currently, entities described in section 1903(m)(2)(B) of the Act are included in the definition of PHP, and subject to PHP regulations that are not as strict as the rules that have applied to HMOs.

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, these requirements apply to an MCO whether the MCO is participating in a mandatory managed care enrollment program (either under section 1932(a) of the Act or a waiver) 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 MCE 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 mandated. 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. Lastly, 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; methods for establishing certain enrollment practices, as found in § 438.56; and the default enrollment process, as found in § 438.56.

The terms managed care organization (MCO) and managed care entity (MCE) are used in the statute and in this rule to identify where different requirements apply. As defined 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 recipients within the area served by the entity, and meets the solvency standards of § 438.116. Thus, in general, HMOs that participate in Medicaid are labeled as MCOs. For purposes of this rule, as described in detail under § 438.8, most requirements that apply to MCOs also apply to prepaid health plans (PHPs).

The term MCE is defined in § 438.2 as either an MCO with a comprehensive risk contract under section 1903(m) of the Act or a primary care case manager. As specified in the statute, primary care case managers are only subject to the requirements in this proposed rule that specifically apply to MCEs except, as described in § 438.8 when certain primary care case managers meet the definition of a PHP. These requirements are specified in individual sections of this proposed rule, but include some or all of the requirements pertaining to information (§ 438.10), choice of MCEs (§ 438.52), enrollment and disenrollment (§ 438.56), marketing activities (§ 438.104), and emergency and post-stabilization services (§ 438.114).

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), like the current § 434.20(a), provides 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.

Section 438.6(b) includes the requirement currently in § 434.23, that contracts must specify the actuarial basis for capitation payments and must provide that capitation payments and any other payments provided for in the contract do not exceed the upper payment limits set forth in § 447.361.

Section 438.6(c) includes the enrollment requirements currently in § 434.25. We specify that an MCE contract must provide for an open enrollment period when the MCE 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(c)(2), we have added language expressly providing for three exceptions to the requirement that enrollment be voluntary.

Section 438.6(d) includes language currently in § 434.20(d) and provide that an MCO contract may cover services not provided under the State plan to non-enrolled beneficiaries. These additional services may be provided without regard to statewideness and comparability requirements. 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, HCFA waives statewideness and comparability requirements if additional services are offered.

Section 438.6(e) would retain the requirement currently found in § 434.20(e)(1), that contracts comply with the general contract requirements in § 438.6. Among these requirements is the requirement that contracts conform to the procurement rules in 45 CFR part 74.

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

Section 438.6(h) 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.

Section 438.6(i) implements the statutory requirement that ''HIOs'' which 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.

Finally, proposed § 438.6(g) would implement the physician incentive plan requirements in section 1903(m)(2)(A)(x) of the Act, which currently are implemented in paragraphs (2) through (4) of § 434.70(a) of the regulations. 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 apply 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 that incentive plans that place physicians at ''substantial financial risk'' for services they do not provide must conduct enrollee surveys, and provide ''adequate and appropriate'' stop-loss protection. Section 1876(i)(8) of the Act is implemented in § 417.479, which defines ''substantial financial risk'' and ''adequate and appropriate'' stop-loss protection. The existing Medicaid physician incentive regulations in § 434.70(a)(2) through (4) incorporate the requirements in § 417.479.

Under section 1876(k)(1)(B) of the Act (enacted by the BBA), Medicare risk HMO contracts under section 1876 of the Act may not be renewed after January 1, 1999, and organizations with such contracts must enter into M+C contracts under the new Part C of Title XVIII if they wish to continue to contract with Medicare. The physician incentive rules in part 417 of the regulations that implement section 1876(i)(8) of the Act will no longer have any applicability, and will eventually 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) of the Act as part of the new M+C regulations in part 422, published as an interim final rule on June 26, 1998 (63 FR 34967). 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 will no longer apply in 1999, we did not revise the regulations in part 417 to eliminate this reporting requirement.

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

Section 438.6(j) 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.

4. Provisions That Apply to PHPs. (§ 438.8)

As discussed above in section II.B., PHPs are entities with Medicaid prepaid managed care contracts that are not subject to the statutory requirements in section 1903(m) of the Act, either because they do not have comprehensive risk contracts, or because they are exempted by statute from these requirements. PHPs are, however, subject to regulatory requirements which were promulgated by us under our authority at 1902(a)(4) of the Act to provide for methods of administration determined to be necessary for proper and efficient operation of State Medicaid programs. Under these previous regulations, in part 434, PHPs are subject to many of the same requirements that have been applied to HMOs.

The most significant HMO requirements that were not applied (or applied in some way) to PHPs under existing regulations were the statutory enrollment composition requirements in § 434.26, which require that no more than 75 percent of enrollees be eligible for Medicare or Medicaid and the right to disenroll without cause, which is in § 434.27(b). While PHPs were subject to an enrollment composition requirement, it could be waived by the State agency under § 434.26(b)(4) for ''good cause'' and this was done routinely. Also, since PHP enrollees were not subject to the right to disenroll without cause (see § 434.27(b) that implements section 1903(m)(2)(A)(vi) of the Act, which cannot be waived under section 1915(b) of the Act), State agencies were able to mandate enrollment in a single PHP, or provide for limits on the right to disenroll from a PHP, under a section 1915(b) freedom-of-choice waiver program.

In addition to the above requirements, PHPs were also exempted from the advance directive requirements in § 434.28, and the physician incentive plan requirements in § 434.70(a)(2) through (4), and were not subject to the sanctions provided for in § 434.67. Thus, while entities that the Congress chose to exempt from statutory requirements in section 1903(m) of the Act were subject to regulatory requirements, they were exempted from most requirements in section 1903(m) of the Act.

The BBA, and the legislative history of the Medicaid managed care provisions in the BBA, are silent on the question of how PHPs are to be treated. The BBA did not make any changes to the definition of a comprehensive risk contract that is subject to the requirements in section 1903(m) of the Act, or to statutory provisions exempting certain comprehensive risk contractors from section 1903(m) requirements. The BBA did not change the fact that managed care entities regulated as PHPs are subject only to whatever regulatory requirements we may wish to retain or establish.

We considered retaining a ''two tier'' regulatory scheme, under which PHPs would be subject to a lesser level of requirements than MCOs. Under this approach, which is similar to that taken in the current regulations, PHPs that had statutory exemptions from MCO requirements would receive the benefit of such exemptions to the extent they were not subject to the more vigorous MCO requirements under section 1903(m) of the Act. We determined, however, that the new BBA requirements contain important beneficiary protections that should be extended broadly, to most PHPs. Applying these BBA requirements to the few organizations exempted by statute, however, would virtually deprive them entirely of the benefit of the exemption the Congress intended. For this reason, as noted above, we have revised the definition of PHP to exclude these statutorily exempt entities, and include only entities that do not have comprehensive risk contracts. Based on this revised definition of PHPs, all entities with statutory exemptions from section 1903(m) of the Act would be treated the same as exempted HIOs are now treated under current law.

In the case of the overwhelming majority of PHPs, however, that are not addressed by the Congress, we propose to use our authority in section 1902(a)(4) of the Act to provide for ''proper and efficient'' methods of administration to give enrollees in these PHPs the benefits of most of the new BBA requirements applied to MCOs. Section 438.8 identifies those provisions of the MCO regulations that apply to PHPs and PHP contracts. Under § 438.8, PHPs would be subject to most of the requirements in § 438.6, with the exception of the advance directive requirements in § 438.6(h) and the physician incentive plan requirements in § 438.6(g).

PHPs would also be required to follow the information requirements in § 438.10 that apply to MCOs, the provider discrimination prohibition in § 438.12, the enrollment and disenrollment requirements under § 438.56(e) through (h), the conflict of interest safeguards in § 438.58, the beneficiary protections in subpart C of part 438, and the grievance and appeal requirements in subpart F of part 438, except for § 438.424(b) since PHPs are not subject to section 1903(m)(2)(A) of the Act, which pertains to disallowances for a failure to meet section 1903(m)(2)(A) requirements. (See discussion below.)

In the case of quality requirements in subpart E of part 438, PHPs would have to comply with all MCO requirements that apply to services provided by the PHP.

Under § 438.8(e), the State agency must require, at a minimum, through its contract, that the PHP 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 PHP. The nature of some PHPs may not allow them to report on performance measures in all of the clinical and non-clinical areas as MCOs can. Also, some PHS may not be able to undertake performance projects in the same clinical areas as MCOs can address. The State agency must evaluate the applicability of the MCO performance measures and improvement project areas when establishing the PHP's contractual obligations for its quality assessment and performance improvement program.

We invite comments particularly as to which MCO requirements we propose to

apply to PHPs, and which ones we do not.

We note that while the Congress did not address PHPs in the BBA, it did provide a definition of ''primary care case manager'' that some PHPs could meet. Section 1905(t)(2) of the Act defined a primary care case manager as including ''a physician group practice or an entity employing or having other arrangements with physicians.'' This definition does not preclude payment on a capitation basis.

Based on historical experience, we would expect that in most cases, services furnished to a beneficiary enrolled with a primary care case manager would be reimbursed on a fee-for-service basis to the extent that a primary care case manager is paid on a capitation basis for less than a comprehensive array or set of services. The primary care case manager would also meet the definition of a PHP and be subject to the requirements in § 438.8. In such a case, the primary care case manager would be both a PHP and an MCE. To the extent that the MCO rules that apply to PHPs are stricter than the MCE rules, which ordinarily would apply to a primary care case manager, the primary care case manager would have to follow the MCO rules in such a case, by virtue of its status as a PHP.

While we are proposing to apply MCO requirements to PHPs, State agencies may apply for Federal waiver authority, either 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 PHP. In this instance, the Secretary has the discretionary authority to grant waivers of freedom of choice, under section 1902(a)(23) of the Act, and the beneficiary the right to disenroll (which for PHPs is authorized under section 1902(a)(4) of the Act, and therefore, can be waived) to enable the State agency to establish or continue such a program.

5. Information Requirements (§ 438.10)

Previously, in Medicaid managed care waiver programs, we have required, as a condition for freedom of choice waivers, that beneficiaries be fully informed of the choices available when enrolling with an MCE. 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 MCEs, be in a format that can be easily understood by the individuals to whom it is directed. We propose to implement these provisions in § 438.10. Section 438.10(a) through (h) apply to any use of managed care (State option, waiver, or voluntary) and § 438.10(i) applies only to State option.

As a general rule, each State agency, MCE, and enrollment broker must meet the requirements of § 438.10 that pertain to language and format requirements (as specified in § 438.10(b) and (c)). However, a distinction is made within the regulation as to which information needs to be provided by the MCO, MCE, primary care case manager, and State agency. Further, a distinction is made between which information needs to be provided routinely and which information needs to be provided only upon request.

In § 438.10(b) we establish requirements for the languages in which information must 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 MCE contracts to ensure that materials are available in those specified languages. For example, State agencies could develop methodologies for estimating the composition of the Medicaid population by cultural groups that speak languages other than English, that is, cultural groups that represent at least 5 percent of the Medicaid population. Enrollees and potential enrollees must be informed about how to obtain this information. 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, and MCE be required to have translation services available for each enrollee and potential enrollee who has limited English proficiency, and that potential enrollees be informed about how to obtain these services.

In § 438.10(c)(1), we propose to implement the requirement in section 1932(a)(5)(A) of the Act that all enrollment notices and informational and instructional materials relating to enrollment in MCEs be provided in a manner and form that are easily understood by Medicaid enrollees and potential enrollees. This requirement applies to all State agencies, enrollment brokers, and MCEs, and is taken directly from section 1932(a)(5)(A) of the Act. 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 (such as 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(c)(2) we propose that enrollment notices as well as informational and instructional materials relating to enrollment in MCEs 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 medias such as, large print, Braille, or audio tapes) and for individuals with limited reading proficiency (through video or audio tapes).

In § 438.10(d), we propose that the MCO, or the State agency, if the State agency prohibits the MCO from providing it, must furnish this information to each enrollee within a reasonable time after notice of enrollment. If the State agency prohibits the MCO from furnishing this information, we propose to require that the State agency furnish the information within a reasonable time after notice of enrollment. Further, we propose that the MCO furnish this information to potential enrollees upon request, when not prohibited by the State agency through restrictions on marketing or some other means. In this instance, the State agency, or the subcontractor of the State agency, must provide the information. Annually thereafter the MCO must notify enrollees of their right to request and obtain the information from the MCO. 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 such fundamental elements as enrollees' rights and responsibilities. Further, it is our belief that it is not sufficient for MCOs to merely make this information available at designated locations. Therefore, in keeping with the Congress' intent to provide adequate information to potential enrollees and actual enrollees, according to the Secretary under section 1902(a)(iv) of the Act to establish requirements necessary to ensure * * * proper and efficient operation * * *, we propose to require

MCOs to provide this information. In addition, as is the case in most mandatory managed care systems currently in operation, we propose to require that this information be provided by the MCOs at the time of enrollment, rather than making this information available upon request, as written in the statute.

In § 438.10(e) we set forth the type of information which, under section 1932(a)(5)(B) of the Act, MCOs must provide to enrollees and potential enrollees in their service area, upon request. As discussed below, we propose to require that this information be provided to all new MCO enrollees regardless of whether they request this information.

Consistent with section 1932(a)(5)(B) of the Act, proposed § 438.10(e) would provide that the information that must be furnished to enrollees and potential enrollees include at least the following:

- 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 should include the procedures for obtaining pharmaceuticals and mental health and substance abuse services, as well as the procedure for obtaining out-of-area coverage.
- Names and locations of current network providers, including identification of those 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 potential enrollees explaining how they can obtain this supplemental information. Enrollees making a decision about whether to enroll in a particular MCO 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 informational materials emphasize any limitations on enrollees' provider selections. If the MCO contracts with formal subnetworks, or the MCO's arrangement with primary care providers allow for the establishment of informal subnetworks, the MCO's 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.
- 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 after-hours and emergency coverage.
- Policies on referrals for specialty care and other services not furnished by the enrollee's primary care provider.
- Cost sharing, if any.
- Enrollee rights as described in §§ 438.56 and 438.320 and enrollee responsibilities. Information on responsibilities should include, but is not limited to responsibilities such as providing information needed for treatment, compliance with the MCO's procedures for obtaining services, and becoming involved in specific health care decisions.
- Information on complaint, grievance, and fair hearing rights described in § 438.414(b) and if the State agency chooses to furnish appeal rights to providers, 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 such procedures be provided for by MCOs. 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.''

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

As noted above, section 1932(a)(5) of the Act requires that MCOs provide the above information to enrollees and potential enrollees ''upon request.'' We believe that in the case of beneficiaries who have actually enrolled in the MCO, the above information is essential to an enrollee's ability to access necessary care and exercise his or her rights under the law. Therefore, under our authority in section 1902(a)(4) of the Act to provide for necessary and proper methods of administration, we propose in § 438.10(d) that an MCO be required to provide the above information to each enrollee within a reasonable time after it receives from the State agency or the enrollment broker, notice of the individual's enrollment. This proposed regulatory requirement is consistent with the standard practice of managed care organizations, State law requirements in many States, and requirements that apply under the Medicare program. We invite comment on this requirement.

As required under section 1932(a)(5) of the Act, proposed § 438.10(d) would also require an MCO to provide information to potential enrollees upon request, when not 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). Annually thereafter, the MCO must notify enrollees of their right to request and obtain this information from the MCO.

Proposed § 438.10(f), would provide that an MCO is required to provide enrollees and potential enrollees, when not 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 following information:

- 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.

Unlike the information elements in § 438.10(e) under which the MCO must provide the information to enrollees, in § 438.10(f) we propose that the information be furnished to enrollees and potential enrollees only upon request. We are making this distinction because it is our belief that while some beneficiaries may be interested in receiving these elements of information, and must be able to obtain them, they are not elements of information that every beneficiary typically uses in selecting a provider. By making the

information available by request, interested beneficiaries can obtain the information, and MCOs are not required to furnish information that will not be used.

In § 438.10(g), in accordance with section 1932(a)(5)(D) of the Act, we are proposing to require that a State agency, before or during enrollment, inform enrollees of any benefits to which they may be entitled under the Medicaid program, but which are not made available to them through the MCE. For example, enrollees should be informed about how to access mental health coverage if it is not a service covered by the MCE or the MCE provides only limited coverage. This information must be provided directly by the State agency or through the MCE. The notice must provide information on where and how enrollees may access benefits such as mental health coverage not available through the MCE. In addition, this notice must include any cost-sharing requirements imposed as well as information on how transportation services not covered by the MCE will be furnished.

At § 438.10(h), consistent with section 1932(a)(5)(b) of the Act, we propose to require that primary case managers furnish, upon request, information regarding grievance and appeal processes available to enrollees, including the procedures for obtaining services during the appeals process. While not a requirement for primary care case managers, we suggest that State agencies provide potential enrollees and enrollees of primary care case managers with any additional information, such as on their rights and responsibilities, that would better enable them to receive quality health care and participate in the decision-making process.

In § 438.10(i) we propose to implement section 1932(a)(5)(C) of the Act to require 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. This information must be provided directly by the State agency or through the MCE at least annually, as well as upon request. The information must be presented in a comparative chart-like form that facilitates comparison among MCEs and must be available in the prevalent languages spoken by populations in the geographic area. It should include the following information for each MCE: (1) the service area of the MCE; (2) the benefits covered; (3) any cost-sharing imposed by the MCE; 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 should specify the meaning of ''disenrollment rates'' and the voluntary disenrollment from one plan to another plan.

6. Provider Discrimination (§ 438.12)

At § 438.12, we are proposing requirements consistent with section 1932(b)(7) of the Act. Those requirements 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 such license or certification. The requirements further state that the regulation 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 for different specialties, or from establishing measures designed to maintain quality and control costs consistent with the responsibilities of the MCO.

Section 438.12 should not be construed as an ''any willing provider'' provision. We believe that the Congress intended in section 1932(b)(7) of the Act 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 such discriminatory actions may have provided beneficiaries with fewer choices and may have reduced beneficiaries' overall access to quality health care. Accordingly, MCOs should implement policies with respect to provider participation, reimbursement, and indemnification that are not arbitrary, but rather relate to quality factors such as outcome measures and satisfaction surveys, and other legitimate business concerns.

We also provide in § 438.12 that MCOs must contract with all health care professionals in the manner provided in § 438.314 (discussed in section 4 below).

B. State Responsibilities (Subpart B)

1. State Plan and Contract Requirements: General Rule (§ 438.50)

In this section, we are proposing language to implement section 1932(a) of the Act, which permits State agencies to enroll their Medicaid beneficiaries in managed care entities 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 § 438.50 of the proposed regulations, a State agency no longer needs to request, obtain, and seek periodic renewal of HCFA 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 managed care entities, without being out of compliance with the freedom of choice provisions.

We are requiring State agencies to submit a Medicaid State plan amendment (SPA) 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 SPA, 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's SPA within 90 days of receipt of the State agency's response to the additional information request. As with other SPAs, the effective date provisions specified in the current regulations at §§ 430.20 and 447.256 apply to SPAs submitted to implement a section 1932(a) of the Act request. Thus, section 1932(a) SPAs thus may be effective as early as the first day of the quarter in which a State's SPA is submitted to HCFA.

Under proposed § 438.56(b), the following populations are excluded from mandatory managed care enrollment under this State plan option:

- Dual Medicare-Medicaid eligibles;
- Native Americans who are members of Federally-recognized tribes except when the MCE 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 use a section 1915(b) waiver or section 1115 demonstration authority to mandate enrollment for these individuals in a managed care system. 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 request does demonstrate 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.

Under § 438.50(b), State agencies wishing to utilize the authority in § 438.50 would be required to provide assurances of State compliance with all applicable requirements, and under paragraph (c), assurances that contracts will comply with all applicable requirements.

2. Choice of Managed Care Entities (§ 438.52)

Subject to the exceptions specified below, under section 1932(a)(3) of the Act, a State agency that requires Medicaid beneficiaries to enroll in an MCO must offer to its beneficiaries a choice of at least two managed care entities (MCEs). 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. MCEs are MCOs under section 1903(m)(1)(A) of the Act or primary care case managers under section 1905(t) of the Act. 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.

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 managed care entity 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 HCFA regulations. Second, 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.

In defining the term ''rural,'' for purposes of the rural area exception in section 1932(a)(3)(B) of the Act, we are permitting State agencies the flexibility to either choose between two existing Medicare definitions of rural areas found in parts 412 and 491 of this chapter, or to obtain our approval of a definition developed by the State agency. We are proposing to prohibit a State agency from designating the entire State as a rural area.

While we are proposing to allow State agencies a choice of three options for defining rural areas, we are specifically requesting public comments on whether it would be more appropriate to apply a single definition for rural areas, and which definition would be the most appropriate one. In addition, we are soliciting comments on whether an alternative definition to the two existing Medicare definitions of rural areas found in Parts 412 and 491 of this chapter would be more appropriate, and if so, what the definition should be. A single definition could result in a more consistent approach of a rural area definition for purposes of this exception.

If a State agency elects 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(c)(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 MCE network; (2) when a provider is not part of the MCE network, but has an existing relationship with the beneficiary; or (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. 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.

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

Section 1932(a)(4) of the Act contains new requirements that apply to the enrollment of beneficiaries in MCEs under a mandatory enrollment program under section 1932(a)(1)(A) of the Act and new disenrollment rights that apply to all MCEs, whether enrollment is voluntary or mandated under section 1932(a)(1)(A) of the Act or a 1915(b) waiver.

The State agency must provide assurances that in implementing a mandatory enrollment program under section 1932(a)(1)(A) of the Act the following Medicaid beneficiaries are not required to enroll:

(1) Beneficiaries who are eligible for Medicare;

(2) Indians who are members of Federally recognized tribes, except when the MCE is The Indian Health Service or an Indian health program operated by a tribe or a tribal organization under a contract, grant, cooperative agreement, or compact with the Indian health service.

(3) Children under 19 years of age who are eligible for SSI under Title XVI of the Act; under 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 that receives grant funds under section 501(a)(1)(D) of title J, and is defined by the State agency in terms of either program participation or special health care needs.

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 a primary care case management system in a rural area as described above in § 438.52. In this situation, the beneficiary may not disenroll from the single plan but may change providers within the plan or obtain assistance from any other provider outside the network in appropriate circumstances as defined in

§ 438.52(c)(2). Beneficiaries must also be permitted to disenroll without cause with a particular MCE within the first 90 days of the initial enrollment period of up to 12 months, and annually thereafter. In addition to applying to all enrollees under a mandatory enrollment program under section 1932(a)(1)(A) of the Act, this disenrollment provision is incorporated in the definition of primary care case management contract in section 1905(t)(3) of the Act, and in a revised version of section 1903(m)(2)(A)(vi) of the Act, and thus applies to all primary care case management contracts and comprehensive risk contracts subject to section 1903(m) of the Act. This right to disenroll without cause during the first 90 days of enrollment, with a particular MCE 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 permitting that an enrollee disenroll without cause at any time, or every six months.

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 to all managed care entities (MCEs), rather than a specific type of HMO;
- Requires that recipients 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.

These provisions apply to enrollment and disenrollment in all types of MCEs in all Medicaid managed care programs, with the exception of a temporary exemption for the duration of section 1115 or 1915(b) waiver periods already approved before the BBA was enacted. Once these current waiver periods expire, these provisions will apply unless HCFA grants an exemption from them under section 1115 demonstration authority. Also, section 4757 of the BBA permits an extension for up to 3 years for section 1115 waivers approved or in effect as of August 5, 1997. These waiver extensions must be approved under the same terms and conditions that applied before the extension. Therefore, any exemptions from the BBA requirements to which these programs are entitled may continue during the period of the extended waiver authority.

Section 1932(a)(4)(D)(I) of the Act, also contains the following requirements for the enrollment process when State agencies use the State plan amendment authority in section 1932(a)(1) of the Act to implement managed care on a mandatory basis:

—Individuals already enrolled with an MCE must be given priority to continue that enrollment if the MCE does not have the capacity to enroll all individuals seeking enrollment under the program. Thus, State agencies are required to establish a method for establishing enrollment priorities for managed care entities if they do not have sufficient capacity to enroll new individuals, and to give priority to the continued enrollment of individuals already enrolled with the entity.

State agencies must establish a default enrollment process under which individuals who do not elect an MCE during their enrollment period are assigned to one that meets the requirements of section 1903(m) or 1905(t) of the Act. Under this default assignment process, individuals who do not select a plan must be enrolled by the State agency into an entity that takes into consideration the maintenance of existing provider-individual relationships or relationships with providers that have traditionally served Medicaid beneficiaries. If this cannot be accomplished, the State agency must equitably distribute the individuals among available qualified MCEs.

As mentioned above, these requirements are limited to programs established under the State plan amendment authority for mandatory managed care enrollment.

We note that the language in section 1932(a)(4)(A)(ii) of the Act indicates 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 provide in § 438.56(e)(1)(ii)(A) that the general rule is that the 90 days will begin when enrollment is effective. We provide, however, that if notice to the recipient is delayed, the 90-day period may be extended to compensate for that delay.

We provide that the 90-day period for disenrollment without cause applies only when an individual first enrolls with a particular MCE. 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'' MCE 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 MCE. 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 MCEs effective with the start of their initial enrollment period with a particular MCE. 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 MCE and determine whether they wish to remain enrolled through the enrollment period. This interpretation is consistent with the statutory language, which 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 MCE and see whether it is right for him or her. A beneficiary who has already had such a 90-day period with a particular MCE does not need another one in order to try out that MCE. However, further restricting the application of the 90-day without cause period would mark a departure from statutory language.

Section of the Act 1932(a)(4) of the Act permits individuals to disenroll at any time without cause during the initial 90 days of enrollment with an MCE, and during enrollment periods of at last every 12 months, thereafter. This is problematic when only one MCE option exists, 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, Congress was providing for an implicit exception to the general rule under section 1932(a)(4) of the Act that an

enrollee must be able to disenroll from an MCE. Under these exceptions we are proposing in § 438.56(e)(2) that the requirements in section 1932(a)(4)(A) of the Act be 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 managed care entity. This would make it unnecessary for a State agency to operate a parallel FFS 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 MCE 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), since they are exempt from section 1903(m) requirements.)

In accordance with section 1932(a)(4)(B) of the Act, we provide in proposed § 438.56(g) for the enrollee's opportunity to disenroll or change enrollment at least 60 days before the enrollment opportunity. Section 1932(a)(4), of the Act requires State agencies to permit disenrollment without cause at least every 12 months after the individuals's enrollment with an MCO. State agencies may fulfill this requirement by having an annual open season for all MCO enrollees or establishing an open enrollment opportunity for each individual based on the individual's date of enrollment.

This provision also proposes that for recipients enrolled under the State plan option as established through section 1932(a)(1) of the Act, the State agency must establish a method whereby individuals already enrolled with an MCE must be given priority to continue that enrollment where the MCE does not have the capacity to enroll all individuals seeking enrollment under the program. In accordance with section 1932 (a)(4)(D) of the Act, we propose § 438.56(d)(2). This provision stipulates 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 existing provider and individual relationships and traditional Medicaid providers, and if these are not possible, utilize an assignment process that equitably distributes enrollees among qualified, available MCEs.

Except when State agencies have a fee-for-service experience or prior MCO 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 in which that provider participates.

When the State agency cannot get a response, the beneficiary has no preference, or the named provider does not participate, consideration must be given to ''traditional providers''. The definition in section 1932(a)(4) of the Act specifically describes providers who have ''traditionally served beneficiaries under this Title.'' As such, we believe the definition of a traditional provider should be defined as a provider who has been the main source of care for any recipient during the last year and has experience and expertise in dealing with the Medicaid population.

Thus, we propose under § 438.56(d)(3) that existing provider-individual relationships be defined as the provider who was the main source of care for the recipient in the last year. This can be established through State records of previous MCE enrollment or FFS experience, or through contact with the beneficiary. Under § 438.56(d)(4) we would define ''traditional providers'' to be any provider who has been the main source of care for a beneficiary within the last year, and has expertise and 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 as defined above. If no traditional providers are available, remaining individuals are to be equitably distributed among qualified MCEs with adequate capacity.

Under § 438.56(d), we propose that with respect to the lock-in and termination of enrollment provisions, default assignment be considered to be the ''election'' of a plan. The lock-in provision previously contained in section 1903(m)(2)(A)(vi) of the Act contains the same language: ''individuals who have elected to enroll with the plan. . . .'' This language also is in the new BBA requirement on disenrollment. The provision has always been applied to individuals who were default-assigned as well as to those who actually elected to enroll in their plans. As such, we believe that this practice may be continued.

Sections 438.56(f) and 438.56(g) of the Act set forth agency procedures including the notice requirements of grievance and appeal rights, and the requirement that a request for disenrollment for cause be submitted in writing to the State agency (or to the MCE if the State agency permits MCEs to process disenrollments). When a State agency permits an MCE to process disenrollment requests, we would require the beneficiary to submit the disenrollment request to the MCE, and require the MCE to make a copy for the State agency.

In § 438.56(f)(2)(i), we propose that the MCE may approve the request for disenrollment if the State agency permits MCEs to process disenrollments for cause. In addition, the MCE must notify the enrollee and State agency in writing that the disenrollment request was approved and indicate the effective date of the disenrollment consistent with paragraph (f)(4) of this section, which requires that disenrollment is effective no later than the first day of the second month following the month in which the enrollee made the request for disenrollment. In § 438.56(f)(2)(iii), we propose that if the MCE, for whatever reason, does not take action to approve the enrollee's request for disenrollment, for which it must notify the State agency within a reasonable timeframe as determined by the State, the State agency will make a good cause determination based on reasons cited in the enrollee's request and information provided by the MCE at the State agency's request.

Section 438.56(h) incorporates Public Law 101–508 section 4732(c), 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 MCEs for the automatic reenrollment of recipients who become disenrolled from the MCE solely by virtue of becoming temporarily (four months or less) ineligible for Medicaid. We note that the provisions in § 438.56(e) through (h) apply to PHPs.

4. Conflict of Interest Safeguards (§ 438.58)

State agencies can not 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 such MCOs or the new 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 USC 423). This provision applies to contracts entered into or renewed by October 1, 1997 and signed by both parties.

This proposed rule is necessary to conform our regulations to section 1932(d)(3) of the Act, which requires that State agencies have conflict-of-interest safeguards ''at least as effective'' as Federal procurement safeguards. 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 contractor.
- Disclosure to unauthorized persons.
- Certification and enforcement matters.

This proposed rule will ensure that there is no undue influence or preference given to an MCO because a State employee has an interest in that MCO. It will force 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.

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

We propose to redesignate § 434.57 as § 438.60, with appropriate changes in terminology.

6. Continued Service to Recipients (§ 438.62)

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

7. Computation of Capitation Payments (§ 438.64)

We propose to redesignate § 434.61 as § 438.64 with appropriate changes in terminology.

8. Monitoring Procedures (§ 438.66)

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

C. Subpart C—Enrollee Protections

1. Benefits (§ 438.100)

This section requires that contracts with MCOs must specify the services that the organization is required to furnish to Medicaid enrollees. If services covered under the State plan are not covered under the contract, the State agency must make arrangements to furnish these services to the Medicaid enrollee and provide written instructions on how to obtain the services.

2. Enrollee-Provider Communications (§ 438.102)

Under current law, Medicaid beneficiaries are entitled to receive from their health care providers, the full range of medical advice and counseling that is appropriate for their condition. The BBA expands upon this basic right by precluding an MCO from establishing restrictions that interfere with enrollee-practitioner communications. Under the provision, a covered health care professional (we use the term ''practitioner'' interchangeably with the statutory definition of ''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.

While the new law precludes MCOs from interfering with enrollee-practitioner communications, it does not require MCOs to provide, reimburse for, or provide coverage of counseling or referral services for specific services, if the MCO objects to the service on moral or religious grounds. Please note, however, that the State agency remains responsible for assuring access to all covered services. In these cases, the MCO must inform beneficiaries in writing of its policies before and during enrollment. If the MCO 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.

This provision is consistent with a similar provision on anti-gag rule provisions contained in the M+C regulation. In addition, this provision is consistent with the CBRR provision regarding participation in treatment decisions whereby all treatment options should be discussed between a provider and his or her patient.

3. Marketing Activities (§ 438.104)

We currently require under § 434.36 that each MCO have in its contract the 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 strengthens consumer protections and prohibits fraud and abuse by restricting marketing activities by managed care entities. Section 1932(d)(2) of the Act requires that marketing materials be distributed to the entire service area covered under contract and that marketing materials not be distributed without the prior approval of the State agency. Marketing materials may not contain false or materially misleading information. We propose to implement these BBA provisions and prohibit certain other marketing practices under § 438.104.

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 MCE, used to communicate with individuals who are not its enrollees and which can reasonably be interpreted as intended to influence the individuals to enroll or reenroll in that particular MCE.

a. Required Marketing Activities. In § 438.104(b)(2)(ii) we propose to reflect the requirement in section 1932(d)(2)(B) of the Act that MCEs must distribute marketing materials to the entire service area in which they have contracts under sections 1903(m) or 1903(t)(3) of the Act.

b. Prohibited Marketing Activities. In § 438.104(b)(2) we propose to reflect the provision in section 1932(d)(2)(A)(i) of the Act that provides that prior approval from the State agency must be obtained before an MCE or any agent or independent contractor of the MCE distributes any marketing materials within any State. 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 such consultation, this requirement became effective on July 1, 1998. For purposes of this requirement, we define marketing materials in § 438.104(a) as discussed above.

In addition, we propose in § 438.104(b) to implement the provision in section 1932(d)(2)(A)(i)(II) of the Act on the distribution by MCEs, or any agents, of marketing materials that contain false or materially misleading information by requiring that MCE 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 MCE to get Medicaid benefits, or that the MCE is recommended or endorsed by HCFA.

In § 438.104(b)(2)(iv), we propose to reflect the prohibition in section 1932(d)(2) of the Act on the MCE or any agent attempting to influence enrollment with the MCE in conjunction with the sale of any other insurance.

For example, the entity or independent contractor of such entity may not assert that a recipient will lose Medicaid benefits if he or she does not enroll in the entity's plan. Further, the entity or independent contractor may not claim that it is recommended or endorsed by us.

In § 438.104(b)(2)(iv), we propose to reflect the prohibition in section 1932(d)(2) of the Act on the MCE or any agent attempting to influence enrollment with the MCE in conjunction with the sale of any other insurance. We interpret this to mean that managed care entities may not entice a potential enrollee to join the MCE 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. The conditions that we have prescribed to ensure accurate information for an informed beneficiary are set forth in § 438.10 (discussed in section 1 above), which is referenced in § 438.10.

In § 438.104(b)(2)(iii) we propose to reflect the requirement in section 1932(d)(2)(D) of the Act that MCEs comply with the information requirements set forth in § 438.10 to ensure that each potential enrollee receives accurate oral and information in order that the potential enrollee can make an informed decision whether or not to enroll.

In § 438.104(b)(2)(v) we propose to reflect the prohibition in section 1932(d)(2)(E) of the Act barring an MCE, directly or indirectly, from conducting door-to-door, telephonic, or other ''cold call'' marketing of enrollment. MCEs 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 MCEs 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, potential enrollees 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 law. 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 such entity. This would include such 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 potential enrollees decision to enroll with a particular plan.

c. Consultation in State agency approval of marketing materials. In § 438.104(c) we propose to reflect the requirement in section 1932(d)(2)(A)(ii) of the Act that State agencies provide for consultation with a Medical Care Advisory Committee (MCAC) in the process of reviewing and approving marketing materials. Currently, MCAC is listed 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 the identical membership described above and in § 431.12.

4. Liability for Payment (§ 438.106)

In § 438.106 we propose to reflect the requirement in section 1932(b)(6) of the Act (enacted in section 4704(a) of the BBA), to require that MCOs must 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, if the MCO were to become bankrupt, the Medicaid enrollee would not have to assume responsibility for costs that the MCO was responsible for covering, nor any of the debts of the providers affiliated with the MCO. In addition, if the MCO fails to receive payment from the State agency, or if a provider fails to receive payment from the State agency or the MCO, 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 had directly provided the service.

We are requesting public guidance on the part of this provision that refers to beneficiary liability for payments to a provider ''in excess of the amount he or she would have owed.'' Other than nominal cost sharing, Medicaid law at section 1916 of the Act specifically prohibits States or plans from imposing additional cost sharing on Medicaid beneficiaries. We do not believe Medicaid beneficiaries would ''owe'' an MCO any payment amounts beyond nominal costsharing.

5. Cost Sharing (§ 438.108)

This section would reflect amendments made by section 4708(b) of the BBA, which amended sections 1916(a)(2)(D) and 1916(b)(2)(D) of the Act. As a result of these changes, the prohibition on cost-sharing for services furnished by MCOs has been eliminated. Copayments for services provided by MCOs, thus, may now be imposed in the same manner as copayments are applied under fee-for-service.

Accordingly, State agencies should 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. 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 law from having to pay copayments under fee-for-service would continue to be excluded from any copayment responsibility with respect to managed care services. These beneficiary groups include children, pregnant women, and institutionalized beneficiaries. Also prohibited are copayments for emergency services and family planning services.

6. Assurances of Adequate Capacity and Services (§ 438.110)

Section 1932(b)(5) of the Act, added by section 4704(a) of the BBA, requires MCOs to provide to the State agency and the Secretary with adequate assurances, in a time and manner to be determined by the Secretary, that each organization, with respect to its service area, has the capacity to serve the expected enrollment in such service area. Section 1932(b)(5) of the Act also specifies that these assurances must demonstrate that each MCO offers an appropriate range of services and a sufficient number, mix, and geographic distribution of providers of services.

Current regulations at § 434.6(a)(2) and (5) require that all contracts, whether with health maintenance organizations, (now called MCOs), or PHPs, identify the population covered by the contract and allow for the State agency and HHS to evaluate through inspection or other means, the quality, appropriateness and timeliness of services performed under such contract. Under § 434.50(b), a State agency is required to obtain proof, from each contractor, of the contractor's ability to provide the services under the contract efficiently, effectively, and economically. In addition, under § 434.52, a State agency is required to obtain proof that each contractor furnishes the health services required by enrolled recipients as promptly as is appropriate, and that the services meet the agency's quality standards.

In § 438.110, we propose to add additional requirements that implement the provisions in section 1932(b)(5) of the Act, requiring MCOs to provide adequate assurances of their capacity and services. We propose to interpret ''adequate assurances'' referenced in section 1932(b)(5) of the Act to require documentation of the adequacy of capacity and services in the service area, rather than simply a ''certification'' to this effect.

In § 438.110(a), we propose a general requirement that each MCO submit documentation to the State agency and to us, demonstrating that it has the capacity to serve the expected enrollment in its service area. The nature and purpose of the documentation is further described in § 438.110(b). In that paragraph, we provide that the documentation must address three requirements. These are: (1) that the MCO offers an appropriate range of services, including access to preventive services, primary care services, and specialty services for the anticipated number of enrollees in the service area; (2) that the MCO maintains a network of providers that is sufficient in number, mix, and geographic distribution; and (3) that the MCO meets the availability of services provisions in § 438.306 of subpart E. While section 1932(a)(5)(A) of the Act refers only to ''preventive and primary care services'', we believe that access to specialty services is also critical. We accordingly have added specialty services in proposed § 438.110(b)(1), in accordance with our authority under section 1902(a)(4) of the Act.

Information that may be provided by an MCO to comply with the above requirements includes, but is not limited to, documentation that describes the expected enrollment by geographic location; a list of all of the primary, preventive and specialty care services to be provided by the MCO; the names, types, and geographic location of providers and specialists who will furnish the contracted services; the hours of operation for each MCO facility and provider site; the timeliness standards being observed by the MCO; a description of the MCO's plan for identifying and furnishing care to pregnant women; a description of the MCO's plan for identifying and assessing beneficiaries with serious or complex medical conditions; and the MCO's plan for assuring culturally competent services. These examples are not intended to be an exhaustive list or mandatory requirements. Rather, the State agency should tailor its own documentation requirements to assure itself that the MCO has demonstrated adequate capacity and services, and thereby has met the availability of services provisions outlined under proposed § 438.306, discussed in section 4 below.

In § 438.110(c), we propose that the MCO submit the documentation described in § 438.110(b) to the State agency no less than every 2 years, but also upon entering or renewing a contract with the State agency, and at any time when the State agency has determined that there has been a significant change in the MCO's delivery network or enrollee population. We emphasize with this requirement that the MCO must minimally submit the information described in § 438.110(b) to the State agency at least every two years, even if the contract is in effect for a longer period. In addition, under this requirement, the State agency should have sufficient flexibility to determine whether or not the MCO has maintained adequate capacity in the event that there has been a significant change in the organization's delivery network or enrollee population.

In § 438.110(d), we propose that, following the State agency's review and any changes made to the documentation as a result of that review, the MCO submit to HCFA the same documentation it sent to the State agency. This provision is in accordance with BBA statutory language, which specifically requires that assurances be provided to the State agency and to HCFA. It is our expectation that the documentation submitted will be in an electronic format, when possible, and will include a summary of the contents of the documentation and an explanation of how each individual piece of the documentation relates to the availability of services provisions in § 438.306 of subpart E.

Our intent in proposing these provisions is not to supersede the State agency as the decision maker of whether or not the MCO has demonstrated adequate capacity and services. Rather, we propose in paragraph § 438.110(d) that MCOs seek certification from the State agency before the organization submits documentation to us. This certification can be in a format decided upon by the State agency. However, the content should specify whether the MCO has demonstrated that it has sufficient capacity and services in accordance with the requirements of this section and § 438.306 of subpart E.

7. 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 primary care case manager 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 Congress required primary care case managers and MCOs 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 that pays for hospital services generally, must pay for the cost of emergency services obtained by Medicaid enrollees. We interpret coverage in the primary care case management context to mean that the primary care case managers must allow direct access to emergency services without prior authorization. We apply different meanings to the word ''coverage'' because while primary care case managers are individuals paid on a fee-for-service basis, they receive a State payment to manage an enrollee's care. While primary care case managers, unlike MCOs, 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 primary care case manager. Accordingly, we propose to provide in § 438.114(d)(2) that enrollees of primary care case managers 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 such services under Medicaid that are needed to evaluate or stabilize an emergency medical condition. 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 with respect to 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).

Section 1932(b)(2)(A)(ii) of the Act also provides MCE 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 such rules ''apply to M+C plans offered under Part C of title XVIII.'' Under the last sentence 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(a) and 438.114(c)(2), which define ''post-stabilization services'' and require that MCEs (including primary care case managers) with risk contracts that cover post-stabilization services must pay for such post-stabilization services. Specifically, § 438.114(c)(2) requires that such MCEs must pay for post-stabilization services that are pre-approved by the MCE, or that have not been pre-approved because the MCE did not respond to a request for approval within 1 hour of a request by a provider, or could not be contacted for approval. Under § 438.114(c)(3), the MCE must continue to pay for post-stabilization services until other arrangements for care are made and the provider of post-stabilization services is notified While such an MCE is required to pay for post-stabilization services, in proposed § 438.114(c)(4) and (c)(5) we provided that an enrollee of a primary care case manager is entitled to obtain post-stabilization services under the same terms as an MCO enrollee, when they are approved by the primary care case manager, or when the primary care case manager cannot be reached or fails to respond to a request for authorization within one hour. Where post-stabilization services are not covered by the MCE risk contract, the State agency must pay for post-stabilization services that were requested and either approved by the MCE or not approved, due to untimely or absent response.

''Post-stabilization care'' means medically necessary, non-emergency services needed to ensure that the enrollee remains stabilized from the time that the treating hospital requests authorization from the MCE until (1) the enrollee is discharged; (2) an MCE physician arrives and assumes responsibility for the enrollee's care; or (3) the treating physician and MCE agree to another arrangement. Because an untimely response to a request for approval would unduly delay the delivery of the post-stabilization care services, thereby potentially compromising their effectiveness, we have established a 1-hour timeframe in the regulation as an enrollee protection. Because a completely accurate assessment of an enrollee's need for post-stabilization care services cannot be made until the enrollee is stabilized, we expect that the provider of the post-stabilization care services will not request the MCO's approval of the services until after the enrollee is stabilized, at which time enough details about the enrollee's condition should be known to allow the organization to make an informed decision on whether to approve the care within one hour.

Sections 438.114(c)(2) and 438.114(d)(1) require that MCEs (or the State agency, under § 438.114(c)(4)) 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(d)(1) provides that an MCO must pay for emergency services regardless of whether the entity that furnishes the services has a contract with the MCO. Proposed § 438.114(d)(2) provides that if a primary care case management contract is a risk contract that covers such services, a primary care case management system must allow enrollees to obtain emergency services outside of the primary care case management system.

Proposed § 438.114(e) further clarifies financial responsibility. In § 438.114, MCOs 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 be a condition, in which the absence of immediate medical care would result 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 or primary care case manager cannot deny payment if the enrollee obtained services based on instructions of a practitioner or other representative of the MCO. Proposed § 438.114(e)(2) also provides that the MCO is not responsible for services obtained outside the MCO unless the services are emergency services or post-stabilization services covered under § 438.114(c)(2).

Proposed § 438.114(f) 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 for coverage purposes.

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 primary care case management model is a delivery system unique to Medicaid; and there is no Medicare counterpart to the special rules described above that apply to primary care case manager enrollees. Also, it should be noted that the emergency provisions in § 438.114 relate directly to, and are consistent with, the CBRR provision regarding access to emergency services. See discussion in section I above. The CBRR requires health plans to educate their members about the availability, location, and appropriate use of emergency services. It also requires plans to cover emergency screening and stabilization services both in and out of network without prior authorization consistent with the prudent layperson standard. The Medicaid regulations in § 438.306 (network adequacy), § 438.310 (benefits information) as well as § 438.114 address the CBRR issues.

8. 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 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 such centers by the State agency. For further clarification, the term ''control'' (with respect to 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 were not held liable for the debts of the MCO in the case of its insolvency.

Under section 4710(b)(4) of the BBA, the new solvency requirements are applicable for MCO contracts entered into or renewed (that is, signed by both parties) October 1, 1998 or later. In addition, the requirements do not apply to fully capitated MCOs under contract as of the date of enactment of the BBA until 3 years after the date of enactment of the BBA, which is August 5, 2000. Proposed § 438.116(c)(6) would reflect these effective dates.

D. Quality Assessment and Performance Improvement (Subpart E)

1. Background

Prior to 1997, Medicaid law and regulations specified certain quality assurance requirements for HMOs subject to section 1903(m) of the Act. Section 434.34 required HMOs to have an internal quality assurance plan that met limited requirements. Section 434.53 required State agencies to conduct periodic medical audits of HMOs to ensure that each organization furnished quality and accessible health care to all Medicaid enrollees. Section 1902(a)(30)(C) of the Act further required State agencies to conduct, on an annual basis, an independent, external review of the quality of services furnished under each State agency contract with an HMO. Other requirements that were 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 (§ 434.67).

Before enactment of the BBA, Medicaid law also included several proxy measures or indirect assurances relating to quality. The law required State agencies to contract with HMOs that met specific enrollment composition requirements (that is, at least 25 percent of a health plan's enrollment was to consist of persons not covered by Medicare or Medicaid) and required State agencies to establish solvency standards for HMOs serving Medicaid beneficiaries.

Additional general provisions governing State Medicaid programs required State agencies to ensure that access and quality of services provided under managed care were comparable to those provided under the fee-for-service program. However, prior to the enactment of the BBA, neither the statute nor the regulations specified the specific methods or standards to support these assurances.

HCFA and State agencies developed tools and interpretive guidance to provide more specific and standardized methods for quality assurance and improvement. As described above in the Overview of Medicaid Managed Care section, we developed ''A Health Care Quality Improvement System for Medicaid Managed Care—A Guide for States,'' as the product of the Quality Assurance Reform Initiative (QARI). Other technical assistance tools and guidance were developed subsequently.

In 1996, HCFA 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 National Committee for Quality Assurance, 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 believe would most effectively measure and improve health care quality in managed care both today and in the years to come. From the perspective of the Medicaid program, in developing QISMC, we have endeavored to balance the need to establish a high minimum threshold for entities interested in contracting with States agencies, with the desire to ensure that MCOs continually improve the quality of the care they provide.

QISMC standards articulate a vision for how managed care will be provided that is consistent with the standards sought by other forward looking purchasers in the private and public sectors. An initial draft of QISMC was released for public input in January 1998, with further input sought through May 1998. An Interim QISMC document will be released this fall.

The quality assurance provisions of the BBA espouse the same philosophy and goals for performance improvement as are reflected in QISMC. Accordingly, in implementing the BBA provision, we have drawn extensively upon the knowledge and expert guidance that informed the design of QISMC. These proposed regulations set forth actions that we view as necessary on the part of State agencies to fulfill the provisions of the BBA. The forthcoming QISMC ''interim'' document is comprised of standards, which will be consistent with the regulatory requirements on the State agencies in this proposed rule and on the health plans in the interim final rule for the M+C program, and additional implementation and monitoring guidelines. Should the standards in either of these regulations change as they are finalized, QISMC will similarly change as it moves from ''interim'' to ''final'' State agencies have the authority to develop their own approaches, which we will review and evaluate. While HCFA will not require State agencies to use the QISMC guidelines, we will consider MCO strategies that are based on QISMC to be in compliance with these proposed regulations that relate to the internal MCO quality activities. We believe that State agencies that use QISMC will be more effective business partners by using standards consistent with those of the Medicare program, and will be able to assure Medicaid beneficiaries and their advocates, and others, that the State agency is moving effectively to promote high quality care.

It is in this context that we interpret and propose to implement the BBA provisions governing quality and beneficiary protections in Medicaid managed care. This preamble provides a general introduction to the following proposed regulations to implement section 1932(c)(1), which describes requirements for States' quality assessment and improvement strategies as applied to contracts with Medicaid managed care organizations (MCOs).

2. Overview of State Strategies

Under section 1932(c)(1) of the Act, as added by section 4705(a) of the BBA, each State agency that elects to furnish services to Medicaid beneficiaries through an MCO must develop and implement a quality assessment and performance improvement strategy to ensure that beneficiaries have access to and receive quality health care and other services related to quality. This requirement applies whether the arrangement is mandatory or voluntary. Prior to the BBA, the Medicaid statute included a number of disjointed, incremental provisions addressing quality. Additionally, some of these provisions were duplicative (for example, the regulatory requirement at § 434.53 for periodic audits of managed care plans by State agencies and the requirement that HMOs receive an external review of quality from an agent of the State found in section 1902(a)(30)(C) of the Act). In addition, regulatory provisions had failed to allow for improvements in the technology of measuring and improving quality (for example, use of performance measures and consumer surveys). As a consequence, it was unclear how the various statutory and regulatory requirements were to fit together to effectively and efficiently ensure (and where appropriate improve) quality. This uncertainty potentially placed Medicaid beneficiaries at risk for not having the strongest possible oversight of their health care.

Limits to available resources in both the public and private sectors for quality of care measurement and improvement also increase the importance of the efficient and effective use of quality oversight tools through well-considered, coordinated strategies. Since it is not possible for any quality oversight system to measure every episode of care furnished to any particular patient or all patients (consumers), it is very important for the quality oversight tools employed by any health care delivery system to be utilized in a way that maximizes their efficiency and effectiveness. For the first time, Medicaid law, in section 1932(c)(1)(A) of the Act, requires that each State Medicaid program design and implement an overarching quality assessment and performance improvement strategy designed to address the effectiveness of its managed care program. Under section 1932(c)(1)(B) of the Act, this strategy must be ''consistent with standards'' that we establish in regulations. Subpart E of part 438 contains the HCFA standards established pursuant to section 1932(c)(1)(B) of the Act. We believe that the quality assessment and performance improvement strategy developed by each State agency should be used as a tool to ensure that contracts with MCOs are effective in delivering quality health care services. Through the use of its quality strategy, each State agency has a mechanism to use in planning for the effective and efficient use of the multiple tools for quality assessment and improvement that are being produced in the public and private sectors. Each State agency must also ensure that the State strategy it develops is comprehensive in nature and provides for the coordinated, efficient delivery of quality health care. Therefore, it is each State agency's responsibility to continually review its quality strategy, and to work collaboratively with its MCOs and other stakeholders in order to ensure that it is functioning effectively and is meeting the goal of the State agency.

Under our proposed regulations, discussed in greater detail below, each State strategy would at a minimum be required to include various program standards, including access, structure and operations, and quality measurement and improvement standards for managed care organizations. Each State strategy would be required to ensure, through its access standards, that MCOs have a health care delivery system in place that can provide enrollees with available and appropriate services, including additional or supplemental services not provided directly by the MCO. We are also proposing that standards must be developed to ensure that the MCO's delivery network ensures access to covered services, as in § 438.306. Such standards would be required to assess whether the MCO has a sufficient volume of providers to ensure adequate access to services, whether the MCO provides adequate access to medically appropriate speciality care, and that services are provided in a timely and culturally competent manner. In addition, as discussed above, each State agency is required by statute to ensure that beneficiaries are given a choice of

managed care entities, with limited exceptions as discussed in § 438.52.

As part of the access standards we are proposing, each State agency would be required to ensure that all covered services are available and accessible to enrollees. Through its contracts with MCOs, State agencies must ensure that MCOs meet standards relating to continuity of care and coordination of services as specified in proposed § 438.308, discussed below. The contracts would also be required to include descriptions of the benefits that an MCO would provide, as well as the processes for prior authorization, grievances, and appeals (proposed § 438.310).

Each State strategy would also be required to include standards related to aspects of how a managed care organization is structured and operated that directly relate to quality of care; for example, each MCO would be required to implement a documented process for selection and retention of affiliated providers, as specified in proposed § 438.314. These standards would also address aspects of a State agency's contract with an MCO that must be in place to ensure that beneficiaries receive quality health care, and that beneficiaries are afforded certain protections with respect to the care and services they receive. Therefore, the State strategy would have to include standards for the information that will be provided to enrollees and others regarding all available MCOs (as specified in proposed § 438.318), written policies with respect to an enrollee's rights within the MCO (as specified in proposed § 438.320), standards relating to the enrollment and disenrollment processes for enrollees in MCOs (in accordance with proposed § 438.326), confidentiality of enrollee health information within MCOs (as specified in proposed § 438.324), and adherence to established grievance systems, established as specified in the proposed subpart F of this part. Finally, each State agency would be required to ensure that each MCO, as specified in proposed § 438.330 oversees and is accountable for any functions or responsibilities that the MCO delegates to any subcontractor.

In addition to access, structure, and operational standards, each State strategy would be required to include measurement and improvement standards to ensure that each MCO undertakes and reviews a quality assessment and performance improvement program and maintains a health information system capable of achieving the objectives of this subpart.

Section 1932(c)(1)(A)(iii) of the Act requires that the State agency's quality assessment and improvement strategy include procedures for monitoring and evaluating the quality and appropriateness of care and services to enrollees that reflect the full spectrum of populations enrolled under an MCO's contract. This subpart of the proposed rule proposes minimum procedures that the State agency would be required to use when monitoring and evaluating each MCO.

The annual, external independent review of each MCO required by section 1932(c)(2) of the Act, as created by section 4705 of the BBA, will also serve as an essential component of the State agency's plan for monitoring and evaluating each MCO. The provisions in section 1932(c)(2), however, will be implemented in separate rulemaking in the near future. In the interim, before this separate rulemaking is finalized, State agencies must continue to provide for an annual, external independent review of the quality of care provided by each MCO, as required by section 1902(a)(30)(C) of the Act.

Essential to the successful implementation of the State strategy is a system capable of collecting and analyzing all necessary data. Therefore, the State agency would be required under this proposed rule to establish a data system sufficient to support its strategy.

3. Review of State Agency Strategies

After each State agency has developed its quality strategy, it would be required under this proposed rule to review the entire strategy to ensure the effectiveness of the overall State level program at achieving its desired results. It is important for the State agency to review each component of the strategy as well as the entire strategy to ensure that quality care is being delivered to beneficiaries and that performance improvement is occurring. Under this proposed rule, it would be the State agency's responsibility to specify the goals and desired results for its quality strategy and to ensure that these goals and desired results are being met. The reviews of the State strategy would be conducted on a regular and periodic basis as determined by each State agency to be appropriate, but no less frequently than every 3 years. The frequency should be determined by the State agency with input from enrollees and their advocates, managed care organizations, and other stakeholders with respect to the State's progress towards meeting its desired outcomes.

Enforcement of the requirements of the State strategy will be at least as important as the development and review of the strategy. As State agencies develop their enforcement strategies, HCFA encourages them to recognize that technical assistance to plans may be necessary to help them meet performance goals. HCFA encourages State agencies to provide such technical assistance and to be flexible as they work with plans of different types to meet the standards. Therefore, the regulation does allow for the imposition of sanctions. As specified in proposed subpart I of this part, State agencies are required under the BBA to establish a process for imposing intermediate sanctions against MCOs. There are different types of intermediate sanctions outlined in subpart I. We encourage State agencies to use these intermediate sanctions or to develop their own. In addition, State agencies have the authority under section 1932(e)(4) of the Act (implemented in proposed § 438.718) to terminate an MCO's contract, if the MCO no longer meets the applicable requirements of sections 1903(m), 1905(t)(3) or 1932 of the Act. Therefore, termination of an MCO's contract could occur if the MCO no longer meets the specifications of the State strategy, as specified in this subpart. Finally, section 1903(m)(2)(A)(xi) of the Act required that MCOs comply with applicable requirements in section 1932 of the Act, as a condition for Federal matching in the MCO's contract, as discussed below. See discussion of § 438.306, below. A failure by an MCO to comply with State requirements established pursuant to the proposed regulations in subpart E could also result in a disallowance of Federal matching in the MCO's contract.

Proposed Provisions of Subpart E

4. Scope (§ 438.300)

This section sets forth the scope of subpart E.

5. State Responsibilities (§ 438.302)

This section sets forth the State responsibilities in implementing its quality strategy. Specifically, proposed § 438.302 would require that each State agencies that contracts with an MCO have a strategy for assessing and improving the quality of managed care services provided by the MCO, ensure compliance with standards established by the State agency, consistent with subpart E, and conduct regular, periodic reviews to evaluate the effectiveness of its strategy, as the State agency determines appropriate, but at least every 3 years. We selected 3 years as the maximum interval for review and evaluation of State strategies, because

the field of quality is evolving at a fast pace, and State agencies, working with input from advocates, managed care organizations, quality experts and others, need to reevaluate their strategies in light of new developments and changing priorities.

6. Elements of State Quality Strategy (§ 438.304)

This proposed section sets forth the minimum elements of a State quality strategy, including (1) contract provisions that incorporate the standards specified in subpart E; (2) Procedures for assessing the quality and appropriateness of care and services furnished to all Medicaid enrollees under the contract, including, but not limited to, continuous monitoring and evaluation of MCO compliance with the standards; (3) arranging for annual, external independent reviews of quality outcomes, and timeliness of, and access to, services covered under each MCO contract; (4) appropriate use of intermediate sanctions; (5) an information system sufficient to support initial and ongoing operation and review of the State's quality strategy; and (6) standards, at least as stringent as those required under proposed §§ 438.306 through 438.342. With regard to external independent review, we will shortly promulgate proposed regulations addressing the External Quality Review Organizations, as required by the BBA.

In developing a strategy, we would expect that State agencies will work with beneficiaries and their advocates, quality experts, managed care organizations, and other stakeholders to develop performance goals that are clear, fair, and achievable.

Access Standards

7. Availability of Services (§ 438.306)

a. Scope. Section 1932(c)(1)(A)(i) of the Act, as added by section 4704 of the BBA, 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 within reasonable timeframes and in a manner that ensures continuity of care, adequate primary care, and specialized services capacity.

b. Choice. As part of the State quality assessment and improvement strategy, if a State agency limits freedom of choice, the State agency must comply with the requirements of § 438.52, discussed in section II.D.2. above, which specifies the choices that the State agency must make available.

c. Access to Services not Covered Under Contract. Under proposed § 438.306(c), if an MCO contract does not cover all services under the State plan, the State agency must arrange for those services to be made available from other sources and instruct all enrollees on where and how to obtain them, including how transportation is provided.

d. Delivery Network. Current regulations at § 434.6(a) require that contracts include provisions that define a sound and complete procurement, identify the population covered under the contract, and specify the amount, duration, and scope of medical services to be provided. They also provide that the State agency and HHS may evaluate through inspection or other means, the quality, appropriateness, and timeliness of services performed under the contract. In § 434.50(b) of those same regulations, a Medicaid agency must obtain proof from each contractor of its ability to provide services under the contract efficiently, effectively, and economically. Section 434.52 further requires the State agency to obtain proof that each contractor furnishes the health services required by enrolled recipients as promptly as is appropriate, and that the services meet the State agency's quality standards.

In § 438.306(d), we propose new requirements, pursuant to section 1932(c)(1)(B) of the Act and in accordance with the requirements in section 1932(c)(1)(A)(i) of the Act, to ensure that all covered services under a contract are available and accessible to enrollees. These requirements are imposed on State agencies, which in turn must enforce these requirements on MCOs.

In § 438.306(d)(1), we propose that the State agency require all MCOs to maintain and monitor a network of appropriate providers that is supported by written arrangements and is sufficient to provide adequate access to covered services. This requirement is more detailed than the M+C regulation. This specificity was included to ensure that State agencies and MCOs fully consider all components when determining adequate access. In this context, adequate access generally means that all contracted services, other than out-of-area emergency care services, are available within the MCO's network (which generally consist of employees and facilities of the MCO, and providers who have entered into written agreements to serve the MCO enrollees).

In proposing this requirement, we recognize that there are some circumstances that would justify contracts with providers outside of the approved service area. As an example, a comprehensive MCO operating solely in a non-metropolitan area may make a particular service, which is not a primary care or an emergency care service, available outside the area if it is unable to contract with a sufficient number of speciality providers within the area. As another example, an MCO may contract with a provider outside of its service area if, for reasons of geography, it would be easier for some of its enrollees to reach that provider than it would be for them to reach a comparable provider located within the service area.

Because the enrollees' specific needs, the types of providers used by an MCO to meet those needs, and other factors, such as availability of public transportation, will vary for each MCO, we are not proposing a single set of fixed guidelines for all populations and circumstances, such as prescribed primary physician/enrollee ratios. Rather, we propose that the State agency set its own standards for MCOs serving specific areas and populations within its State, and that the State agency ensure that those Statewide standards are met by all MCOs with which it contracts. However, standards or ranges of standards that are currently used are referenced in subsequent paragraphs as examples that State agencies may consider. The proposed rule anticipates that State agencies will take responsibility for ensuring that MCOs assess the needs of the populations they enroll and provide or arrange a network that will meet those needs. The State agency's review should focus on the MCO's service planning and on the organization's basic assumptions for determining that its network is ready to serve Medicaid enrollees in a given area.

We propose in § 438.306(d)(1)(i) and (d)(1)(ii) that the State agency's assessment ensure that the MCO's network reflects the anticipated enrollment in the MCO, with particular attention to children and pregnant women, and the expected utilization of services. This includes the aggregate number of providers needed, and their distribution among different specialities; keeping in mind that numbers and types will vary according to the MCO's projected population in terms of age, disability, and prevalence of certain conditions. Expected utilization may also be affected by practice patterns within an MCO, such as the rate of referrals for specific services.

Under § 438.306(d)(1)(iii), and (d)(1)(iv), the State agency's assessment must ensure that each MCO take into

consideration the numbers and types of providers needed to furnish contracted services and the number of providers who are not accepting new patients. The numbers of providers needed to meet an expected level of demand for service may be based on national norms (such as typical patient/physician ratios) or on the MCO's past experience. For example, population-to-primary provider ratios in the range of 1500:1 to 2500:1 have been used to represent adequate staffing levels both in federal health programs such as the Department of Health and Human Services' Health Resources and Services Administration, and individual States.

If more than one type of provider is qualified to furnish a particular item or service, the State agency should ensure that the MCO's standards define the types of providers to be used, and ensure that those standards are consistent with State laws requiring such organizations, when applicable, to make specific types of providers available. Simple counts of providers, or even providers reportedly accepting new patients, are insufficient to establish capacity. Rather, the assessment of capacity necessarily should consider the volume of services being furnished to patients other than the MCO's enrollees.

In terms of assessing geographic access, we propose in § 438.306(d)(1)(v) that the State agency ensure the MCO's network is structured in a way that considers the geographic location of providers and enrollees, including such factors as distance, travel time, and the means of transportation normally used by enrollees. In addition, we propose with this requirement that State agencies and MCOs take into consideration the physical access of facilities for enrollees with disabilities. A provider network should be structured in a manner so that an enrollee residing in the service area should not have to travel an unreasonable distance, beyond what is customary under a Medicaid fee-for-service arrangement, to obtain a covered service. This standard is required under section 1903(m)(1)(A) of the Act and the definition of MCO in proposed § 438.2. In areas where Medicaid enrollees rely heavily on public transportation, the State agency should ensure that the MCO's network is structured so that providers are accessible through these means within the same timeframes as enrollees who have their own means of transportation (unless the MCO ensures access through alternative means, such as home visits). Additionally, State agencies and MCOs should consider whether or not facilities are physically accessible when reviewing the MCO's delivery network. Enrollees with disabilities should have an appropriate choice of accessible providers.

In proposing § 438.306(d)(1)(v), we recognize that standards vary across States with respect to geographic access. Some State agencies contracting with MCOs have established maximum travel and distance times that include a 30 minute travel time standard. (This standard is used currently by the Health Resources and Services Administration in defining rational primary care service areas.) Other State agencies have established alternative standards such as a 10 to 30 mile travel distance, depending on the local terrain. Both are examples of geographic access standards that would comply with this provision. For instance, a State agencies could require that all primary care services and commonly-used speciality and referral services be available within 30 minutes driving time or bus time from any point in the service area, with possible exceptions for certain rural areas or other low-population/low-density areas where residents customarily travel greater distances to obtain specialty and referral services.

In § 438.306(d)(2), we are proposing that the State agency be required to ensure that MCOs allow women direct access to a women's health specialist within the MCO's network for women's routine and preventive services. We have determined that this is necessary in order to provide ''access * * * in a manner that ensures * * * adequate * * * specialized services'' as required under section 1932(c)(1)(A)(i) of the Act. This requirement is proposed in addition to requirements under § 438.308 that the MCO maintain a primary care provider for each enrollee. It allows a woman to directly access a women's health specialist within the MCO's network without the need for prior authorization from her primary care provider. In this context, a women's health care specialist may include a gynecologist, a certified nurse midwife, or another qualified health care professional. Our primary intent in proposing this requirement under the authority of section 1932(c)(1)(B) of the Act, and in accordance with the above requirements in 1932(c)(1)(A)(i)of the Act, is to provide women with what we believe to be necessary access to an appropriate provider for women's routine and preventive services. This is also consistent with beneficiary rights recommended in the CBRR, as discussed in section I. above.

In § 438.306(d)(3), we are proposing that the State agency ensure the MCO, if seeking an expansion of its service area, demonstrate that it has sufficient numbers and types of providers to meet the anticipated additional volume and type of services the added enrollee population may require. Similar to § 438.306(d)(1)(i) through (d)(1)(v), the State agency should ensure that each MCO, in demonstrating the sufficiency of the numbers and types of providers available, take into consideration the anticipated enrollment, the expected utilization of services, the numbers and types of network providers who are not accepting new patients, and the geographic location of providers and enrollees.

In § 438.306(d)(4), we are proposing that the State agency ensure each MCO demonstrates that its providers are credentialed as described in § 438.314. We propose this paragraph to apply to all providers, including subcontracted providers. Thus, as an example, if an MCO's provider subcontracts allow such providers to enter into sub-subcontracts with other providers for services to Medicaid enrollees, either the MCO or its subcontractor should determine that each sub-subcontractor is appropriately qualified and is not excluded in any way from participation in the Medicaid or Medicare programs.

In § 438.306(d)(5), we are proposing that, when medically appropriate, the State agency ensure that each MCO make services available and accessible 24 hours a day, 7 days a week. This applies, at a minimum, (1) to emergency services and post-stabilization services, and (2) to non-emergency services that are required immediately because of an unforeseen illness.

In § 438.306(d)(6), we are proposing that the State agency require MCOs to ensure that provider hours of operation are convenient to enrollees and do not discriminate against Medicaid enrollees. Because of varying enrollee needs, the types of providers used by an MCO to meet those needs, and other factors specific to each MCO, we are not proposing a single set of fixed guidelines for hours of operation. Rather, the State agency should ensure that the MCO assess the needs of the population it proposes to enroll and require that the MCO's network have hours of operation that meet those needs. In addition, the State agency should ensure that the MCO's provider network does not have different hours of operation for the organization's Medicaid enrollees than those offered for other non-Medicaid patients. A Medicaid enrollee should have the same opportunity to be seen by the provider as non-Medicaid patients.

Provision of Services

In § 438.306(e), we are proposing requirements, consistent with section 1932(c)(1)(A)(I) of the Act, to require State agencies to ensure that all MCOs comply with the requirements of this section, governing the provision of services.

In § 438.306(e)(1)(i), we are proposing that the State agency require each MCO to meet, and require its providers to meet, State-established standards, required under proposed § 438.304(f) as part of the State's quality strategy, for timely access to care and member services, taking into account the urgency of need for services. Under this requirement, the State agency should ensure that the MCO establish timeliness standards for appointments. Such standards should include criteria for the classification of requests for services by level of urgency and should take into consideration in-office waiting times for each type of service, the immediacy of member needs, and common waiting times for comparable services in the community. An example of timeliness standards for primary care services (and which is reflective of many existing managed care contracts) includes: urgent but non-emergent care provided within 24 hours; non-urgent but symptomatic care in need of attention provided within 1 week; and routine and preventive care provided within 20 days.

In § 438.306(e)(1)(ii) and (e)(1)(iii), we are proposing that the State agency require the MCO to establish mechanisms to ensure compliance, and monitor continuously for compliance. Examples of tools for monitoring might include a member survey; analysis of member complaints and grievances; provider self-reports of appointment and in-office waiting times that are supplemented with random calls or audits; and for the MCO's own services, test calls and ongoing monitoring of telephone abandonment rates (the percentage of callers who terminate a call before reaching an MCO representative.) The MCO's work in this area should evaluate access and availability for all services the organization is responsible for providing under its contract. Thus, as an example, the State agency should ensure that an MCO does not base its monitoring solely on general surveys of its enrolled population that do not yield information on availability of specialty or other services, or that do not provide a sufficient sample of enrollees requiring such services.

We also propose in § 438.306(e)(1)(iv) that the State agency ensure that each MCO take corrective action if there is a failure to comply. With this requirement, the State agency should ensure that the MCO not only initiates a corrective action plan, but also includes a process for assessing the effectiveness of the corrective action. For example, if a problem of minimum compliance arises that applies to an entire service type or specialty, a potential corrective action might be that the MCO proposes to expand its facilities or provider network. If the problem involves a specific provider, the MCO might instead propose, as part of its corrective action, that it close off the provider to new enrollees or, in the alternative, monitor the provider. We emphasize here that the MCO should not aim toward merely complying with the State agency's minimum standards but rather promote its own continuous quality improvement above and beyond those minimum standards.

Incorporated in all four provisions of § 438.306(e)(1) is the affirmative requirement that MCOs make affiliated providers aware of the timeliness standards and have in place mechanisms for complying. As an example, for primary care providers, an MCO could obtain documentation of backup arrangements for vacations and other absences, and ensure that backup providers are familiarized with MCO's procedures, such as approval requirements for referral services. As another example, an MCO could have in place standards for responsiveness of member services' telephone lines that include, but are not limited to, standards specifying minimum average waiting times to reach a non-recorded voice and standards that take into account the likelihood that such members may not have access to touch-tone systems and may be using telephones outside their residences.

In § 438.306(e)(2), we are proposing that the MCO must provide an initial assessment of each enrollee's health: (1) within 90 days of the effective date of enrollment for each enrollee, and (2) within some shorter period of time, specified by the State agency, for pregnant women and enrollees with complex and serious medical conditions. The intent of § 438.306(e)(2)(i) is to ensure that all enrollees, and not just pregnant women or individuals with complex and serious medical conditions, receive a baseline health risk assessment. A variety of assessment tools may be used to meet this requirement; however, a baseline health risk assessment must be completed for each enrollee within 90 days from his or her effective date of enrollment. In addition, for pregnant women and individuals with complex or serious medical conditions, the MCO must complete a baseline assessment in a shorter period of time than 90 days, as specified by the State agency, to ensure that these vulnerable population groups receive timely and appropriate care.

In § 438.306(e)(3), we propose that the State agency ensure that MCOs have procedures in place that have been approved by the State agency, so that the MCO: (1) timely identifies and furnishes care to pregnant women; (2) timely identifies individuals with complex and serious medical conditions, assesses the conditions identified and identifies appropriate medical procedures to address and monitor them; and (3) implements treatment plans that: are appropriate for the conditions identified and assessed in § 438.306(e)(3)(ii), are for a specified time period, specify an adequate number of direct access visits to specialists as required by the plan, and are updated periodically by the physician responsible for overall coordination of the enrollee's health.

''Enrollees with complex and serious medical conditions'' generally refers to enrollees with serious or multiple medical conditions, whether they be physical-health, mental-health, or substance-abuse-related in nature. Health risk assessment tools should be utilized by the MCO at the time of enrollment to identify pregnant women and individuals with complex or serious medical conditions and to ensure that all enrollees are provided with continuous and seamless health care. We emphasize that treatment plans for individuals with complex and serious medical conditions must be time-specific and be updated periodically by the physician responsible for the enrollee's overall health care.

Our intent, in proposing § 438.306(e)(3)(ii), and (e)(3)(iii) is to ensure that, under BBA authority, Medicaid enrollees with complex and serious medical conditions have the ability to directly access specialists within the network for an adequate number of visits under a plan of treatment. This is explicitly intended to encompass the right to access specialists as set forth in the CBRR. Examples include, but are not limited to, a female patient under an approved treatment plan with metastatic breast cancer who is referred to a specialist within the network for a course of chemotherapy; a multiple sclerosis patient under an approved treatment plan with a sacral decubitus who is referred to a specialist within the network for surgical debridement and wound care; or a

situationally depressed patient under an approved treatment plan who is referred to a specialist within the network for a course of psychotherapy.

In § 438.306(e)(4), we are proposing that the State agency ensure that each MCO provide services in a culturally competent manner, including at least satisfying the language requirements in § 438.10(b). This requirement is proposed here because of our recognition that more than half of Medicaid program beneficiaries are members of a racial or ethnic minority group. We know that managed care organizations and advocates have made great strides in developing culturally competent approaches and would expect a State agency to work with them and others in setting its standards. Accordingly, State agencies should ensure that MCOs identify significant sub-populations within their enrolled population that may experience special barriers in accessing health services such as the homeless or enrollees who are part of a culture with norms and practices that may affect their interaction with the mainstream health care system. State agencies should ensure that MCOs make continued efforts to improve accessibility of both clinical and member services for these specific groups.

Cultural competency requires awareness of the culture of the population being served. Therefore, in order to ensure services are provided in a culturally competent manner, State agencies should require MCOs to give racial and ethnic minority concerns full attention beginning with their first contact with an enrollee, continuing throughout the care process, and extending afterwards when care is evaluated. Translation services must be made available when language barriers exist, including the use of sign interpreters for persons with hearing impairments and the use of braille for persons with impaired vision. Further, for each racial or ethnic minority group, the MCO's network should include an adequate number of providers, commensurate with the population enrolled, who are aware of the values, beliefs, traditions, customs, and parenting styles of the community. This awareness includes, but is not limited to, a provider being cognizant, among other things, of the importance of non-verbal communication, the recognition of specific dietary customs unique to certain populations, and the existence of folk medications or healing rituals that may be used by an enrollee. In addition, cultural competence requires network providers to have knowledge of medical risks enhanced in, or peculiar to, the racial, ethnic, and socioeconomic factors of the populations being served. Accordingly, MCOs should have accurate epidemiological data from which to form appropriate education, screening, and treatment programs.

8. Continuity of Care (§ 438.308)

Current regulations at part 434, Contracts, do not contain specific requirements governing continuity of care. Rather, § 434.52 requires that the State agency obtain assurances from each contractor that it furnishes the health services required by an enrolled recipient as promptly as is appropriate; and that the services meet the agency's quality standards.

In accordance with section 1932(c)(1)(A)(i) of the Act we are proposing requirements in § 438.308 to ensure that a State agency requires MCOs to maintain continuity of care for its enrollees. For MCOs, § 438.308(a) requires that MCOs have in place and adhere to written policies that provide each enrollee with an ongoing source of primary care appropriate to the enrollee's needs, and a health care practitioner who is formally designated as primarily responsible for coordinating the enrollee's overall health care. It also requires MCOs to specify in their policies whether coordination is provided by the enrollee's primary care provider or a different practitioner.

Traditionally, many health maintenance organizations and similar entities have used a gatekeeper model, under which the enrollee's usual source of primary care serves as the entry point for all other medical care services (often a distinct entry point was established for mental health and substance abuse services). While this model is still quite common, some MCOs have systems under which a health care professional other than the enrollee's usual source of primary care, such as a case manager, coordinates services. Whether or not the MCO uses a gatekeeper model, a single health care professional, or a team of health care professionals, a designated person or team of persons must have primary responsibility for evaluating the enrollee's needs, recommending and arranging the services required by the enrollee, and facilitating communication and information exchange among the different providers treating the enrollee. If this person or team is not the enrollee's primary care provider, the State agency should ensure that the MCO make every effort to promote a relationship between the enrollee and the primary care provider, since an ongoing relationship with the usual source of primary care plays an important role in promoting continuity and quality of care.

In meeting the requirements of § 438.308(a)(1), the MCO may establish different mechanisms for different types of enrollees. Care of most enrollees might be coordinated by the primary care provider, while a case manager may coordinate care of enrollees with complex needs, chronic illnesses, or functional disabilities. Additionally, an MCO may provide for separate coordination of physical health services and of mental health and substance abuse services. In these instances, the State agency should ensure that the MCO has procedures to ensure the exchange of necessary information between physical health providers and mental health and substance abuse providers (for example, with respect to prescribed medications).

In proposing § 438.308(a)(2), we acknowledge the fact that, although primary care is ordinarily furnished by general practitioners, family practitioners, pediatricians, and internists, an MCO may determine that it is appropriate for some enrollees to obtain routine care from a specialist. This may be particularly true with enrollees with complex or serious medical conditions.

In § 438.308(b), we are proposing that the State agency ensure that MCOs coordinate services both internally, and with services available from community organizations and other social programs. As an example, an MCO that provides services to enrollees with mental illness, substance abuse problems, developmental disabilities, functional disabilities, or complex problems involving multiple medical and social needs (for example, HIV/AIDS, homelessness) should have a program or policies for ensuring coordination among medical, mental health, and substance abuse services, and available social services or other community supports. These programs or policies should include procedures that specify when and under what conditions a primary medical care, mental health, or substance abuse provider would refer an enrollee for a multi-disciplinary assessment and development of a plan for coordination of medical and social services. Further, the policies should specify the types of enrollees who are candidates for this program, as well as the types of providers or disciplines to be included in the assessment team.

With respect to mental health and substance abuse services, the State agency should ensure that the MCO has general procedures to ensure the exchange of information among primary acute care and mental health and

substance abuse providers. As an example, the MCO could implement training programs for primary care providers to familiarize them with common mental health and substance abuse problems, and additionally, programs to ensure that primary care providers can identify enrollees in need of referral for these services. The expectation under § 438.308(b) is that the MCO will identify conditions that are prevalent in its population and for which continuity and effectiveness of care would be improved through targeted programs.

In § 438.308(c), we are proposing that the State agency ensure that MCOs and providers have information necessary for effective and continuous patient care and quality improvement, including procedures to ensure that (1) providers maintain, for Medicaid enrollees, health records that meet the requirements established by the MCO, taking into account professional standards; and (2) there is an appropriate and confidential exchange of information among providers. While confidentiality of records is discussed elsewhere (§ 438.324), it must be underscored that the confidentiality of patient records must be of paramount concern.

In § 438.308(d), to ensure optimum enrollee participation, we are proposing that State agencies require MCOs to implement procedures to ensure that providers (1) inform enrollees of specific health conditions that require follow-up and, if appropriate, provide training in self-care; and (2) deal with factors that hinder enrollee compliance with prescribed treatments or regimens. In meeting the requirements under § 438.308(d)(1), the State agency should, for example, ensure that the MCO provides enrollees with information they need to participate fully in their own care. This information includes, but is not limited to, subjects on self-care, medication management and the use of medical equipment, potential complications and when such complications should be reported to providers, and scheduling of follow-up services. To comply with § 438.308(d)(2), the MCO may, for example, ensure that counseling and facilitating services are available on referral from providers or staff for enrollees who are unable to, or are failing to, cooperate in their own treatment. Such counseling services might include identification of social, financial, or other barriers that are preventing enrollees from following guidance or instructions from providers, with referral to appropriate social services as necessary.

9. Coverage and Authorization of Services (§ 438.310)

As part of the access standards, we are proposing requirements to ensure that each contract with an MCO describe and identify all services offered under the contract and follow written policies and procedures for processing requests for services in a manner that ensures access to these services. Further, we are proposing requirements to ensure that utilization management activities are not structured in a manner that is detrimental to enrollees. These standards are consistent with section 1932(b)(1) of the Act. To the extent appropriate and applicable, these standards are consistent with the Medicare + Choice regulations at § 422.112.

In paragraph § 438.310(a), we are proposing that the State agency ensure through its contracts with MCOs that each MCO identifies, defines, and specifies all Medicaid benefits that the MCO must furnish. This provision is intended to protect enrollees by ensuring there is no ambiguity concerning the range of Medicaid-covered services that will be available to them under the contract. To achieve this result, the description must specify the amount, duration, and scope of services that the MCO must offer. Further the contract must specify what constitutes medically necessary services to the extent they are described in the State plan and provide that the MCO furnishes the services in accordance with that provision. While we are not proposing a definition of medical necessity because of variances among States agencies, the contract terminology should be drafted with sufficient precision so that at a minimum the enrollee will be able to receive services (either directly through the MCO or the State agency) to the same degree as the services covered under the State plan. Further, we expect the State agency to use the same definition of medical necessity for all its contacts. Any services included in the State plan but not required under the contract are the responsibility of the State agency, including those services that are inadvertently not covered in the contract because of ambiguity in the contract language.

In § 438.310(b), we propose to require that, in processing requests for initial or continuing authorization of services, the MCO and its subcontractors follow written policies and procedures that reflect current standards of medical practice and that they utilize the services of appropriately trained health care personnel to make these decisions.

In § 438.310(b), we are also proposing that the State agency ensure through its contracts with MCOs that the MCO, and any subcontractor, follows written policies and procedures, reflecting current standards of medical practice, for processing requests for initial authorization of services or requests for continuation of services. While we require that these policies and procedures be in compliance with requirements defined by the State agency, and reflect current standards of medical practice, at a minimum, they must specify the timeframe for responding to such requests for initial and continued authorization consistent with § 438.310(d), provide for expedited response to requests for authorization of services needed in an urgent manner, specify information required for authorization decisions, and provide for consultation with requesting providers when appropriate. We propose that the State agency set its own timeframes for responding to requests for initial and continued authorization consistent with § 438.310(d), such that these timeframes are not longer than those established in the M+C regulation. We recognize that timeframes may differ according to the urgency of the need for the requested services and the complexity involved in evaluating the request; however, the State agency must be able to demonstrate that its timeframes are reasonable. The policies and procedures must specify the information that is ordinarily required to process and authorize the request, and the circumstances under which additional information may be required. The MCO information standards must ensure that the authorization process is not unduly burdensome for practitioner, provider staff, or enrollees. Information should not be required that is not in fact used in the evaluation or recording of the request. In addition, policies must provide for consultation with requesting providers when appropriate.

We propose in § 438.310(b)(2) that mechanisms must be in place to ensure consistent application of review criteria and compatible decisions. The MCO should be required to ensure that all employed or contracted reviewers understand coverage policies and review criteria, through manuals, training programs, or other means. In addition, the MCO should have to periodically assess the consistency of authorization decisions. Possible approaches may include review of test cases by different utilization management staff or audits of samples of recent decisions. In addition, upon request, the organization should furnish

enrollees (or their representatives) and requesting provider(s) the review criteria that is used to reach a decision.

Under proposed § 438.310(c), the MCO would be required to provide the requesting provider and the enrollee written notice, in accordance with § 438.404 of any decisions to deny, limit, or discontinue authorization of services. Appropriate information regarding rights to file a grievance or request a State fair hearing must also be included with this notice as described in subpart F of this part. Further, information must be included regarding how continuing care can be received during an appeal process. In setting the timeframe for providing this notification, the State agency should ensure that the timeframe could not jeopardize an enrollee's health. The manner in which this notice is provided is also not prescribed in this rule; however, it must occur in a manner that ensures that the State agency can document when the requesting provider receives the information and whether enrollees are able to comprehend what is stated.

We propose in § 438.310(d) that the timeframes established by State agencies under § 438.310(c) for response to requests for initial and continued services may be no longer than the following two provisions. First, for a case not requiring expedited review, the decision must be rendered as expeditiously as the enrollees health condition requires but no longer than 14 calendar days after the request for services, or up to 14 additional days if the enrollee requests the extension or the MCO justifies (upon request, to the State agency) that it needs additional information, and why the delay is in the interest of the enrollee. Second, in the case where applying the timeframe for a standard review could seriously jeopardize the life or health of the enrollee, or the enrollee's ability to regain maximum function, resolution of the request for service must occur as expeditiously as the enrollee's health condition requires but no later than 72 hours of receipt for the request or up to 14 additional days if the enrollee requests the extension or the MCO justifies to the State agency (upon request) the need for additional information, and the delay is in the interest of the enrollee.

In proposed § 438.310(e) we provide that, consistent with §§ 438.6(g) and 422.208 of this chapter, compensation to the organization or persons that conduct utilization management activities is not structured so as to provide incentives for the denial, limitation, or discontinuation of medically necessary services for any individual.

Structure and Operation Standards

10. Establishment of Provider Networks (§ 438.314)

We are proposing that State agencies ensure that MCOs have written policies and procedures for the selection and retention of practitioners. These policies include items such as criteria for credentialing and re-credentialing of practitioners appropriate to the nature of the services to be furnished to enrollees.

In general, credentialing is a process for the review of qualifications and other relevant information pertaining to a practitioner who seeks employment from or a contract with an MCO. The initial credentialing process often includes steps such as written applications and site visits, if appropriate, as well as verification from primary sources of licensure, disciplinary status, and eligibility for payment under Medicare. Re-credentialing often includes re-verification of items such as licensure, clinical privileges, malpractice coverage, and history of professional liability claims. Recredentialing must be in accordance with timeframes set by the State agency, but may not occur less frequently than what the State agency requires for private HMOs.

Similar provisions regarding the recredentialing process, provider qualifications, and selection are found in the M+C regulation.

By requiring State agencies to ensure that MCOs document the qualifications of their providers, these provisions are consistent with the CBRR. In particular, these provisions are consistent with the right of consumers to information on health professionals such as education and board certification. Further, they are consistent with the right of consumers to choose qualified specialists for women's health services and for individuals with complex medical conditions.

11. Enrollee Information (§ 438.318)

For an enrollee to access quality health care that meets their specific needs, they must first be informed of the choices available to them. Therefore, in addition to the information requirements in proposed § 438.10, which are predominately elements of information that an MCE, MCO, or primary care case manager must provide, in § 438.318 we propose what we consider to be the minimum information elements that must be provided by the State agency, or its contracted representative. In proposed § 438.10(i), we propose information requirements that apply only if a State agency provides for mandatory MCE enrollment under section 1932(a)(1)(A) of the Act. These are not incorporated in § 438.318 as a mandatory part of a State agency's quality strategy under section 1932(c)(1) of the Act, because they are not necessarily appropriate in a non-mandatory program. Instead, as discussed below we are proposing in § 438.318(b) different minimum standards for beneficiary information as part of the State agency's quality strategy than those in § 438.10(i). Under the standards in § 438.318(b), a State agency is not required to provide quality and performance indicators for each contracted MCO unless they choose to do so. Further, within this section, the methodology for presenting this information is left up to the State agency, unlike in § 438.10(i) which requires that the information be provided in a comparative, chart like format with respect to mandatory managed care programs.

Through the requirements at § 438.10 and the minimum requirements in paragraph § 438.318, we believe that we have required that potential enrollees and enrollees receive the basic information elements that are essential for the beneficiary to access health care and participate in decision making about their provider and services received. Further, it is our belief that these requirements are not substantially different from current MCE and State practice.

As a basic rule, we propose to require that the State agency or its contracted representative comply with the applicable requirements in proposed § 438.10 (a) through (h), which specify information that must be provided by the State agency, MCEs, MCOs, and primary care case managers, as well as requirements regarding the manner and format for providing information.

In § 438.318(b)(2), we propose that the State agency, or its contracted representative provide information on: the benefits covered; the cost-sharing imposed by each MCO; the service area of the MCO; current provider network including information on who is not accepting new patients and any restriction on enrollee's ability to select from any affiliated provider; and information on any benefits that the enrollee is entitled to receive under the Medicaid program but which is not made available to them through the MCO, including how transportation services will be provided. Information on the benefits covered should include sufficient detail to ensure that the

beneficiary is aware of any limitation on services as required under § 438.310, such as pharmaceuticals, mental health, and substance abuse services. If cost-sharing is permitted, the enrollees must be informed of this in sufficient detail. Information on the current provider network should include, at a minimum, 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 that informs potential enrollees about how they can obtain this supplemental information. In addition, enrollees making a decision about whether to enroll in a particular MCO may rely on the provider listings in making their selection and may assume that they will be able to obtain covered services from any of the providers listed. If a provider is not accepting new Medicaid enrollees, this must be clearly indicated as this provider may not be available to the enrollee for selection. Further, it is essential that the MCO's informational materials emphasize any limitations on enrollees' provider selections. If the MCO contracts with formal subnetworks, or the MCO's arrangement with primary care providers allows for the establishment of informal subnetworks, the MCO's 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. In addition, we propose to require that information be provided to enrollees that informs them of any benefits that the enrollee is entitled to receive under the Medicaid program but that are not made available to them through the MCO, including any cost sharing requirements and how transportation services will be provided.

In § 438.318(b), we propose to require that the State agency or contracted representative provide this information to any potential enrollee(s) who requests it and to all potential enrollees when they first become eligible for Medicaid, are considering choice of MCOs under a voluntary program, or are first required to choose an MCO under a mandatory enrollment program. Further, the information must be provided within a timeframe that enables them to use the information in choosing among available MCOs. When the State agency is determining this timeframe, factors such as the default assignment process and length of time allotted for a mandatory enrollment period should be considered.

12. Enrollee Rights (§ 438.320)

As part of these standards, we are proposing requirements to ensure that each contract with an MCO have written polices with respect to enrollee rights and that the MCO ensure compliance with Federal and State laws affecting the rights of enrollees. Although not limited to the following, each enrollee has a right to: receive information regarding their health care; have access to health care; be treated with respect and consideration for enrollee dignity and privacy; to participate in decision-making regarding his or her health care; and to receive information on available treatment options or alternative courses of care. In addition, we are requiring that each enrollee has a right to access his or her medical records in accordance with applicable Federal and State laws. 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. Although not as exhaustive as the CBRR, these rights are consistent with the rights expressed in the CBRR.

As a general rule, we propose to require that the State agency have in its contract with MCOs written polices with respect to enrollees' rights and that its staff and affiliated providers understand these requirements and take them into account when furnishing services to enrollees. Further, the MCO must 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. The MCO should monitor compliance with these requirements through analysis of complaints or grievances, requests to change providers, enrollee satisfaction surveys, rapid disenrollment surveys, and other sources of enrollee information. Issues in compliance should be addressed through education or counseling of the staff or providers or other corrective action, and information on compliance with the policies should be considered during the recredentialing and staff evaluation process.

Although not limited to those rights stated therein, as a basic right each enrollee has a right to receive information in accordance with § 438.318 and have access to health care as required in § 438.306 through § 438.310. In addition, each enrollee has the right to be treated with respect and consideration for enrollee dignity and privacy. The MCO must ensure that enrollees' dignity and privacy are respected in its own facilities and must address these issues in site visits to offices or facilities of affiliated providers. Examples of privacy concerns include privacy of examining rooms and measures to assure that enrollees are not interviewed about medical, financial, or other issues within the hearing range of other patients.

In addition, the enrollee has the right to participate in decision-making regarding his or her health care and to receive information on available treatment options or alternative courses of care. The MCO's policies must promote enrollees' understanding of their conditions or problems and facilitate development of treatment goals. While participating in treatment planning is important for all enrollees, special emphasis should be placed on involvement of enrollees and their families in development of plans of care for enrollees with mental health or substance abuse problems.

Enrollees have a right to receive information on available treatment options or alternative courses of care. As required in § 438.102, contracts with providers may not limit a provider's ability to counsel or advise an enrollee of treatment options that may be appropriate for the enrollee's condition or disease, whether or not the options are covered by the organization unless excluded under the terms of § 438.102(c). Enrollees have an affirmative right to a clear explanation of their condition, any proposed treatments or procedures and any alternatives; the benefits, drawbacks, and likelihood of success of each option; and the possible consequences of refusal or non-compliance with a recommended course of care. In addition, as an enrollee right, we require that each enrollee have access to his or her medical records in accordance with applicable Federal and State law. The MCO must have procedures through which an enrollee can obtain timely access to all medical records and health information maintained by the organization, including records maintained by subcontracting providers from whom the enrollee has received services.

In § 438.320(c), we require MCOs and their subcontractors to 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; Section 504 of the Rehabilitation Act of 1973; the Age Discrimination Act of 1975; Titles II and III of the Americans with Disabilities Act; Section 542 of the Public Health Service Act pertaining to nondiscrimination against substance abusers; and Title 45, Part 46 of the Code of Federal Regulations, pertaining to research involving human subjects. While these laws are enforced by agencies other than HCFA or State agencies, to the extent feasible and appropriate, assessment of compliance should be included in the organization's credentialing procedures. For example, site visits to individual practitioners' offices should include a general assessment of physical accessibility.

13. Confidentiality (§ 438.324).

Current regulations at 42 CFR part 431, subpart F govern the safeguarding of beneficiary information at the State agency level. The regulations in this subpart specify, among other requirements, the types of information to be safeguarded, when such information may be released, and how such information is to be distributed.

In § 438.324, we are proposing that the State agency, consistent with the regulations at part 431 subpart F, ensure, through its contracts with MCOs, that each MCO establish procedures:

- To develop and promulgate policies in accordance with Federal and State law establishing who is authorized to receive such information;
- To safeguard the privacy of any information that identifies a particular enrollee by ensuring that: information from the MCO or copies of records may be released only to authorized individuals; unauthorized individuals cannot gain access to or alter patient records; and original medical records must be released only in accordance with Federal or State law, court orders, or subpoenas;
- To address the confidentiality and privacy for minors, subject to applicable Federal and State law;
- To ensure timely access to enrollees who wish to examine their records; and
- To abide by all Federal and State laws regarding confidentiality and disclosure for mental health records, medical records, other health information and any information about an enrollee.

The requirements we are proposing in this section are consistent with section 1932(c)(1)(A)(ii) of the Act. The proposed requirements are also consistent with the right to confidentiality of health information supported by the CBRR.

In § 438.324(a), we propose that the State agencies ensure that MCOs keep records in an accurate and timely manner.

In § 438.324(b), we are proposing that the State agency safeguard the privacy of any information that identifies a particular enrollee. It should ensure that each MCO's confidentiality procedures apply, not just to medical records, but to any information in the possession of the organization or its contractors that could disclose medical conditions or the use of specific services, such as claims information collected in the course of quality assessment and performance improvement, utilization management, or other processes. The procedures should address both written materials and information created in other formats, such as electronic records, facsimiles, or electronic mail.

As part of the above requirement, we specify that any such information from the MCO or copies of records may be released only to authorized individuals. Thus the MCO must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records must be released only in accordance with Federal and State law, court order, or subpoena. This requirement pertains to the release of information to third parties and is not meant to impede the exchange of information within the MCO or among its affiliated providers and other contractors as necessary to carry out the organization's contractual responsibilities. However, the MCO procedures should ensure that information on enrollees will be released to outside parties only with the consent of the enrollee (or authorized representative) except when required by a subpoena or other legal requirements (such as the mandatory reporting of certain communicable diseases).

In § 438.324(c), we are proposing that the State agency ensure that each MCO procedure address the confidentiality and privacy for minors, subject to applicable Federal and State law. These procedures should define whether and under what circumstances treatment may be furnished to a minor without parental consent and what information will be released to a parent upon request. Specific issues to be addressed by the procedures should include family planning and mental health and substance abuse services, taking into account any State law requirements with respect to these issues.

In § 438.324(d), we are proposing that the State agency ensure that each MCO establish and communicate to enrollees procedures under which enrollees can obtain access to all records and information about themselves. The procedures should include reasonable time limits for providing such access, and should include provision for explaining and interpreting the records to an enrollee, as well as procedures for identification and correction of errors found by enrollees in their own records.

In § 438.324(e), we propose that the State agency ensure that the MCO's policies regarding use and disclosure of enrollee information comply with all laws governing the confidentiality of the information they hold.

14. Enrollment and Disenrollment (§ 438.326) and Grievance Systems (§ 438.328)

These proposed sections require, consistent with section 1932(c)(1)(A)(ii) of the Act, that a State agency include as part of its quality strategy ensuring compliance with the enrollment requirements in proposed § 438.326 and the grievance requirements in subpart F.

15. Subcontractual Relationships and Delegation (§ 438.330)

With some exceptions, an MCO may, by written subcontract, delegate any activity required under its primary contract with the State agency. However, an MCO entering into a contract with the State agency remains entirely accountable to the State agency for the performance of any delegated function. It is the sole responsibility of the MCO to ensure that the delegated function(s) is performed in accordance with applicable contractual requirements.

Subcontracts that delegate (in whole or in part) functions from the MCO should clearly indicate what function(s) has been delegated and if functions are only partially delegated, which entity retains responsibility for each function.

The MCO should document that it has approved its subcontractors' policies and procedures with respect to the delegated function. In addition, the MCO should have written procedures for monitoring and review of delegated activities. Such monitoring should be conducted by MCO staff who are qualified to assess the delegated function(s).

Finally, these provisions are consistent with the CBRR as they relate to consumer choice of provider networks that are adequate to serve the needs of consumers. In particular, these provisions ensure that State agencies, through their contracts with MCOs, hold plans accountable for the availability and adequacy of all covered services.

Measurement and Improvement Standards

16. Practice Guidelines (§ 438.336)

In order to achieve greater consistency across public and private sector quality standards, this section addresses the need for each MCO to use practice guidelines as a component of its quality measurement and improvement activities. The science of quality measurement (and by that, the ability to improve health care quality) is dependent upon having a strong base of evidence on what constitutes effective health care (that is ''evidenced-based'' practice guidelines). The critical importance of the existence and use of practice guidelines in the delivery of quality health care services has been widely accepted by experts in health care quality measurement and improvement. The President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry (Commission) underscored the importance of the adoption and use of clinical practice guidelines in its report, ''Quality First: Better Health Care for All Americans.'' This report stated that,

> The development and dissemination of practice guidelines by the Federal government, professional associations and health plans have accelerated during the 1990s. The benefits of practice guidelines include developing an evidenced-based consensus of the best practices for a particular condition, consolidating disparate sources of information regarding clinical effectiveness and outcomes, and preparing health research into a useable format for practitioners.

The National Committee for Quality Assurance's (NCQA's) standards for the accreditation of managed care organizations include as a standard, ''The managed care organization is accountable for adopting and disseminating practice guidelines for the provision of acute and chronic care services that are relevant to its enrolled membership.'' NCQA's standards also include more detailed requirements addressing the use of clinical practice guidelines; however, we chose not to include those details in this proposed rule.

17. Quality Assessment and Performance Improvement Program (§ 438.340)

Section 438.340(a) requires that a State agency that contracts with an MCO require the MCO to have an ongoing quality assessment and performance improvement program for the services it furnishes to its enrollees. The quality assessment and performance improvement program as outlined in this section of the rule incorporates and expands upon the quality assurance activities currently required of MCOs under § 434.34, with one exception. Section 434.34(a) requires that an HMO's internal quality assurance system be consistent with the utilization control requirements of part 456. Because incentives to reduce unnecessary services are inherent to a risk capitation system of payment, we believe the application of utilization control requirements as prescriptive as those of part 456 to MCOs is unwarranted, and we will not require compliance with these requirements; rather, we believe it is appropriate to hold them to the same general requirements that must be met by organizations that contract with Medicare under the M+C program. These requirements are: that the MCO, in processing requests for initial or continued authorization of services, follow written policies and procedures that reflect current standards of medical practice; and, that the MCO have in effect mechanisms to detect both underutilization and overutilization of services. The former requirement is found in § 438.310 (''Coverage and authorization of services''), and the latter is found in § 438.340(b).

Section 438.340(b) specifies the basic elements of an acceptable quality assessment and performance improvement program for MCOs. The rule takes a two-tiered approach to ensuring quality: First, the MCO must achieve minimum performance levels on standardized quality measures. Second, the MCO must conduct performance improvement projects.

a. Minimum Performance Levels. Section 438.340(c) elaborates on § 438.340(b)(1) by requiring that the MCO measure its performance, using standard measures required by the State agency; report its performance to the State agency; and achieve any minimum performance levels that the State agency establishes on those standard measures.

The rule permits the standard measures to be specified in uniform data collection and reporting instruments required by the State agency. As was noted earlier, some State agencies have already begun requiring reporting of standardized quality measurement data through instruments such as HEDIS. The rule does not specify the particular measures for which reporting will be required. The State agency will be expected to identify required measures as part of its MCO contract specifications.

There are two key reasons for making performance measurements and minimum performance levels a part of the contracting process. First, it will give the State agency the flexibility needed to respond to new developments in the state of the art of quality measurement and improving performance levels. Second, when necessary, it will allow the State to focus on measures that are appropriate for a specific MCO so that the measures will reflect the characteristics and needs of the MCO's enrolled population and take into account its past performance.

In establishing minimum performance levels, the State agency should ensure that the targets are achievable, meaningful, and equitable. The State agency must consider historical plan and fee-for-service Medicaid performance data and trends. Other criteria that should guide the selection of measures for which minimum performance levels would be established, include their significance for the health of the MCO's enrolled population and the likelihood that they fairly reflect the MCO's performance.

The State agency must establish the minimum performance levels prospectively upon contract initiation and renewal, so that the MCO will have the entire contract year in which to take action to meet them. By the end of the contract year, the MCO must meet the minimum performance levels. Often, the next contract year will already have begun by the time the State agency learns whether the MCO has met the minimum performance levels established for the previous year. However, the rule guarantees the State agency the right to non-renew the MCO's contract in the year that the State agency determines that the MCO failed to meet the minimum performance levels, even if the failure itself was in the prior contract year.

The strategy of relying on performance measurement and performance levels to assess and improve quality is heavily dependent on the validity of the data collected and reported by plans. For that reason, § 438.342 requires that each MCO, whatever the design of its particular information system, ensure the completeness and accuracy of the data it compiles for external reporting or for use in its own quality improvement efforts. However, the rule does not impose uniform requirements for MCOs' data systems; for example, it does not require automated patient records.

b. Performance Improvement Projects. Section 438.340(d) elaborates on paragraph § 438.340(b)(2) by requiring that an MCO's performance improvement projects focus on specified areas of clinical and non-clinical services. It also requires the State

agency to set contractual obligations for the number and distribution of these projects among the specified areas. In addition, it authorizes the State agency to direct an MCO to undertake specific performance improvement projects as the State agency determines appropriate.

Section 438.340(d)(1) describes the components of performance improvement projects. All projects must involve measuring performance, implementing system interventions, evaluating the effectiveness of the interventions, and planning for sustained or increased improvement.

Section 438.340(d)(2) requires that projects address the entire population to which the performance measure is relevant. After a topic has been selected, the MCO must ensure that its measurement and improvement efforts are system-wide. Each project must, to the extent feasible, reach all enrollees and providers in its network who are involved in the aspect of care or services to be studied. This does not mean that MCOs must review the performance of each and every provider who furnishes the services that are the subject of the project, or that it must survey every affected enrollee. Sampling is acceptable so long as the MCO ensures that its samples are genuinely random. The MCO could do so by showing, for example, that:

- Each relevant provider and enrollee has an equal chance of being selected; no provider or enrollee is systematically excluded from the sampling;
- Each provider serving a given number of enrollees has the same probability of being selected as any other provider serving the same number of enrollees; and
- Providers and enrollees who were not included in the sample for the baseline measurement have the same chance for being selected for the follow-up measurement as providers and enrollees who were included in the baseline.

Section 438.340(d)(3) requires the State agency to establish contractual obligations for the number and distribution of projects among the specified clinical and non-clinical areas.

Section 438.340(d)(4) specifies certain focus areas of clinical care that must be addressed by the MCO for the full spectrum of populations enrolled under the contract. These minimum focus areas address: preventive care, care of chronic and acute conditions, high-volume and high-risk conditions, and continuity and coordination of care.

Section 438.340(d)(5) specifies certain non-clinical focus areas to be addressed by performance improvement projects: appeals, grievances, and complaints; and, access to and availability of services. Additional non-clinical focus areas the State agency may consider requiring through contract include: denials of authorization or payment for services and cultural competence. Cultural competency means the development and provision of systems of care for diverse populations, and a demonstrated awareness and integration of: health related beliefs and cultural values, disease incidence and prevalence, and appropriate management and prevention of disease. The period of time that an MCO will be given to undertake projects in all of the required focus areas will be established in contract.

Within each clinical and nonclinical focus area, the State agency should give an organization considerable freedom to select its own particular topics for measurement and improvement, so that it can conduct projects relating to aspects of care and services that are significant for its own population. In this way, the State agency can achieve a balance between encouraging flexibility and innovation and ensuring that every MCO conducts meaningful projects over a broad spectrum of care and services. Additional mechanisms to ensure that MCOs conduct meaningful projects are established in § 438.340(d)(6). The first is the authority for the State agency to require that an individual MCO conduct particular performance improvement projects that are specific to the MCO. This would be necessary when the MCO demonstrates significantly weaker performance in a particular area than its counterparts. The second is the option for the State agency to require that all of its MCOs participate annually in at least one statewide performance improvement project. In such a statewide performance improvement project, the State agency would be responsible for identifying an aspect of care that is of high priority, and for specifying the quality indicators (which will be discussed below) that its MCOs must use in assessing the success of their efforts to improve their performance in the aspect of care the State agency has identified.

In general, we believe that a clinical or non-clinical topic selected for study should affect a substantial portion of the MCO's Medicaid enrollees (or a specified subpopulation of enrollees) and have a potentially significant impact on enrollee health, functional status, or satisfaction. There may be instances in which less frequent conditions or services warrant study, as when data show a pattern of unexpected adverse outcomes. However, the prevalence of a condition or volume of services involved should be sufficient to permit meaningful study.

A project topic may be suggested by patterns of inappropriate utilization—for example, frequent use of the emergency room by enrollees with a specific diagnosis. However, the project should be clearly focused on identifying and correcting deficiencies in care or services that might have led to this pattern, such as inadequate access to primary care, rather than on utilization and cost issues alone. This is not to say that the MCO may not make efforts to address overutilization, but only that such efforts might not be considered projects for the purpose of assessing compliance with this rule, unless the primary objective is to improve health outcomes. Thus, it would be acceptable for a project to focus on patterns of overutilization that present a clear threat to health or functional status, for example, a high risk of iatrogenic problems or other adverse outcomes.

Because the achievement of demonstrable improvement is a central criterion in the evaluation of projects, they should necessarily focus on areas in which meaningful improvement can be achieved through system interventions by the MCO. It will therefore generally be advisable for the MCO to avoid projects that focus on clinical areas in which outcomes are largely dictated by factors that are unlikely to be influenced by delivery system changes. Most MCOs are likely to give priority to areas in which there is significant variation in practice and resulting outcomes within the MCO, or in which the MCO's performance as a whole falls below acceptable benchmarks or norms.

It is recognized that the requirement for demonstrable improvement creates incentives for MCOs to focus all of their projects on aspects of care in which rapid and measurable improvement is possible through simple interventions. It is not the intention of this rule to discourage MCOs from undertaking more complex projects or innovative projects that have a high risk of failure but that offer some offsetting potential for making a significant difference in the health or functional status of enrollees. MCOs considering such projects should avail themselves of the opportunity to work in consultation with the State agency to develop long-range goals for projects and set agreed-upon criteria for evaluation of the MCO's progress in implementing its project.

Section 438.340(d)(7) requires that the MCO assess its performance for each project using one or more quality indicators, and the paragraph

establishes criteria for selecting indicators. The rule requires that the quality indicators measure outcomes such as changes in health status, functional status, and enrollee satisfaction, or valid proxies of these outcomes. We recognize that relatively few standardized performance measures actually address outcomes. Even when outcome measures are available, their utility as quality indicators for projects may be limited because outcomes are substantially affected by factors outside the MCO's control. In other instances improvement is possible, but the resources and sophistication needed to analyze the complex factors involved in the outcome and develop meaningful interventions might be beyond the reach of many MCOs.

Therefore, the rule does not require that quality indicators be outcome measures. Process measures are acceptable so long as the MCO can show that they are valid proxies, that is, there is strong clinical evidence that the process being measured is meaningfully associated with outcomes. To the extent possible, this determination should be based on published guidelines that support the association and that cite evidence from randomized clinical trials, case control studies, or cohort studies. An MCO may furnish its own similar evidence of association between a process and an outcome so long as this association is not actually contradicted by a published guideline. Although published evidence is generally required, there may be certain areas of practice for which empirical evidence of process or outcome linkage is limited. At a minimum, the MCO should be able to demonstrate that there is a consensus among relevant practitioners as to the importance of a given process. We encourage State agencies to consider using HEDIS as a standardized tool for performance reporting.

While MCOs must consider enrollee satisfaction as an important aspect of care, improvement in satisfaction should not be the sole demonstrable outcome of a project in any clinical focus area. Some improvement in health or functional status should also be measured. (Note that this measurement can rely on enrollee surveys that address topics in addition to satisfaction. For example, self-reported health status may be an acceptable indicator; reduction in school absence could be used as an indicator of functional status in children.) For projects in the non-clinical areas, use of health or functional status indicators is generally preferred, particularly for projects addressing access and availability. However, there may be some non-clinical projects for which enrollee satisfaction indicators alone are sufficient. We would encourage State agencies and plans to use the CAHPS instrument when surveying enrollee satisfaction and experiences with care.

Section 438.340(d)(8) requires that the MCO's assessment of its performance on the selected indicators be based on systematic, ongoing collection, and analysis of valid and reliable data. We expect that data will most commonly be derived from administrative data generated by the MCO's health information system or from review of medical records. (In assessing non-clinical services, other sources such as enrollee or provider surveys may be appropriate.) When data are derived from the health information system, their reliability is obviously a function of the general reliability of the system. By contrast, when data are derived from direct review of medical records or other primary source documents, steps must be taken to ensure that the data are uniformly extracted and recorded. Appropriately qualified personnel should be used; this will vary with the nature of the data being collected and the degree of professional judgment required. There should be clear guidelines or protocols for obtaining and entering the data; this is especially important if multiple reviewers are used or if data are collected by multiple subcontractors. Inter-reviewer reliability should be assured through, for example, repeat reviews of a sample of records.

Section 438.340(d)(9) requires that the MCO's interventions result in improvement that is significant and sustained over time. The State agency might choose to consider judging improvement to be significant when the MCO either (1) achieves a benchmark level of performance that is defined in advance by the State agency; or (2) achieves a reduction specified by the State agency in the percentage of enrollees who do not achieve the outcome defined by the indicator. The State agency might choose to consider requiring a 10 percent reduction in adverse outcomes. An MCO would meet this requirement if, for example, its child immunization rate is 80 percent in the baseline and increases to 82 percent, because the percentage of children *not* immunized has dropped from 20 percent to 18 percent, a 10 percent reduction. An MCO whose baseline rate is 60 percent would have to reach 64 percent—a reduction in non-immunized children from 40 percent to 36 percent. (Note that, to ensure uniform computation of improvement across indicators, all indicators must first be stated in the form of a positive outcome, and improvement measured as a reduction in its inverse.)

We suggest that the State agency require a 10 percent reduction in adverse outcomes for several reasons. First, the use of a constant percentage reflects the likelihood that change is harder to achieve when a MCO's baseline performance is already superior. Thus, the MCO with an 80 percent immunization rate is only expected to achieve a 2 percent improvement, while the MCO with a 60 percent rate must achieve a 4 percent improvement. Second, the 10 percent level is consistent with results HCFA has observed in successful improvement projects sponsored by the agency.

Note that improvement in an *indicator* is not necessarily the same as improvement in the health or functional status of enrollees. For example, the ''health of seniors'' indicator under HEDIS 3.0(c) will track, over time, changes in the functional status of elderly enrollees. Each enrollee's functional status may remain stable or actually decline. However, an MCO would demonstrate improvement on the indicator if it slowed the rate of decline, whether or not it actually improved enrollees' functional status. The State agency might choose to consider judging improvement to be sustained when the MCO demonstrates through continued measurement that its performance gains have endured for at least one year.

We recognize that many MCOs still have limited experience in conducting well-designed performance improvement projects, and that any given project may take some time to produce measurable improvement. Therefore, we encourage the State agency to incorporate into the contract process a gradual phase-in of the number of focus areas for which improvement must be demonstrated. State agencies and plans desiring further technical instructions in designing quality improvement projects are directed to the NCOA publication, ''Health Care Quality Improvement Studies in Managed Care Settings—Design and Assessment'' developed under HCFA contract #HCFA–92–1279.

Section 438.340(d)(10) requires the MCO to report the status and results of each project to the State agency as requested.

c. Program review by the State agency. Section 438.340(e) requires that the State agency review, at least annually, the impact and effectiveness of the MCO's quality assessment and performance improvement program. The review must include the MCO's performance on the standard measures on which the MCO is required to report,

and the results of the MCO's performance improvement projects.

In addition, § 438.340(e) authorizes the State agency to require that the MCO have in effect a process for its own evaluation of the impact and effectiveness of its quality assessment and performance improvement program. The State agency might choose to direct the MCO to consider whether the activities in its work plan are being completed on a timely basis or whether commitment of additional resources is necessary. The State agency might choose to require that the MCO's evaluation include recommendations for needed changes in program strategy or administration, and that these recommendations be forwarded to and considered by the policy making body of the MCO.

18. Health Information Systems (§ 438.342)

Section 1932(c)(1)(iii) of the Act requires State agencies that contract with Medicaid managed care organizations to develop a State quality assessment and improvement strategy that includes procedures for monitoring and evaluating the quality and appropriateness of care and services to enrollees that reflect the full spectrum of populations enrolled under the contract and that includes requirements for provision of quality assurance data to the State agency by MCOs using the data and information set that the Secretary has specified for use under Part C of Title XVIII or such alternative data as the Secretary approves, in consultation with the State agency.

In § 438.342, we are proposing that the State agency ensure through its contracts with MCOs that each MCO be required to maintain a health information system that collects, analyzes, integrates, and reports data that can achieve the objectives of this part. We would expect the State agency to work with plans, providers, and others in developing its requirements and that the requirements will reflect the differing capabilities and structures of different kinds of plans. Every MCO should be able to collect and integrate data from all components of its network, in order to develop a comprehensive picture of enrollee needs and utilization. Each MCO should be able to use these data in its quality assessment and performance improvement program, as well as in other management activities. Under proposed paragraph § 438.342(a), we provide that the system should provide information on areas including, but not limited to, utilization, grievances, disenrollments and solvency.

In § 438.342(b)(1), we are proposing that the State agency ensure through its contracts with MCOs that each MCO be required to collect data on enrollee and provider characteristics as specified by the State agency, and on plan services furnished to enrollees through an encounter data system or such other methods as may be specified by the State agency. Although an encounter data system may be the most efficient means of meeting the requirements of this standard, the organization may use any methods or procedures for data collection, so long as it can demonstrate that its system achieves the objectives of this standard.

In § 438.432(b)(2), we are proposing that the State agency ensure through its contracts with MCOs that each MCO be required to ensure that data received from providers are accurate and complete by verifying the accuracy and timeliness of reported data, screening the data for completeness, logic, and consistency, and by collecting service information in standardized formats to the extent feasible and appropriate. Each organization must have an ongoing process for ensuring the reliability of the data, whether compiled in its own facilities or reported by outside contractors. It must have a system for comparing reported data to a sample of medical records to verify the accuracy and timeliness of reporting or transmission. It must have mechanisms to ensure that reported data contain all data elements required by the organization's standards. Standard formats are needed to ensure that data elements are reported uniformly by all providers, and that reports from multiple sources are comparable and can be reliably merged.

In § 438.342(b)(3), we are proposing that the State agency through its contracts with MCOs require that each MCO make available all collected data upon request to the State agency and HCFA. The BBA includes significant new requirements for State agencies and for plans. We are cognizant of the immediate need of State agencies and plans to modify and test existing systems to ensure no disruption at the millennium and that this additional burden could jeopardize the success of those efforts. One area in particular is that some State agencies may need to develop or modify systems to meet the requirements in subpart E to establish an information system that will support initial and ongoing operation and review of the State's quality strategy. Similarly, we are aware that plans may be required to develop or modify information systems to meet requirements in their States. We encourage State agencies to remain cognizant of plans' need to modify and test their systems for millennium compliance and the possible and burden that this could create. Specifically, we invite comment on the following areas.

- What type of system changes do State agencies envision necessary for implementation of this proposed rule?
- How long do State agencies envision these system changes to take and what is an estimate of the cost associated with such changes?
- What other systems are likely to be affected by these changes?
- What type of system changes do plans envision necessary in implementing the BBA requirements and this proposed rule?
- Will efforts to achieve millennium compliance affect plans' ability to make any necessary systems changes?

E. Grievance Systems (Subpart F)

Section 4704(a) of the BBA added section 1932(b)(4) to the Act to require MCOs to establish internal grievance procedures ensuring that Medicaid managed care enrollees may challenge denials of coverage of medical assistance or payment for medical assistance under managed care contracts.

In this subpart, we propose regulations that lay out the required elements of this grievance system: describing what constitutes a notice (that is, the first step in the grievance system); how to handle complaints and grievances after they are in the system; how to resolve grievances; and how to notify enrollees of the resolution. We then propose to address grievances that require expedited resolution (that is, describing how special situations must be handled). Next, we propose to require that MCOs clearly and fully inform enrollees of the entire system so that they are aware of it and how to use it. When MCOs inform enrollees, materials should be understandable to enrollees at a fourth to fifth grade reading level, or at another level established by the State agency that adequately reflects the enrollee population. In addition, any materials should be in prevalent languages spoken by the populations in the geographic area in order to facilitate enrollee understanding. Finally, we include proposed requirements relating to record keeping, monitoring, and consequences of noncompliance. We propose to require effective record keeping (while ensuring confidentiality), sensible monitoring of the whole system (to keep it working well), and compliance with this subpart.

This proposed regulation also would explicitly reflect in regulations HCFA's longstanding policy that managed care enrollees are entitled to a hearing in the State fair hearing process provided for under subpart E of part 431, if they are denied benefits by their MCO. These fair hearing regulations have never been amended to reflect the fact that a substantial proportion of Medicaid beneficiaries are enrolled in managed care. We also make clear that the requirement for an internal grievance process does not substitute for a right to a State fair hearing. We are specifically requesting comments on the interaction of the proposed provisions of subpart F, set forth in this proposed rule, which address MCOs' internal grievance systems, and the existing regulations regarding the Medicaid State fair hearing process (in subpart E of part 431). Several issues were raised during the development of this proposed regulation concerning whether the timeframes specified in the current fair hearing regulations are adequate for managed care, specifically for the timely consideration of prior approvals and for grievances that involve access to services. We especially invite public comment on the following issues:

- The adequacy of the length of time specified in the current fair hearing regulation for review of MCO denials of services, particularly in circumstances warranting expedited action;
- The need to classify and differentially process at the fair hearing level different types of denials such as pre-service denials, service denials involving continuation of benefits, and denials of payment for services that have already been received;
- The inclusion an expedited appeals process as well as of a medical exigency standard consistent with the M+C regulations in § 422.590;
- Addressing grievances arising from primary care case manager services (particularly denial of prior approval) in the State fair hearing regulation; and
- Automatic referral of some or all kinds of MCO denials to the fair hearing process.

Based on comments we receive on these issues, we may revise the fair hearing regulation as it pertains to managed care in the final regulation.

We considered several sources in developing this proposed regulation including: Negotiating the New Health System, a nationwide study of Medicaid Managed Care Contracts developed by the Center for Health Policy Research at the George Washington University Medical Center, which reviewed and analyzed 54 separate Medicaid managed care contracts; the current 1915(b) and 1115 waiver programs, specifically the State experiences of Iowa, Kansas, Kentucky, Minnesota, Missouri, Nebraska, North Carolina, Ohio, Pennsylvania, and Tennessee; the Quality Improvement System for Managed Care (QISMC); the Consumer Bill of Rights; the Medicare+Choice regulations; and comments received at public forums from members of the American Public Human Services Association (APHSA) and beneficiary advocates.

1. Statutory Basis and Definitions (§ 438.400)

In § 438.400(a), we set forth the statutory basis for the regulations in subpart F. In addition to section 1932(b)(4) of the Act, which requires MCOs to have an internal grievance system, these regulations are also based on section 1902(a)(4) of the Act, which authorizes HCFA to provide for necessary and proper methods of administration, and section 1902(a)(3) of the Act, which requires that Medicaid beneficiaries have the right to a fair hearing when denied Medicaid benefits.

Terms used in the proposed regulations in this subpart are defined in § 438.400(b). We acknowledge that terminology used in describing grievance and appeal processes differs greatly from State to State and program to program. We believe, however, that it is necessary to define such terms as ''complaint'' and ''grievance'' that are critical to the grievance system to ensure a basic level of consistency in State and MCO practice and beneficiary protection.

In developing definitions for ''compliant'' and ''grievance'', we consulted with beneficiary advocacy groups and reviewed definitions and concepts used by State agencies, as well as those reflected in the CBRR, various model grievance acts and other sources. We were interested in reflecting that, from the beneficiary's perspective, many disputes that are ultimately appealed arise in the context of broader expressions of confusion or dissatisfaction. This approach underlies the process and consumer assistance requirements of this subpart.

We therefore elected to define ''complaint'' as broadly as possible, as any oral or written communication, made by or on behalf of an enrollee expressing dissatisfaction with any aspect of an MCO's or provider's operations, activities or behavior, regardless of whether remedial action is sought. We defined ''grievances'' as written communications explicitly addressing dissatisfaction with the following: the availability, delivery, or quality; payment, treatment, or reimbursement of claims for services; or issues unresolved through the complaint process. Our proposed definition of grievance is consistent with the definition used by the National Association of Insurance Commissioners (NAIC) in its 1996 version of the ''Model Grievance Act'', which we believe is among the most comprehensive and widely-used definitions of the term.

As discussed further under § 438.402, each MCO must provide for a grievance system that consists of a complaint process, a grievance process and a link to the fair hearing process. The complaint process would address those communications that are not grievances. Examples of topics that would likely be addressed as complaints in this process would include such issues as waiting times, operating hours, demeanor of health care personnel and the adequacy of facilities. We believe this use of complaints is consistent with the use of the term in most State Medicaid programs. (It should be noted, however, that Medicare and Medicaid use different terms for similar concepts. Under the M+C reguation (like earlier Medicare HMO regulations), this grievance definition most closely resembles Medicare's definition of a ''reconsideration request.''

In addition to the terms we defined in the proposed rule, many terms are being used in practice; however, we chose not to include them in the proposed rule either because we did not consider them part of the grievance system or we believed inclusion would cause confusion. For example, the term ''inquiry,'' as defined by the State of Missouri, means a request from a member to MCO consumer relations departments for information that would clarify health plan policy, benefits, procedures, or any aspect of health plan function that may be in question. Although inquiries are not part of the formal grievance system, we believe that MCOs ought to thoroughly explore inquiries in order to address misunderstandings as soon as they arise. We are interested in learning of State and MCO best practices to address issues associated with enrollee inquiries. (For example, we are interested in receiving information concerning MCO policies and procedures to log and track inquiries and to identify inquiry patterns, so as to minimize the possibility of complaints being treated as inquiries.)

2. General Requirements (§ 438.402)

The proposed rule would provide for a grievance system consisting of multiple avenues of recourse available

for enrollees in Medicaid managed care to resolve issues arising from their membership in an MCO. At a minimum, the grievance system includes the enrollee's initial contact with a designated office within the MCO (as described in § 438.406) to inquire about the MCO's policies and procedures; two tracks for MCO review (the complaint process and grievance process); and access to the State fair hearing system. The MCO has to allow the enrollee a reasonable time from the date that notice of intended action is mailed (at least the 90 days permitted for beneficiaries in the fair hearing process at § 431.221) to file a grievance. Note that the timeframe may be shorter if the beneficiary wishes to continue to receive services while resolution of the grievance is pending (see discussion of § 438.420.)

Under proposed § 438.402(b)(2) and (3), both the complaint and grievance processes must be approved by the State agency and the MCO's governing body. Proposed § 438.402(b)(3) and (4) would require that the MCO's governing body be responsible for effective operation of these processes and that it review and resolve the complaints and grievances, unless it delegates this responsibility to a grievance committee.

We believe that the grievance process is a more formal stage in the overall system than the complaint process because it is also used to resolve issues relating to quality of care; and therefore its requirements are more extensive than those for the complaint process. For example, a complaint may involve an enrollee's dissatisfaction with the rudeness of the physician's office staff. On the other hand, a grievance could address a restricted number of therapy visits or denials of a particular type of specialist referral. The grievance process must be available for disputes between the MCO and the enrollee concerning the following: denials, reductions, or terminations of services; dissatisfaction with providers; appropriateness of services furnished; availability of services; the inability to obtain culturally and linguistically appropriate care; or disputes concerning disenrollment.

In order to ensure that matters related to the timely acquisition of needed services are resolved as expeditiously as the enrollee's health requires, under proposed § 438.402(c), the grievance process is required to include clearly explained steps, time limits for intermediary steps established by the State agency, and, as discussed more fully below, resolution of grievances within timeframes consistent with those established by Medicare (as described in §§ 438.406 through 438.410). In any event, resolution of all issues must be made by a certain date that would allow the State agency to proceed with a fair hearing, if applicable, and ensure a final decision within 90 days of the initial grievance. As noted earlier, we are seeking comment on whether and how to extend the requirement for attention to the medical exigency of the appeal to the fair hearings process.

The grievance process under proposed § 438.402(c)(3) would require that an in-person hearing be provided at the option of the enrollee. In addition, proposed § 438.402(c)(4) would require that final grievance decisions wholly or partially adverse to the beneficiary must be forwarded to the State agency for review and monitoring. We considered but rejected requiring that adverse MCO decisions automatically proceed to the fair hearing process. Such a policy would have required no further beneficiary involvement to obtain a fair hearing and would have further ensured the State agency's ability to resolve grievances within 90 days of the initial filing of the grievance.

Automatic filing for a State fair hearing would also have been consistent with Medicare's requirement that M+C organizations automatically forward to HCFA's external review entity the appeal case file of any reconsideration that is not fully favorable to the enrollee. We decided to deviate from Medicare on this point because we are sensitive to the burden on State fair hearing systems that such a requirement would impose. We seek comments on this policy. While we are not requiring that grievances automatically proceed to a fair hearing, we are setting the timeframes for forwarding the decision and all supporting documentation to the State agency under proposed § 438.402(c)(4) to be no greater than these in Medicare, that is, these must be forwarded as expeditiously as the medical condition of the enrollee dictates or within 30 days of the beneficiary's filing a standard grievance (or the date of the extension's expiration) or 24 hours after an expedited decision.

Finally, proposed § 438.402(c)(5) would reflect our current longstanding policy that an MCO's internal grievance process is not a substitute for the State fair hearing system. The State system is an additional avenue of recourse for Medicaid managed care enrollees. Under proposed § 438.402(c)(6), State agencies would be required to define a process that either permits individuals to pursue grievances simultaneously through State fair hearing and MCO grievance systems, or alternatively, to provide that individuals will be entitled to a fair hearing only after they have exhausted administrative consideration by their MCO. The intent of this proposed regulation is that if the State agency requires the beneficiary to use the MCO grievance process prior to accessing the State fair hearing system then such an ''exhaustion requirement'' would be an attribute of the State design of the grievance system as it applies to all MCOs and would not vary for each MCO.

As noted in a policy letter sent to State Medicaid Directors on February 20, 1998, providers do not have an independent right under Federal law to challenge MCO coverage decisions, but may bring a challenge on behalf of an enrollee, with that enrollee's consent. However, this proposed regulation would not prohibit a State agency from granting providers with such an independent right to challenge MCO decisions. For further information, please refer to the State Medicaid Director Letter dated February 20, 1998.

3. Notice of Intended Action (§ 438.404)

We are proposing that the notice MCOs 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 will take action such as denying payment or denying, limiting, reducing, delaying, or terminating a service through a service authorization decision. The notice should, therefore, be easy-to-read and understand.

In these proposed regulations, Medicaid is requiring the State agency to establish service authorization procedures that, at a minimum, comply with Medicare timeframes for organizational determinations. Medicare requires M+C Organizations to make organizational determinations in a case requiring standard resolution as expeditiously as the enrollee's health condition requires but no later than 14 calendar days after the request for services, with the possibility of an extension of up to 14 additional days if (1) the enrollee requests the extension; or (2) the M+C Organization justifies (upon request, to the State Medicaid agency) a need for additional information, and why the delay is in the interest of the enrollee. Medicare also requires M+C organizations to make expedited organizational determinations in circumstances that could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function, as expeditiously as the enrollee's health condition requires but no later than 72

hours after the request, with the possibility of an extension of up to 14 additional days if (1) the enrollee requests the extension or; (2) the M+C Organization justifies a need for additional information, and why the delay is in the interest of the enrollee. We do not propose that MCOs be required to submit written justifications of grievance timeframe extensions prior to exercising these extensions.

Although not mentioned under the definition of service authorizations in § 438.310(d), we would like to clarify that timeframes for a notice of intended MCO payment denials should, at a minimum, follow the standard timeframes outlined in § 438.310(e). We chose that timeframe because payment denials will occur after care has already been delivered to the member and not involve circumstances jeopardizing the life or health of the enrollee or the enrollee's ability to regain maximum function.

The notice would be required to include 10 elements that are listed in proposed § 438.404, and would clearly explain how to access the grievance system.

The 10 elements that would be required in a notice under § 438.404 are the following:

- The action the MCO intends to take;
- The reasons for the intended action or the delay;
- Any laws and rules that support the action;
- The enrollee's right to file a complaint or grievance with the MCO and to request a State fair hearing;
- The circumstances under which expedited grievance review is available and how to request it;
- How to file complaints, grievances and State fair hearing requests;
- That if the enrollee files a grievance, he or she has a right to appear in person before the MCO personnel assigned to resolve the grievance;
- The circumstances under which benefits will continue pending resolution of the grievance or issuance of a State fair hearing decision;
- How to contact the designated office described in § 438.406(a); and
- How to obtain copies of the enrollee's records, not limited to medical records.

The reasons for the intended action should be written in plain English and clearly identify whether the reason for denial is based on medical reasons or insurance coverage.

It is important to note that, while this section specifies MCO requirements for complaint and grievance notices to enrollees, it does not diminish or eliminate State requirements for fair hearing notices to Medicaid beneficiaries as delineated in part 431, subpart E. Each State agency may delegate its responsibilities for fair hearing notices to the MCO, and each State agency must determine how State fair hearing and MCO complaint and grievance notices are given to beneficiaries. A single combined notice may, at the option of the State agency, be used for both purposes if such notice meets both the requirements under part 431, subpart E and in this proposed rule.

We considered, but rejected, the proposal of some advocates that notices should also include an explanation of the availability of free legal services. At this time we have not provided for such notification in this regulation. We invite comment on this issue.

4. Handling of Complaints and Grievances (§ 438.406)

We propose in § 438.406(a) that each MCO be required to establish and maintain a designated office that is adequately staffed and that serves as the central point of contact for enrollee issues, including complaints. Such an office could be generally available to all plan enrollees, but its availability to Medicaid enrollees would have to be made clear. This office would function as an initial step in the grievance system, where staff can receive inquiries from enrollees or their representatives by telephone or in person. Ideally such contracts would result in many complaints being resolved satisfactorily on an informal basis. Although these consumer relations activities operate through verbal communication, MCO staff would be required under § 438.406(b) to acknowledge receipt of each complaint or grievance, and, as discussed below, under proposed § 438.416, to document the communication and maintain adequate records of all communications. As discussed below, we propose in § 438.416 that if the MCO does not use a separate log for Medicaid recipients, the general log should distinguish Medicaid enrollees from other MCO enrollees. This information would be required to be available and regularly reported in aggregate form to the State agency, as described in § 438.416.

With regard to grievances, we considered, but did not include, a requirement that all grievances be filed first with the State agency, as is required by the State of Tennessee. We are concerned that the central log-in system used by that State agency would not necessarily work well in other States. Associated administrative costs and the need for a well-developed infrastructure to support such a system could be unduly burdensome for many States. Therefore, we decided not to include a similar system in this proposed rule. Furthermore, we believe that other parts of this proposed rule will result in many of the same benefits promised by advocates of the approach used by Tennessee. For example, advocates have noted that a central log-in system would enhance the program's ability to use complaint information in quality monitoring. We believe the quality strategies that State agencies will establish under to part 438, subpart E of this proposed rule will serve the same purpose. Beneficiary advocates have suggested that MCOs or State agencies should establish ombuds programs to assist beneficiaries through the grievance process. After careful consideration, we have decided not to include this requirement; however, we support their creation and encourage State agencies and MCOs to work together to establish such programs, if they believe they are desirable for that particular State. We believe that each State agency should establish its own approach to how enrollees obtain assistance for the full grievance process including the State fair hearing process. In proposed § 438.406(c), we would require only that the MCOs provide assistance in completing forms or take other steps to obtain resolution of the complaint or grievance within the MCO. More general assistance could be part of a more comprehensive ombuds program.

Another important aspect of proposed § 438.406(d) is the requirement that the MCO conduct the grievance process using persons not involved in any previous level of review or decision making and that reviews of denials based on a lack of medical necessity be performed by physicians with appropriate clinical expertise. The reviewer(s) in each step of the process would have to be impartial. Both of these requirements are consistent with those imposed under the M+C program. Medicare requires that any reconsideration that relates to a determination to deny coverage based on a lack of medical necessity must be made only by a physician with an expertise in the field of medicine that is appropriate for the services at issue (§ 422.590(g)(2)).

Proposed § 438.406(e) provides that all complaints and grievances must be resolved within the timeframes specified in § 438.408.

5. Grievance Resolution and Notification (§ 438.408)

In proposed § 438.408(a), we would require that an MCO investigate grievances; resolve the grievances within specified timeframes; base its decision on the case record, including a hearing; and give parties written notice of the decision within specified timeframes. As noted above, the timeframes within which grievances must be resolved (and notices of the decision must be sent) are based on those that apply to Medicare managed care contractors under the new Medicare+Choice regulations, as discussed in § 422.590.

Specifically, in the case of a grievance not requiring expedited resolution, the grievance must be resolved, and notice to the enrollee must be provided in writing, as expeditiously as the enrollee's health condition requires, but no later than 30 days after receipt of the beneficiary grievance. The MCO may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an MCO's decision to deny). As noted above, with respect to authorization timeframe extensions (§ 438.310), we are not proposing that MCOs be required to submit written justification grievance timeframe extensions before to exercising those extensions. Instead we propose that justifications for extensions would only be required to be submitted to the State agency upon request during retrospective reviews.

In the case of a grievance that is required to be expedited under proposed § 438.410 (discussed below), grievances must be resolved, and notice provided, as expeditiously as the enrollee's health condition requires but no later than 72 hours after receipt of the grievance. Again, this timeframe may be extended by up to 14 days for the reasons set forth above.

The decision to require a Medicaid MCO to notify a Medicaid enrollee of a complaint or grievance decision that is adverse to the enrollee prior to an external hearing is not consistent with Medicare policy. In the M+C appeal process, the M+C organization only issues a written decision if it is fully favorable to the enrollee (that is, constitutes complete reversal of the earlier decision to deny service or payment). If the M+C organization does not completely reverse the earlier decision, it automatically forwards the appeal case file with a written explanation to the external reviewer, which makes the final decision.

To address a recommendation by the CBRR that an independent external system be made available to review an adverse decision made by the MCO to deny, reduce, or terminate coverage or deny payment for services, we have clarified the interaction of the State fair hearing process and the MCO grievance system by making conforming changes to part 431, subpart E. That subpart now expressly provides for a fair hearing under the situations described in part 438, subpart F. Specifically, language was added to clarify that members of Medicaid MCOs are eligible to appeal adverse decisions through the State fair hearing regulations. We believe that this policy ensures MCO enrollees the type of independent external review recommended by the CBRR. As stated earlier, we are interested in receiving comments about the fair hearing process as it applies to managed care.

We considered requiring MCOs to automatically resolve in the enrollee's favor any dispute that it did not resolve within a defined timeframe. Beneficiary advocates supported such a requirement; however, we believed it was inappropriate for this proposed rule. As with other aspects of the grievance process, we invite comments on this issue.

In § 438.308(b), we specify the content of the notice that would have to be provided to enrollees (or, if adverse, forwarded to the State agency). This notice would have to include the following information:

- The name of the staff person who resolved the grievance;
- The results of the grievance process and the date it was completed;
- A summary of the steps taken on behalf of the enrollee to resolve the issue;
- A clear explanation of the right to a State fair hearing, if the enrollee is dissatisfied with the decision, and how to timely file for a fair hearing;
- If a grievance decision is wholly or partly adverse to the enrollee, the notice must also explain the circumstances under which—

—Benefits will continue if he or she files the fair hearing request timely; and

—The enrollee may be required to pay the cost of any services furnished during the pendency of the appeal, if the final decision is adverse.

6. Expedited Resolution of Grievances (§ 438.410)

Under proposed § 438.410, MCOs would be required to implement an expedited grievance resolution process for issues requiring immediate resolution. Some States, such as Tennessee and Minnesota, have recognized the need to establish an expedited hearing process for cases involving urgently needed care. For example, if the complaint involves a dispute about an urgently needed service in Minnesota, the plan uses an expedited process appropriate to the particular situation and notifies the Commissioner of Health within 2 business days from the date the complaint was registered. This practice has reduced the number of appeals that become stalled at the MCO level, potentially placing an enrollee's health in jeopardy. The CBRR and beneficiary advocates have both recommended the adoption of this provision.

Under proposed § 438.410, beneficiaries would now have a choice to request either standard or expedited resolution of their grievances. Any oral request made by a beneficiary or a provider must be followed up within 24 hours in writing. If the beneficiary or their provider believes that taking the time for a standard non-expedited resolution could seriously jeopardize the enrollee's life, health, or ability to regain maximum function, the beneficiary and provider would be allowed to request a more expedited resolution process. If a beneficiary makes the request without the support of a physician, the MCO would decide whether the standard for expedited review is met. If a physician makes the request, or supports a beneficiary request, and attests that the standard for expedition is met, the MCO would be required to expedite the grievance. If the MCO decides not to expedite a beneficiary's request for grievance, the MCO would be required to automatically transfer a request to the standard timeframe and make the determination within the 30-day timeframe and give the enrollee prompt oral notice of the denial and follow up, within 2 working days, with a written letter meeting the requirements in § 438.410(f)(2).

Requiring an expedited grievance resolution process is consistent with the requirements that apply under the M+C program. In the case of expedited reconsiderations, an M+C organization must issue the determination no later than 72 hours after it receives the request for expedited reconsideration, with the possibility of up to a 14-day extension for certain circumstances (for example, the organization justifies a need for additional information and how the delay is in the interest of the enrollee). Also, in Medicare, the request

for an expedited decision may be made by any physician, not just a physician participating in the M+C program or the particular M+C plan. The Medicaid expedited grievance resolution provision was written using the same timeframes and physician criteria as the Medicare expedited reconsideration process.

As has been previously mentioned, in Medicare, if the reconsidered decision is not entirely favorable to the enrollee, the decision is automatically subject to further review by an independent review entity contracted by HCFA. In instances involving expedited requests, the M+C organization must forward its decision to the independent entity as expeditiously as the enrollee's health condition requires, but not later than within 24 hours of its affirmation of the adverse organization determination. We have retained this timeframe for forwarding documentation from the MCO to the State agencies.

There is one significant difference between the timeframes used by the external review entity for the expedited grievance resolution process in the M+C program and the Medicaid managed care program. In Medicare, an expedited decision subject to further review by the independent entity must be decided within the same timeframes that M+C organizations resolve expedited grievances (within 72 hours or the date of the extension's expiration). Conversely, in Medicaid, the State fair hearing process does not specifically recognize expedited decisions but requires resolution within 90 days of the beneficiary request, a much longer time period than that required of M+C organizations. We invite comment on the question of whether this 90 day timeframe should be shortened.

7. Information about the Grievance System (§ 438.414)

Under proposed § 438.10(d)(1)(i) and (e)(10), enrollees would receive easy-to-read information about how to access the grievance process, including both the MCO complaint and grievance processes and the State fair hearings, at the time they enroll. Proposed § 438.10(d)(1)(ii) would require that the same information be provided to potential enrollees upon request. Under proposed § 438.404, information on grievances would also have to be provided whenever a service requested by a health care provider, enrollee, or enrollee representative is denied or before an ongoing course of treatment is reduced or terminated. Under proposed paragraph (a)(3) of § 438.414, this information would have to be provided to all providers, at the time of subcontracting with the MCO.

While the MCO would be required to notify all enrollees of the grievance process in writing, it may also notify enrollees of the grievance process orally (for example, for disabled or illiterate people, where necessary). All written and oral information about the complaint process must be available in a format that beneficiaries can understand. Iowa and Missouri and some other States specify use of standard MCO handbook language in their contracts with MCOs. In California, enrollees receive descriptions of the process in handbooks and annual notices; additionally, whenever a plan denies services requested by a health care provider, a notice must be given to the enrollee and the enrollee's representative on a standardized form and must explain the right to representation and the right to use the plan's grievance process before or at the same time the beneficiary is pursuing a State fair hearing.

In proposed § 483.414(b), we specify the content of the information on grievances and appeals that would have to be provided. Specifically, we propose to require that the following information be provided as specified in § 438.10 and § 438.414(a)(3):

(1) Specification of what constitutes grounds for a complaint, grievance, or State fair hearing request;

(2) An explanation of how to file complaints, grievances and State fair hearing requests, and the timeframes for doing so;

(3) An explanation of the availability of assistance with the grievance process and State fair hearings;

(4) Toll-free numbers for the MCO that the enrollee can use to register a complaint or complete a grievance form by telephone (the toll-free numbers must have adequate TTY and interpreter capability);

(5) The specific titles and telephone numbers of the persons in the MCO who have responsibility for the proper functioning of the grievance process and the authority to require corrective action;

(6) Assurance that filing a grievance or requesting a State fair hearing will not negatively affect or impact the way the MCO and its providers, or the State agency treat the enrollee;

(7) Information on procedures for obtaining care or services during the grievance and fair hearing processes as specified in § 438.420.

In § 483.414(c), we propose that MCOs provide enrollees with aggregate or summary information, derived from the information collected under § 438.416(e). This information may be publicly disclosed by the State agency in consumer information materials; however, such disclosure must maintain the confidentiality of enrollees.

8. Record Keeping and Reporting Requirements (§ 438.416)

We propose to require under § 438.416(a) and (b) that MCOs maintain a log of all complaints and grievances and their resolution, and track each grievance through its final resolution. At a minimum, the MCO must have a system for monitoring its progress in reviewing and resolving each grievance, to ensure that each step is completed within the timeframe specified in the MCO's grievance processes. The tracking should include a log maintained for all complaints and grievances containing sufficient information to identify the grievant, date of receipt, nature of the grievance, and the date the grievance is resolved.

Under proposed § 438.416(c), MCOs would be required to record any disenrollment, and the reason for the disenrollment, even if it occurs before the grievance process is completed. We believe that State agencies, as part of their overall monitoring of MCOs, monitor the completeness of the reporting of MCO data on disenrollments. Proposed § 438.416(d) would require that records of complaints, grievances (including their resolution) and disenrollments, for 3 years, in a central location accessible to the State agency. If any litigation, claim negotiation, audit, or other action involving the documents or records has been started before the expiration of the 3-year period, the MCO should retain the records until completion of the action and resolution of issues that arise from it or until the end of the regular 3-year period, whichever is later. See also 45 CFR part 92.

Under proposed § 438.416(e), the MCO must also maintain, aggregate and analyze information on the nature of issues raised by enrollees and on their resolution, including inquiries, disenrollments, complaints, grievances, and fair hearings. Under part 438 subpart E, this information must be used to develop activities under the organization's Quality Assessment and Performance Improvement (QAPI) program, both to improve the issue resolution process itself and to make improvements that address other system issues raised in the process. Improvement goals and corrective action plans must be established as necessary.

Our goal in requiring this information is to establish a standard of accountability, consistent with the MCO's own activities, that will permit the State agency, and if needed HCFA, to assure that enrollee disputes are resolved in a fair, complete, and timely manner. We recognize that not all Medicaid providers and MCOs are alike, and welcome comments on how best to meet our goal without presuming that ''one size fits all.''

9. Continuation of Benefits Pending Grievance Resolution or State Fair Hearing Decision (§ 438.420)

In § 438.420, we are proposing that when the dispute involves the termination or reduction of a service currently being provided, the MCO must continue the enrollee's benefits until issuance of the final grievance decision or State fair hearing decision, if all of the following occur: (1) the initial grievance (standard or expedited) or the State fair hearing request is filed in a timely manner, (2) the enrollee requests continuation of the services, and (3) the services were ordered by an authorized MCO physician. Although we allow for State agency flexibility in defining timely filing timeframes, this continuation of benefits requirement should, at a minimum, meet the requirements outlined in the current State fair hearing process at §§ 431.230 and 431.231 (that is, at a minimum, meet the 5- or 10-day timeframes). We seek comments on the appropriateness of these timeframes for managed care services.

This provision only applies when the MCO physician initially authorized the services (that is, it does 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 a grievance or fair hearing in a timely manner is not sufficient for benefits to be continued). The continuation of benefits provision will 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.

Beneficiaries who have received continuation of benefits while they appeal to the MCO are not obligated to pursue their appeal further through the fair hearing process if the plan denies their appeal unless they so choose. It is important to note, however, that enrollees who lose their appeal at either the plan or 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 mentioned earlier, we had 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.

10. Effectuation of Reversed Grievance Resolutions (§ 438.421)

In § 438.421, we are proposing that if the MCO reverses its grievance resolution, the MCO must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days after the date the MCO receives the request for reconsideration. Furthermore, if the MCO's grievance resolution is reversed under the State fair hearing process, the MCO must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires within timeframes established by the State agency, but no less than 60 calendar days from the date the MCO receives notice reversing the MCO's grievance resolution.

11. Monitoring of the Grievance System (§ 438.422)

In § 438.422, we are proposing that the MCO and State agency use the complaint and grievance logs and annual grievance summary for contract compliance and quality monitoring. The specific contract compliance and quality monitoring should, at a minimum, include the MCO and State agency reviewing the logs and summary for trends in complaints and grievances against a particular provider or in a particular service, and the MCO conducting following up reviews, reporting results of the reviews to the State agency, and taking corrective action when necessary.

Some State agencies do not currently make full use of complaint and grievance data to monitor contracts with MCOs or to improve the functioning of Medicaid managed care. State agencies should review the types of complaints filed with each MCO to determine whether they point to systemic problems and should review MCOs' responses to complaints for both adequacy and timeliness.

12. Consequences of Noncompliance (§ 438.424)

Under section 1932(e)of the Act and § 438.718 of the regulations, discussed below, a contract with an MCO may be terminated if the MCO fails to comply with section 1903(m)(2)(A) or section 1932 of the Act. Proposed § 438.424(a) provides that the State agency may terminate the MCO's contract if it fails to comply with requirements in subpart F.

In addition, under section 1903(m)(2)(A)(xi) of the Act, absent a statutory exemption, Federal financial participation (FFP) in comprehensive risk contracts is conditioned on compliance with applicable requirements in section 1932 of the Act. The regulations in this subpart implement the grievance requirements in section 1932(b)(4) of the Act. Accordingly, compliance with these requirements is a condition for Federal matching, and failure to comply could result in a disallowance. In order to emphasize the importance of the grievance and appeal requirements in subpart F, proposed § 438.424(b) provides that if an MCO fails to comply with the provisions of this subpart, HCFA may deny FFP in payments under the contract.

F. Certifications and Program Integrity Protections (Subpart H)

Section 438.600 of subpart H contains provisions pertaining to plan certification of data, information, and material and general contract provisions.

Sections 1902(a)(4) and (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 to certify the accuracy, completeness, and truthfulness of any data, including but not limited to, enrollment information or encounter data, that may be submitted to determine the basis for payment from a State agency. In addition, MCOs must certify the accuracy and completeness of information provided in contracts, requests for proposals, or other related documents specified by the State agency. We are also requiring that any entity seeking to contract as an MCO must have certain procedures in place designed to guard against fraud and abuse that include provisions for reporting to the State agency, HCFA, and the OIG information of violations of

law by the MCO, subcontractors, or enrollees for a determination as to whether criminal, civil, or administrative action may be appropriate.

G. Sanctions (Subpart I)

Section 1932(e)(1) of the Act requires, as a condition for entering into or renewing contracts under section 1903(m) of the Act, that State agencies have in place intermediate sanctions that the State agency may impose on MCOs if an MCO commits one of six specified offenses discussed below (in the case of an offense involving marketing, the Congress provides for sanctions against primary care case managers as well as MCOs). The Congress also in section 1932(e)(2) of the Act provides specific sanction authority under Federal law (civil money penalties, the appointment of temporary management, disenrollment rights for enrollees, and suspension of enrollment or payment) that State agencies can use to fulfill the sanction obligation in section 1932(e)(1) of the Act. In addition, section 1932(e)(3) of the Act requires that specified sanctions (temporary management and enrollee disenrollment rights) be imposed on MCOs with chronic violations, and section 1932(e)(4) of the Act authorizes State agencies to terminate MCE contracts if they fail to meet the requirements in sections 1932, 1903(m), or 1905(t) of the Act. Finally, certain sanctions (suspension of enrollment or of payment for new enrollees) may be imposed on any MCE for a failure to comply with requirements in section 1932 of the Act generally (or, in the case of an MCO, a failure to comply with section 1903(m) of the Act, as discussed below). This new sanction and termination authority under section 1932(e) of the Act would be implemented in proposed regulations in subpart I.

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, HCFA is provided with authority to impose sanctions when Medicaid-contracting HMOs committed essentially the same offenses as those identified in section 1932(e)(1) of the Act. In light of the fact that Medicaid is a State-run program, HCFA implemented section 1903(m)(5) of the Act in regulations that provided for State agencies to monitor for the HMO (now MCO) offenses in question, make findings on violations, and propose sanctions that would be deemed to be HCFA sanctions if HCFA did not inform the State agency that it disagreed with the State agency recommendations, as discussed in § 434.67. HCFA also retains the right under § 434.67 to directly sanction Medicaid MCOs. Because the Congress left the sanction authority in section 1903(m)(5) of the Act in place, we are proposing to retain the regulation implementing this separate sanction authority, with non-substantive revisions, and recodify it as part of this sanctions subpart as proposed in § 438.730, ''HCFA Sanctions.''

In addition to the opportunity State agencies have had to recommend that HCFA sanctions be imposed under section 1903(m)(5) of the Act and § 434.67 of the regulations, most State agencies already utilize some type of sanction authority of their own, even though previously there was no Federal requirement that State agencies have sanctions established. We consulted extensively with the Medicaid Quality Technical Advisory Group (Q-TAG) to receive their input on the proposed provisions described in this subpart and to gain a better understanding of how State agencies use intermediate sanctions against MCOs.

1. Basis for Imposition of Sanctions (§ 438.700)

Proposed § 438.700(a) sets forth the six MCO offenses that, under section 1932(a)(1)(A) of the Act, must make an MCO subject to sanction. These offenses are as follows:

- A failure to provide medically necessary items and services that are required (under law or contract) to be provided to an enrollee;
- The imposition of premiums or charges in excess of those permitted under title XIX;
- Any act to discriminate among enrollees on the basis of health status or requirements for health care services, including expulsion or refusal to reenroll an individual (except as permitted by title XIX), or engaging in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment with the organization by eligible individuals whose Medical condition or history indicates a need for substantial future medical services;
- A misrepresentation or falsification of information furnished to the following:

—HCFA or the State under title XIX; or

—An enrollee, potential enrollee, or health care provider under title XIX; and

- A failure to comply with the physician incentive requirements under section 1903(m)(2)(A)(x) of the Act.

Proposed § 438.700(b) would implement the last sentence in section 1932(e)(1)(A) of the Act, which provides that a State agency may also sanction a primary care case manager if it determines that it distributed (directly or through an agent) marketing material that was not approved by the State agency or was misleading in violation of section 1932(d)(2)(A)(i)(II) of the Act and proposed § 438.104(b) of the regulations.

2. Types of Intermediate Sanctions (§ 438.702)

Proposed § 438.702(a) sets forth the types of intermediate sanctions that State agencies may impose under Federal law in fulfillment of their obligation under section 1932(e)(1)(A) of the Act (in the case of MCOs) or under their authority in section 1932(e)(1)(A) of the Act (in the case of MCEs). These sanctions are (1) civil money penalties, in amounts specified in § 438.702 (discussed below); (2) the appointment of temporary management of the MCO (this sanction may not be imposed on a primary care case manager); (3) granting enrollees the right to terminate enrollment without cause, and providing notice of such right; (4) suspension or default of all enrollment of individuals in the MCO or MCE; and (5) suspension of payment for new enrollees.

Proposed § 438.702(b) implements the additional authority in sections 1932(e)(2)(D) and (E) if the Act to suspend enrollment, or payment for new enrollees in the case of any MCE that violates section 1903(m) or section 1932 of the Act. Because the requirements in section 1903(m) of the Act apply only to MCEs that are MCOs, and thus could not be ''violated'' by a primary care case manager, we specify in proposed § 438.702(b) that only MCOs can be sanctioned for violating section 1903(m) of the Act.

3. Amounts of Civil Money Penalties (§ 438.704)

In proposed § 438.704, we reflect the civil money penalty amounts that, under section 1932(e)(2)(A) of the Act, can be imposed by State agencies for specified violations. These specified maximum amounts range from $15,000 to $100,000, depending upon the violation. In the case of overcharges to enrollees, the penalty is based on double the amount of the excess charges.

We note that the maximum amounts specified in section 1932(e)(2)(A) of the

Act and proposed § 438.704 only apply to the extent the State agency is relying upon this Federal law as authority for the sanction it is imposing. State agencies remain free to provide for sanctions under State law that may be more severe than those authorized under section 1932(e)(2)(A) of the Act.

4. Special Rules for Temporary Management (§ 438.706)

In proposed § 438.706, we would implement the authority in section 1932(e)(2)(B) of the Act to appoint temporary management of an MCO in the case of continued egregious behavior or threats to enrollee health. In proposed § 438.706(a), we set forth the grounds for such a sanction set forth in section 1932(e)(2)(B) of the Act.

In proposed § 438.708, we implement the requirement in section 1932(e)(3) of the Act that State agencies impose the temporary management sanction in section 1932(e)(2)(B) of the Act, and the enrollee right to disenroll without cause under section 1932(e)(2)(C) of the Act, when the State agency finds that an HMO has repeatedly failed to meet requirements in sections 1903(m) or 1932 of the Act. This provision is designed to protect enrollees from organizations that have a pattern of providing substandard care or continually putting an enrollee's health at risk. After consultation with Q-TAG members, we realize that this provision may be particularly burdensome for State agencies. By using ''repeatedly fails'' language, the Congress left it to HCFA or the State agency to decide how many violations trigger the temporary management requirement. Our intent with this provision is to maintain as much State flexibility as possible. Therefore, we want to be clear that State agencies have the authority to first terminate a contract with an MCO that violates contractual provisions before resorting to temporary management, as long as the cause for termination falls short of the State Plan's threshold (number and severity) of violations agreed upon by the Secretary that would cause temporary management to take effect. We also do not believe that the Congress intended to mandate the imposition of this sanction in the case of minor or technical violations, even if these occur repeatedly. We accordingly provide in § 438.708 that State agencies are only required to impose this sanction in the case of repeated substantial violations of sections 1903(m) or 1932 of the Act. The proposed regulation allows the State agency to temporarily manage MCOs through any administrative means it deems necessary. This means that States may utilize resources beyond what those agencies that have Medicaid jurisdiction traditionally provide. For example, a State could involve, entirely or in part, its Insurance Commission, or even contract with private organizations to assist in temporary management.

5. Notice of Sanction; Due Process (§ 438.710)

Under section 1932(e)(5) of the Act, before imposing the sanctions under section 1932(e)(2) of the Act (other than the temporary appointment of management), the State agency must provide the MCO (or, where applicable, primary care case manager) with notice and such other due process protections as the State agency may provide except that ''a State agency may not provide a pre-termination hearing before imposing the sanction'' of appointing temporary management.

In proposed § 438.710(a), we would require that, except as provided in § 438.710(b), before imposing any sanction in this subpart, the State agency must give the affected MCE ''timely'' written notice that explains the basis and nature of the sanction, and provide other due process protections that the State agency may elect to provide, which must be explained in the notice of intent to sanction. This provision is intended to provide MCEs some level of warning and protection against sanctions imposed by State agencies. Under proposed § 438.710(a)(1), the State agency must provide ''timely'' notice, and this notice must include which intermediate sanction the State agency is going to impose and the State agency's reason(s) for imposition. The State agency may also provide any other due process, as defined by the State agency, as it sees fit. Each State agency will have the flexibility to define ''timely.'' § 438.710(b) would reflect the statutory prohibition on providing a ''pre-termination hearing'' to an MCO prior to imposing the temporary management sanction under § 438.706 or § 438.708. We believe the intent of this provision is to allow State agencies to take swift, corrective action when necessary to protect the health of enrollees.

6. Termination of an MCE Contract (§ 438.718)

Proposed § 438.718 would implement the authority in section 1932(e)(4) of the Act to terminate an MCE contract for failing to comply with its contract, or requirements under sections 1932, 1903(m) (in the case of MCOs), or 1905(t) of the Act (in the case of primary care case managers). We note that section 1932(e)(4) of the Act does not refer to the requirements of ''this section'' (1932), but to ''this part.'' We are interpreting this reference to have been intended to refer to requirements in section 1932 of the Act.

7. Hearing on Contract Termination (§ 438.720)

Proposed § 438.720 would implement the requirement in section 1932(e)(4)(B) of the Act that an MCE receive a right to a hearing before its contract is terminated. In proposed § 438.720(b)(1), we require that State agencies provide written notice of an intent to terminate within 30 days of deciding to terminate, and that this notice provide the reasons for the proposed termination, and the time and place of a hearing. Proposed § 438.720(b)(2) provides that the hearing must be not less than 30 or more than 60 days after the notice, unless the State agency and MCE agree in writing to a different date. The purpose of the timeframe requirements is to allow the MCE appropriate time to prepare for the hearing. In § 438.720(c), we would require that if the proposed termination decision is affirmed following the hearing, the State agency must indicate the date the termination is effective.

8. Disenrollment During Termination Hearing Process (§ 438.722)

Proposed § 438.722 would implement section 1932(e)(4)(C) of the Act, which provides that the State agency may provide individuals enrolled with an MCE that is the subject of a termination hearing that a decision to terminate the MCE's contract is under appeal, and permit such enrollees to disenroll immediately without cause. This authority provides an additional tool for a State agency to use during the contract termination hearing process.

9. Notice to HCFA (§ 438.724)

Under proposed § 438.724(a), the State agency would be required to give notice to the HCFA Regional Office whenever it imposes or lifts a sanction. Proposed § 438.724(b) would require that this notice specify the kind of sanction at issue, and the reason for the State agency's decision to impose or lift it. This provision was added in order that HCFA may be ensured that State agencies and contractors are in compliance with the requirements of section 1932(e) of the Act.

10. Sanction by HCFA (§ 438.730)

We propose to redesignate § 434.67 as § 438.730 with non-substantive revisions and appropriate changes in terminology.

H. Conditions for Federal Financial Participation (Subpart J)

In subpart J, we propose to include both existing and new regulations

pertaining to State eligibility for Federal financial participation (FFP) in payments under managed care contracts. As discussed above, 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. These section 1903(m)(2)(A) of the Act requirements include meeting the definition of MCO, payment on an actuarially sound basis, prior approval by HCFA 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 established under subpart E, the beneficiary protections in subpart C, and the grievance requirements in subpart F. Indeed, 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 in section 1932.

1. Basic Requirements (§ 438.802)

We provide in proposed § 438.802 that FFP is available in expenditures for payments under an MCO contract only for such periods during which the contract meets the requirements of part 438 and is in effect.

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's 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 law or regulations made for monetary increases of the threshold amount in future years.

We propose technical and conforming revisions to § 438.808, which would contain the rules currently found in § 434.80 (redesignated as § 438.802).

3. 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 such entity or provider, nor may the individual have been debarred by any Federal agency or subject to civil penalties under the Act.

In addition, State agencies would, under our proposed rule, be required to submit to HCFA all initial enrollment broker contracts or Memoranda of Agreement (MOA) for approval prior to the effective date of the contract or MOA. Contracts being renewed with the same contractor would not be subject to prior 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 in advance whether an enrollment broker arrangement meets requirements for FFP. We accordingly believe that it is ''necessary and proper'' for the State agency to obtain prior approval of broker arrangements. HCFA will review contracts or MOAs to ensure that they meet the requirements for FFP.

4. Costs under Risk and Nonrisk Contracts (§ 438.812)

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

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

1. Amendments to Part 400

We propose to amend § 400.200 to add explanations of the acronyms ''HIO,'' ''MCE,'' ''MCO,'' and ''PHP.''

2. Amendments to Part 430

We propose to add a new § 430.5, containing definitions that currently appear in part 434 or elsewhere. We propose to include several current definitions unchanged, for example, Federally qualified HMO, clinical laboratory, health insuring organization, and risk contract. We also propose to revise several definitions. We propose to revise the current definition of ''capitation fee'' to refer to ''capitation payment.'' We believe this more accurately reflects the terminology actually used, and eliminates any confusion between capitation payments and ''fee'' for service payments that may arise from the use of the word ''fee.''

We propose to revise the current definition of ''risk comprehensive contract'' to refer more logically to a ''comprehensive risk contract.'' More importantly, we are proposing to revise this definition to separately identify each discrete service that is incorporated in the statutory definition of a contract subject to the requirements in section 1903(m)(2)(A) of the Act. Under section 1903(m)(2)(A) of the Act, a risk contract is subject to the requirements in section 1903(m)(2)(A)of the Act (and is considered a ''comprehensive risk contract'') if it includes inpatient hospital services and any one of several State plan services identified through citations to the statutory subsections providing for coverage of the services, or any three of the identified services. Confusion was created, however, by the fact that in some cases services were clustered together in a single subsection. For example, nursing facility services, EPSDT services, and family planning services were all in one cited subsection. Questions were raised as to whether a contract had to include all the services in a cluster in order for the services to count as an additional service when inpatient hospital services are covered, or as one of three outpatient services that would trigger section 1903(m)(2)(A) of the Act when inpatient hospital services are not provided. Also, when a cluster included three services, questions were raised as to whether covering three services in a single cluster counted as a single service, or as three services for purposes of the three services rule. The current regulation defining comprehensive risk contracts, § 434.21(b), does not do anything to resolve these questions, since it contains the same ''clusters'' of services as the statute. In our proposed revised definition of comprehensive risk contract, with the exception of ''laboratory and x-ray services'' that are

considered together as a single service, the services referenced in section 1903(m)(2)(A) of the Act are all listed separately, and it is clear that offering inpatient hospital services and any one of these nine services, or any three of these nine services, would trigger the definition of ''comprehensive risk contract,'' and (absent a statutory exemption) the requirements in section 1903(m)(2)(A) of the Act.

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.

Finally, we propose to revise the definition of non-risk contract to reflect the fact that under such a contract, the contractor is paid based on costs to the extent they do not exceed the upper payment limit in § 447.362.

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 B.5. above, 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 above, we propose to revise part 434 to remove provisions relating to managed care, which we have moved to part 438 as described above.

5. Revisions to Part 435

a. 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 B.5., 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.

b. 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 agency's option to guarantee up to 6 months of eligibility in two ways: (1) it expands the types of MCOs 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. In the revised § 435.212, we refer to services ''furnished to the beneficiary as an MCE enrollee.'' With respect to 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 which 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 subsection 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(j). 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 agency'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

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

b. 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 such 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 such 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.

IV. Effective Date of the Final Rule

When this regulation is published as a final rule, we intend to make it effective 60 days following publication. Provisions that must be implemented through contracts with MCOs, PHPs, HIOs, or enrollment brokers will be effective with contracts entered into or revised on or after 60 days following the effective date, but no longer than 12 months from the effective date. Of course, many provisions in this proposed rule reflect statutory requirements that are already in effect. HCFA has provided State agencies with guidance on implementing these provisions through a series of letters to State Medicaid Directors. These letters appear on the HCFA Home Page and can be accessed at http://www.hcfa.gov. We invite comment on the proposed implementation timeframe.

V. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the ''DATES'' section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. 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.

A. Section 438.10 Information Requirements

1. Section 438.10 (d), (e), and (f)

a. Requirement. In summary, § 438.10 (d) and (e) state that each State agency, MCE, or enrollment broker, as appropriate, must furnish information to enrollees and potential enrollees, to meet the requirements of this section. The basic information listed in § 438.10(e) of this section must be provided as follows:

- To each enrollee, by the MCO, within a reasonable time after it receives, from the State agency or the enrollment broker, notice of the recipient's enrollment;
- To any potential enrollee that requests it, by the MCO or by the State agency, if the State agency prohibits MCOs from providing it; and
- On an annual basis thereafter, the MCO must notify enrollees of their right to request and obtain this information. The information that must be provided includes the following:

—Kinds of benefits and amount, duration, and scope available under the contract;
—Procedures for obtaining services, including authorization requirements;
—Names and locations of current network providers, including identification of those who are not accepting new patients;
—Any restrictions on the enrollee's freedom of choice among network providers;
—The extent to which enrollees may obtain services from out-of-network providers;
—Provisions for after-hours and emergency coverage;
—Policy on referrals for specialty care and for other services not furnished by the enrollee's primary care provider;
—Cost-sharing, if any;
—Enrollee rights and responsibilities, such as §§ 438.56 and 438.320; and
—Grievance and appeals processes for the enrollee and health care provider, including procedures for obtaining care or services during the appeals process.

In addition, § 438.10(f) requires that information related to MCEs and health care facilities, their licensure, certification, and accreditation status. Information that includes, but is not limited to, education and board certification and recertification of health professionals must be furnished, upon request, to each enrollee, by the MCE, and to each potential enrollee, by the MCE, or by the State agency if the State agency prohibits MCEs from providing it.

b. Burden. We believe the burden placed on State agencies, MCEs, or enrollment brokers as a result of this requirement is the time associated with the 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 MCE to modify existing information materials to conform with the requirement above. We further estimate that there are approximately 568 MCEs, equating to an initial modification burden of approximately 6,800 hours. After the initial modification, we estimate that it will take MCEs approximately 4 hours each to annually update the information materials, equating to an annual total burden of approximately 2,300 hours.

We expect that it will take MCEs or State agencies approximately 5 minutes per enrollee to mail the initial packet, for an estimated 19,400,000 total enrollees. The total burden associated with this requirement is approximately 1,616,700 hours, approximately 2,800 hours per MCE or 33,700 hours per State agency.

We similarly estimate that it annually will take MCEs or State agencies 5 minutes per enrollee to mail

information materials upon request. We estimate that 10 percent of enrollees and potential enrollees will request information annually, equating to approximately 2,075,800 enrollees and potential enrollees. The annual mailing burden associated with this requirement is estimated to be 2,075,800 individuals multiplied by 5 minutes per person, for a total burden of approximately 173,000 hours (approximately 300 hours per MCE or 3,600 hours per State agency).

Finally, we estimate that it will annually take MCEs or State agencies 5 minutes per enrollee to notify enrollees of their right to receive information. Five minutes multiplied by an estimated total enrollee population of 19,400,000 individuals equates to an annual burden of approximately 1,616,700 hours or approximately 2,800 hours per MCE or 33,700 hours per State agency.

2. Section 438.10(g)

a. Requirement. Section 438.10(g) states that before or during enrollment, the State must, directly or through the MCE, provide information to Medicaid enrollees on (1) any benefits to which they may be entitled under the Medicaid program, but which are not covered under the MCE contract, (2) specific instructions on where and how to obtain these benefits, including how transportation is provided and, (3) cost sharing, if any.

b. Burden. The burden associated with this requirement is the time it would take State agencies to collect and mail this information to enrollees. We believe that it will take State agencies approximately 12 hours each to collect and prepare the information materials associated with this requirement, equating to an initial burden of 48 States times 12 hours, or 576 hours. The additional mailing time associated with this requirement is approximately 5 minutes per enrollee, equating to an annual mailing burden of 5 minutes multiplied by 19,400,000 enrollees, or approximately 1,616,700 hours (approximately 33,700 hours per State).

3. Section 438.10(h)

a. Requirement. Section 438.10(h) states that each primary care case manager must, upon request, provide information about the grievance processes available to enrollees and health care providers, including procedures for obtaining services during the appeals process.

b. Burden. The burden associated with this requirement is the amount of time required by primary care case managers to mail the required information to enrollees. We believe that it will take the estimated 60 primary care case managers approximately 5 minutes per enrollee to mail this information. We estimate that there are a total of approximately 4,300,000 primary care case manager enrollees, and that 10 percent of those enrollees will request this information. This equates to an annual burden of 5 minutes multiplied by 430,000 enrollees, or approximately 35,800 hours (approximately 600 hours per primary care case manager).

4. Section 438.10(i)

a. Requirement. In summary, section 438.10(i) states that if a State agency MCO or PHP provides for mandatory MCE enrollment under section 1932(a)(1)(A) of the Act, the State agency must provide information either directly or through the MCE to potential enrollees whenever they request it, and at least once a year in a comparative, chart-like format. The information must include the MCE's service area, the benefits covered under the contract, any cost sharing imposed by the MCE and, to the extent available, quality and performance indicators, including but not limited to disenrollment rates and enrollee satisfaction.

b. Burden. We believe that the additional burden on State agencies (that is, not yet captured in the above provisions) is the length of time associated with creating the comparative chart. We estimate that it will take State agencies approximately 4 hours each to create the comparative chart. We further estimate that approximately 3 State agencies per year will avail themselves of the State Plan Option, for a total annual burden of approximately 12 hours.

B. Section 438.56 Enrollment and Disenrollment: Requirements and Limitations

1. Section 438.56(f)

a. Requirement. Section 438.56(f) states that each enrollee must submit a written request for disenrollment to the State agency and to the MCE.

b. 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. We estimate that it will take approximately 2 minutes per enrollee to generate a disenrollment request. We estimate that approximately 5 percent of MCE enrollees will request that they be disenrolled from an MCE. This equates to an annual burden of approximately 2 minutes multiplied by 1,940,000 affected enrollees, or approximately 32,300 hours.

2. Section 438.56(g)

a. Requirement. Section 438.56(g) requires that in a State where that State agency restricts disenrollment under this section, MCEs must notify enrollees and potential enrollees of their disenrollment rights at least 60 days before the start of each enrollment period and at least once a year.

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

C. 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 MCO to cover, furnish, or pay for a particular counseling or referral service if the MCO objects to the provision of that service on moral or religious grounds; and makes written information on these policies available to (1) the State agency, with its application for a Medicaid contract, prospective enrollees, before and during enrollment, and (2) current enrollees, within 90 days after adopting the policy with respect to any particular service.

2. Burden

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

D. Section 438.110 Assurances of Adequate Capacity and Services

1. Sections 438.110(b) and (c)

a. Requirement. Sections 438.110(b) and (c) state that each MCO must give the State agency and HCFA assurances that it has the capacity to serve the expected enrollment in its service area in accordance with subpart E of this part. Each MCO must submit documentation to demonstrate that it (1) offers an appropriate range of services, in accordance with subpart E of this part, including access to preventive services, primary care services, and specialty services 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 and; (3) meets the availability of services requirements in § 438.306 of this part. Each MCO must submit the

documentation described in § 438.110(b) at least every 2 years, and, specifically (1) at the time it enters into or renews a contract with the State and (2) at any time the State agency determines there has been a significant change in the MCO's delivery network or enrollee population.

b. Burden. While these information collection requirements are subject to the Act, we believe that MCOs and PHPs already collect and provide this information to State agencies as part of their customary and usual business practices. Therefore, in accordance with 5 CFR 1320.3(b)(2), the burden associated with these information collection requirements is exempt 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.

The only additional burden on MCOs and PHPs is the length of time required for MCOs and PHPs to compile this information in the format specified by the State agency, and the length of time for the MCOs and PHPs to mail the information to the State and HCFA. We estimate that it will take each MCO and PHP approximately 20 hours to compile the information necessary to meet this requirement, for a total burden of 20 hours multiplied by 502 MCOs and PHPs, or approximately 10,000 hours. In addition, we estimate that it will take MCOs and PHPs approximately 5 minutes each to mail the materials associated with this requirement to States, for an annual burden of approximately 5 minutes multiplied by 502 MCOs and PHPs, or approximately 42 hours.

2. Section 438.110(d)

a. Requirement. Section 438.110(d) states that in addition, after the State agency reviews the documentation, and after the MCO makes any changes required as a result of that review, the MCO must submit to HCFA assurances that include copies of the documentation reviewed by the State agency and the State's certification that the MCO has complied with the State's requirements for access to services, as set forth in the availability of services requirements in § 438.306 of this part.

b. Burden. While these information collection requirements are subject to the Act, we believe that State agencies already assess whether MCOs or PHPs have adequate capacity and services to serve the State's Medicaid population. Therefore, in accordance with 5 CFR 1320.3(b)(2), the burden associated with these information collection requirements is exempt 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.

We believe that the only additional burden on State agencies is the length of time associated with preparing and mailing the certification forms that are required as part of this regulation. We estimate that it will take State agencies approximately 30 minutes per MCO/PHP to create and mail the certification letters. Thus, the annual burden associated with this activity is estimated to be 30 minutes multiplied by 502 MCOs and PHPs, for a total burden of approximately 251 hours.

MCOs and PHPs have an additional burden associated with mailing the documentation and certification letters to HCFA. We estimate this activity to take approximately 5 minutes per MCO and PHP, for a total annual burden of 5 minutes multiplied by an estimated number of 502 MCOs and PHPs, or approximately 42 hours.

E. Section 438.114 Emergency and Post-stabilization Services

1. Requirement

Section 438.114(b) states that at the time of enrollment and at least annually thereafter, each MCO 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 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 requirements are subject to the PRA. However, we believe the burden associated with these requirements is captured in the general information requirements in § 438.10.

F. Section 438.318 Enrollee Information

1. Requirement

Section 438.318(b) states that each State agency or its contracted representative must provide the information specified in paragraph (b)(2) of this section, for each contracting MCO throughout the State to any potential enrollee who requests it, and all potential enrollees, when they first become eligible for Medicaid, are considering choice of MCOs under a voluntary program, or are first required to choose an MCO under a mandatory enrollment program, within a time frame that enables them to use the information in choosing among available MCOs.

2. Burden

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

G. Section 438.340 Quality Assessment and Performance Improvement Program

1. Requirement

Section 438.340(d)(10) states that each MCO must report the status and results of each project to the State as requested.

2. Burden

We expect that, in any given year, each MCO will complete two projects, and will have four others underway. We further expect that State agencies will request the status and results of each MCO's projects annually. Accordingly, we estimate that it will take an MCO 5 hours to prepare its report for each project, for an annual total burden of 30 hours per MCO. In aggregate, this burden equates to 30 hours multiplied by an estimated 389 MCOs, or approximately 11,700 hours. We estimate that the maximum burden on PHPs is also 30 hours per PHP, with an aggregate burden of approximately 3,400 hours (5 hours per project times a maximum number of 6 projects multiplied by 113 PHPs).

H. Section 438.342 Health Information Systems

1. Requirement

Section 438.342(b)(3) states that each MCO must make all collected data available to the State agency and to HCFA, as required in this subpart, or upon request.

2. Burden

The following information collection requirements are 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.

I. Section 438.402 General Requirements

1. Requirement

In summary, § 438.402 states that if the MCO makes a standard grievance decision that is wholly or partly adverse to the enrollee, the MCO must submit the decision and all supporting documentation to the State agency as expeditiously as the enrollee's health condition requires but no later than 30 calendar days after it receives the grievance, for further review in the State's fair hearing system.

2. Burden

The following information collection requirements are subject to the PRA. However, we believe the burden associated with these requirements is captured in the general requirements in § 438.410.

J. Section 438.404 Notice of Intended Action

1. Requirement

In summary, § 438.404 states that if an MCO intends to deny, reduce, or terminate a service or deny payment, or does not furnish a service with reasonable promptness, the MCO must give the enrollee timely written notice that meets the requirements set forth § 438.404(a) through (k).

2. Burden

We estimate that the burden associated with this requirement is the length of time it would take an MCO or PHP to provide written notice of an intended action. We estimate that it will take MCOs and PHPs 5 minutes per action to make this notification. We estimate that approximately 5 percent of the approximately 14 million MCO and PHP enrollees will receive one notice of intended action per year from their MCO or PHP (1395 per MCO/PHP). The notification burden associated with this notice is estimated to be 5 minutes per request (115 hours per MCO/PHP), for a total burden of approximately 58,000 hours.

K. Section 438.406 Handling of Complaints and Grievances

1. Requirement

In summary, § 438.406 states that each MCO must acknowledge receipt of each complaint and grievance.

2. Burden

The following information collection requirements are subject to the PRA. However, we believe the burden associated with these requirements is captured in the grievance resolution and notification requirements in § 438.408.

L. Section 438.408 Grievance Resolution and Notification

1. Requirement

In summary, § 438.408 states that an MCO receiving an expedited grievance must make its decision and notify the affected parties (enrollee and the physician as warranted by the patient's medical condition or situation) in writing of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but not later than 72 hours after receiving the request. Similarly, an MCO receiving a standard grievance must make its decision and notify the affected parties (enrollee and the physician) as warranted by the patient's medical condition or situation) in writing of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires but no later than 30 calendar days after it receives the grievance. MCO notice of both expedited and standard grievance decisions must include the requirements specified in § 438.408 (b)(1) through (b)(5).

2. Burden

We estimate that approximately 1 percent of the approximately 14 million MCO and PHP enrollees will file a complaint with their MCO or PHP (279 per MCO/PHP). The notification burden associated with the acknowledgment of each complaint is estimated to be 5 minutes per request (23 hours per MCO/PHP) for a total burden of approximately 11,670 hours. We also estimate that approximately .5 percent of the approximately 14 million MCO and PHP enrollees will file a grievance with their MCO or PHP (139 per MCO/PHP). The estimated notification burden associated with the acknowledgment of each grievance is estimated to be 5 minutes per request (12 hours per MCO/PHP), for a total burden of approximately 5,800 hours.

For these cases, we estimate that the burden on the enrollee filing a complaint or grievance is approximately 20 minutes per case, for a total aggregate burden of 70,000 hours annually. We estimate that the burden on the MCO or PHP is approximately 4 hours per case. This time includes both the information collection activity and the decision making process. The estimated annual burden on MCOs and PHPs equates to approximately 1,700 hours per MCO/PHP, or approximately 280,000 hours in total. Finally, the estimated notification burden on MCOs and PHPs associated with the grievance resolution is 5 minutes per request (12 hours per MCO/PHP) for an aggregate annual burden of approximately 5,800 hours.

M. Section 438.410 Expedited Resolution of Grievances

1. Section 438.410(c)

a. Requirement. Section 438.410(c) states that if the MCO makes an expedited grievance decision that is wholly or partly adverse to the enrollee, the MCO notifies the State agency of each decision and submits records and documentation to support the decision, as expeditiously as the enrollee's health condition requires, but no later than 24 hours after the expedited decision.

This section contains the applicable requirements for submitting and appealing an MCO's or PHPs's adverse grievance decision through the Medicaid State Fair Hearing process. The required procedures generally involve a written request from an enrollee, preparation of a brief, written explanation and case file by the MCO or PHP organization, and notification of the decision by the MCO or PHP.

b. Burden. We estimate that, annually, approximately 30 percent of grievances result in a decision that is adverse to the enrollee, and will undergo review through the State Fair Hearing process (approximately 42 cases per MCO/PHP). For these cases, we estimate an additional burden on the MCO or PHP of approximately 2 hours per case. Thus, the estimated total annual burden on MCOs and PHPs associated with grievances is 84 hours per MCO/PHP, or an aggregate total burden of 42,000 hours (2 hours multiplied by an estimated 21,000 affected enrollees).

2. Section 438.410(f)

a. Requirement. Section 438.410(f) states that if an MCO denies a request for expedited grievance, it must automatically transfer the request to the standard timeframe process and give the enrollee prompt oral notice of the denial and follow up, within 2 working days, with a written letter that meets the requirements specified in 438.410(f)(2)(i) through (f)(2)(iii).

b. Burden. We estimate that, annually, expedited grievance requests will account for fewer than 30 percent of all grievances filed with MCOs and PHPs (42 per MCO/PHP). We further estimate that MCOs and PHPs will deny less than 2 percent of all requests for expedited grievances (1 per MCO/PHP). We estimate that the burden associated with this requirement is the length of time it would take an MCO or PHP to provide

oral and written notice of this denial. We estimate that it will take MCOs and PHPs 5 minutes per oral notice and 5 minutes per written notice to make this notification (that is, a total burden of 10 minutes per MCO/PHP) for a total aggregate annual burden of approximately 70 hours.

N. 438.414 Information about the Grievance System

1. Requirement

Sections 438.414(a) and (b) state that each MCO must provide information about the grievance system, as specified in § 438.10 and this subpart to (1) enrollees; (2) potential enrollees (as permitted by the State agency); and (3) all providers, at the time of subcontracting. The information must explain the grievance system through a State-developed or State-approved description and must include the information set forth in § 438.414 (b)(1) through (b)(6).

In addition, § 438.414(c) states that upon request, the MCO must provide enrollees and potential enrollees with aggregate information, derived from the collected information in § 438.416(e), regarding the nature of enrollee grievances and their resolution.

2. Burden

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

O. Section 438.416 Record Keeping and Reporting Requirements

1. Requirement

Sections 438.416(a), (c), and (d) state that each MCO must maintain (1) a log of all complaints and grievances and their resolution; (2) a record any disenrollment and the reason for it, even if it occurs before the grievance process is completed; and (3) retain the records of complaints, grievances (including their resolution) and disenrollments for 3 years, in a central location, and make them accessible to the State agency.

In addition, § 438.416(e) states that each MCO must, at least once a year, send to the State agency a summary that includes the following information: (1) the number and nature of all complaints and grievances; (2) the timeframes within which they were resolved, and the decisions; (3) a listing of all grievances that have not been resolved to the satisfaction of the affected enrollee, (4) the number and nature of grievances for which the MCO provided expedited resolution, and the decisions; and (5) any trends relating to a particular provider or a particular service.

This section contains the applicable requirements that MCOs and PHPs must follow to record and track complaints and grievances. We estimate that approximately 1 percent of the approximately 14 million MCO and PHP enrollees will file a complaint with their MCO or PHP (279 complaints per MCO/PHP). The recording and tracking burden associated with each complaint is estimated to be 1 minute per request (5 hours per MCO/PHP) for a total aggregate burden of 2,300 hours (1 minute multiplied by an estimated 140,000 enrollees who would file a complaint).

2. Burden

We estimate that approximately .5 percent of the approximately 14 million MCO and PHP enrollees will file a grievance with their MCO or PHP (139 per MCO/PHP). The recording and tracking burden associated with each grievance is estimated to be 1 minute per request (2 hours per MCO/PHP) for a total aggregate burden of 1,200 hours (1 minute multiplied by an estimated 70,000 enrollees who would file a grievance).

This section also contains the applicable requirements that MCOs and PHPs must follow to submit the annual summary of complaints and grievances. Every MCO and PHP (approximately 502 organizations) must submit an annual report. We estimate that the burden on the MCO or PHP for collecting information and preparing this summary will be approximately 4 hours per MCO/PHP or approximately 2,000 hours total. We estimate that the annual burden on each MCO or PHP for mailing the summary will be approximately 5 minutes per MCO/PHP, or approximately 42 hours in aggregate.

P. Section 438.602 Certification of Data That Determine Payment

1. Requirement

When payments from State agencies to MCOs are based on data submitted by the MCO that includes, but is not limited to, enrollment information, encounter data, or other information required by the State, the MCO must, concurrent with the submission of the data attest to such data's accuracy, completeness, and truthfulness as a condition of receiving such payment.

2. Burden

While the requirement for a MCO to attest to the accuracy of enrollment information, encounter data, or other information required by the State agency, is subject to the PRA, the burden associated with this requirement is captured during the submission of such data. Therefore, we are assigning 1 token hour of burden for this requirement.

Q. Section 438.608 Certification of Proposals or Contracts

1. Requirement

MCOs must certify the accuracy, completeness, and truthfulness of information provided in contracts, requests for proposals, or other related documents specified by the State agency.

2. Burden

While the requirement for a MCO to certify the accuracy, completeness, and truthfulness of information provided in contracts, requests for proposals, or other related documents specified by the State agency is subject to the PRA, the burden associated with this requirement is captured during the submission of such information. Therefore, we are assigning one token hour of burden for this requirement.

R. Section 438.710 Notice of Sanction; Due Process

1. Requirement

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

2. Burden

Based on current knowledge of State law prior to the Federal requirements imposed under BBA, State agencies already impose sanctions against MCEs and provide written notice to MCEs explaining the violation and sanction to be imposed. Accordingly, because this activity constitutes a reasonable and customary business practice on the part of State agencies, as defined in 5 CFR 1320.3(b)(2) and (b)(3), we estimate that there is no additional burden as a result of the requirement in § 438.710(a)(1).

S. Section 438.720 Hearing on Contract Termination

1. Requirement

Section 438.720(b)(1) states that within 30 days after reaching the determination to terminate a MCE the State agency must give the MCE written notice of its intent to terminate, the reason for termination, and the time and place of the hearing.

2. Burden

Based on current knowledge of State law, most State agencies have been terminating contracts with MCEs prior to the imposition of the BBA requirements. In addition, State agencies that have been terminating contracts have also given MCEs written notice of their intent to terminate. Therefore, because this activity constitutes a reasonable and customary business practice, as defined in 5 CFR 1320.3(b)(2) and (3), we believe that this provision imposes no additional burden on State agencies as described in § 438.720(b)(1).

T. Section 438.722 Disenrollment During Termination Hearing Process

1. Requirement

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

2. Burden

State agencies have already had the authority to terminate MCE contracts according to State law and have been providing written notice to the MCEs. State agencies are now given, at their discretion, the option of notifying the MCE's enrollees of the State agency's intent to terminate the MCE's contract. While it is not possible to gather an exact figure, we estimate that 12 States agencies may terminate 1 contract per year. We estimate that it will take States 30 minutes to prepare the notice to enrollees, for a total burden of 6 hours. In addition, we estimate that it will take State agencies approximately 5 minutes per beneficiary to notify them of the termination, equating to a burden of 5 minutes multiplied by 12 States multiplied by 34,000 beneficiaries per MCE, for a total burden of approximately 34,000 hours.

U. Section 438.724 Notice to HCFA

1. Requirement

In summary, § 438.724 states that the State agency must give the HCFA Regional Office written notice whenever it imposes or lifts a sanction that specifies the affected MCE, the kind of sanction, and the reason on which imposition or lifting is based. The notice must be provided no later than 30 days after a sanction has been imposed or lifted.

2. Burden

We estimate that this provision will require State agencies 30 minutes to provide this type of notice per sanction imposed or lifted. In addition, we estimate that a total number of 36 State agencies will impose sanctions, with an average number of 1 sanction per State agency. Therefore, we estimate the total annual burden as a result of this requirement to be 18 hours.

V. Section 438.810 Expenditures for Enrollment Broker Services

1. Requirement

Section 438.810(c) requires that a State agency contracting with an enrollment broker must submit the contract or memorandum of agreement MOA) for services performed by the broker to HCFA 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 agency to mail each the contract to HCFA for review. We estimated that the burden associated with this requirement is 5 minutes per enrollment broker contract, for a total annual burden of approximately 3 hours per State agency (5 minutes multiplied by an estimated 35 enrollment broker contracts).

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.

If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following:

Health Care Financing Administration, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850 ATTN: Louis Blank, HCFA–2001–P

and

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

VII. Impact Analysis

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 annually). This rule meets the criteria of being economically significant, as the impact will be over $100 million. This is also a ''major rule'' under 5 U.S.C. 804.

The RFA requires agencies to analyze options for regulatory relief of small entities. The rule implements Medicaid provisions as directed by the BBA of 1997. The statute does not permit significant regulatory alternatives. Thus, we are not able to consider significant alternatives for reducing the burden on small entities. However, we invite interested parties to submit comments suggesting alternative rules that would reduce the burden. For purposes of the RFA, we prepare a regulatory flexibility analysis unless we certify that a rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, non-profit organizations, and governmental agencies. Most hospitals and other providers and suppliers are small entities, either by nonprofit status or by having revenues of $5 million or less annually. Individuals and State agencies are not included in the definition of a small entity.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any proposed 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 50 beds.

We do not anticipate that the provisions in this proposed rule will have a substantial economic impact on most hospitals, including small rural hospitals. The BBA provisions include some new requirements on State agencies and managed care organizations, but not directly on individual hospitals. The impact on individual hospitals will vary according to each hospital's current and future contractual relationships with managed care organizations. Furthermore, the impact will also vary according to each hospital's current procedures and level of compliance with existing law and regulation pertaining to Medicaid managed care. For these reasons, this

proposed rule would not 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 annual expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation). This rule does not impose any mandates on State, local, or tribal governments, or the private sector that will result in an annual expenditure of $100,000,000 or more.

B. Summary of the Proposed Rule

This 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 regulations address pertinent areas of concern between State agencies and MCEs, including enrollment, access to care, provider network adequacy, and grievance procedures for beneficiaries.

Since 1995, enrollment by Medicaid beneficiaries in Medicaid managed care programs has grown over 50 percent to more than 15 million enrollees in 1997. The Medicaid BBA provisions will likely help to maintain this level of managed care, and may contribute to some additional growth in the Medicaid managed care program.

C. Discussion of Impact

We believe that the overall impact of this proposed rule will be beneficial to Medicaid beneficiaries, MCOs, State agencies, and HCFA. Many of the BBA Medicaid managed care requirements merely codify in Federal law standards widely in place in State law or the managed care industry. Some of the BBA provisions represent new requirements for State agencies and MCOs, as well as expanded opportunities for participation in Medicaid managed care.

The BBA provisions addressed in this regulation that may have significant financial impact on State agencies or MCOs include: (1) State options to use managed care; (2) increased beneficiary protections; (3) new quality standards; and (4) improved administration. Initially, some of these provisions may increase administrative costs for State agencies and MCOs. However, quantifying these costs is difficult, given the disparity in State and MCO current status and capabilities relative to meeting these requirements.

Throughout the development of the regulation, we consulted with State agency representatives in order to gain more understanding of potential impacts. At the November, 1997 meeting of the Executive Board of the National Association of State Medicaid Directors (NASMD), we discussed the process for providing initial guidance to State agencies about the Medicaid provisions of BBA. We provided this guidance through issuance of a series of letters to State Medicaid Directors. From October, 1997 through July, 1998, over 40 of these letters were issued. Much of the policy included in this regulation relating to the State plan option provision was included in these letters. In May, 1998, the Executive Committee of NASMD was briefed on the general content of the regulation. More specific State agency 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 HCFA explored with State agencies their preferences regarding policy issues and the feasibility and practicality of implementing policy under consideration. We will also be seeking public comments as part of the Notice of Proposed Rulemaking process.

It is clear that all State agencies will be affected by the Medicaid regulations, but in varying degrees. Much of the burden will be on MCOs contracting with State agencies, but this will also vary by existing and continuing relationships between State agencies and MCOs. Further, because the Medicaid regulations will have direct authority over the State agencies, not the MCOs, the effects on these MCOs are not incorporated within this impact statement. Nonetheless, these regulations are intended to maximize State flexibility and minimize the compliance cost to State agencies and MCOs to the extent possible consistent with the detailed BBA requirements. We believe the proposed rule will result in improved patient care outcomes and satisfaction over the long term.

Recognizing that a large number of entities, such as hospitals, State agencies, and MCOs, will be affected by the implementation of these statutory provisions, and a substantial number of these entities may be required to make changes in their operations, we have prepared the following analysis. The terminology mainly used throughout this analysis is ''MCOs,'' which includes Federally qualified HMOs or public or private entities determined to meet the following conditions: (1) is organized primarily for the purpose of providing health care services; and (2) makes the services it provides to its Medicaid enrollees as accessible as those services are to other Medicaid recipients within the area served by the entity. Since primary care case managers do not fit this definition, the term ''MCEs'' is not used to describe the healthplans or MCOs in the 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.

D. State Options to Use Managed Care

Managed Care Organizations (MCOs)

Under this provision, a State may amend its State plan to require all Medicaid beneficiaries in the State to enroll in either a managed care organization or a primary care case manager, 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, American Indians, and other groups of children with special needs. Federal review would be limited to a one time State Plan Amendment (SPA) approval, while State agencies would no longer need to request waiver renewals every 2 years for section 1915(b) and 5 years for section 1115 waivers. State agencies may include ''exempted'' populations as voluntary enrollees in State plan managed care programs, or to maintain parallel waiver programs to require enrollment of these groups in managed care, States agencies may also choose to continue to use one waiver process for groups that may be included under the State plan option. Currently, only a few State agencies have expressed interest in using SPAs to require beneficiary enrollment in managed care. In short, the new State plan option provides States agencies with a new choice of method to require participation in managed care. We do not anticipate that it alone will influence the prevalence of mandating managed care in Medicaid. MCOs and providers would continue to

provide care in a manner consistent with current and future standards, regardless of SPAs, and, consequently, Medicaid beneficiaries would receive the same level of health care in compliance with current and future standards.

Pursuing the SPA option rather than a section 1915(b) or section 1115 waiver may reduce State administrative procedures because it would eliminate the need for State agencies to go through the waiver renewals. Similarly, we will 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 us would be small in relation to the overall administrative requirements of the Medicaid program.

E. Primary Care Case Management

Prior to the BBA, many State agencies elected to implement a ''primary care case management'' system through a freedom of choice waiver under section 1915(b)(1) of the Act. Under the BBA, State agencies may now require beneficiaries to use a primary care case manager provider under their State plans without the need for a waiver. State agencies will have another avenue to include primary care case management contracts in Medicaid managed care programs. Most State agencies, however, are already participating in ''primary care case management'' programs. Therefore, while the BBA provision provides potential for more ''primary care case management'' programs to come into being, we do not expect expansion of primary care case managers to be substantial due to the State plan option. To the extent that the use of ''primary care case managers'' increases, patients of these providers will benefit from greater continuity of care and patient protections deriving from new and existing standards.

F. Elimination of 75:25 Rule

Prior to the passage of the BBA, nearly all HMOs 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 to participate without verifying that they comply with this requirement, and eliminates the need for State agencies to monitor enrollment composition in contracting MCOs. This will broaden the number of MCOs available to State agencies for contracting, leading to more choice for beneficiaries.

With greater flexibility for State agency and MCO participation in managed care, providers can serve more Medicaid beneficiaries under managed care programs. Medicaid managed care enrollees will have more choice, better access to care, and improved satisfaction.

G. 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 coverage of medical assistance or denials of payment. While these requirements did not previously exist in Federal law, we believe they reflect widespread current practice and, therefore, do not impose significant incremental costs on MCOs or State agencies.

H. Provision of Information

In mandatory managed care programs, we have required that beneficiaries be fully informed of the choices available to them in enrolling with an MCO. 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, 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 and MCOs for several reasons. We do not have State specific data on what information State agencies currently provide, or the manner in which they provide it. Variability among State agencies indicates that implementing or continuing enrollee information requirements will represent different degrees of difficulty and expense.

As a requirement under the provision of information section, State agencies opting to implement mandatory managed care programs under the SPA option are required to provide comparative information on MCOs to potential enrollees. Currently only a few State agencies have expressed interest in using SPAs to require beneficiary enrollment in managed care. However, for State agencies that do select this option, we do not believe that providing the data elements in themselves represents a burden to State agencies choosing the SPA option, as these are elements of information that most State agencies currently provide. The regulation specifies that the information must be presented in a comparative or chart-like form that facilitates comparison between MCOs. 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 utilize chart-like formats. Consequently, enrollees will benefit from improved mechanisms for selecting MCOs. In the short term, only a few State agencies have opted for SPAs, but it is anticipated that more State agencies will participate over the long term. State agencies that participate in the future will benefit from any comparative tools developed by HCFA and State agencies in the short term.

I. Demonstration of Adequate Capacity and Services

BBA requires Medicaid MCOs and Prepaid Health Plans (PHPs) to provide the State agency and the Secretary of HHS with assurances of adequate capacity and services, including service coverage within reasonable timeframes. State agencies currently require assurances of adequate capacity and services as part of their existing contractual arrangements with MCOs. However, we acknowledge that this information has not been routinely provided to HCFA in the past. Further, we have not required MCOs to submit to HCFA a certification from the State agency that the MCO or PHP has demonstrated adequate capacity and services. This regulation requires plans to send HCFA a copy of the certification they obtain from the State agency. Under this rule, each State agency retains its authority to establish standards for adequate capacity and services within MCO contracts. This may be perceived as a burden to MCOs and PHPs, and for State agencies that have not been required to formally certify that an MCO or PHP meets the State's capacity and service requirements; however, it allows MCOs to demonstrate to HCFA that adequate capacity and services standards established by State agencies are being met or exceeded.

Quantifying the additional burden on State agencies, MCOs or PHPs as a result of implementing this regulation is not feasible for several reasons. First, HCFA does not have State-specific data on the types of detailed information States currently require of their contractors (for example, MCOs and PHPs) to ensure

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 ensure adequate capacity and services. This regulation contemplates that State agencies continue to have that flexibility.

Under this regulation, State agencies will determine and specify both the detail and type of documentation to be submitted by the MCO or PHP to ensure 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, State agencies, and us, Medicaid beneficiaries will receive continued protections in access to health care under both State and Federal law.

J. New Quality Standards

The BBA requires that each State agency and MCO or PHP have an ongoing quality assessment and performance improvement program (QAPI) for health care services it provides to its Medicaid enrollees. The QAPI, 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; (2) examination of other aspects of care and service directly related to quality of care, including grievance procedures and marketing; (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 quality program.

The requirements under this regulation provide that each MCO achieve minimum performance levels on standardized quality measures. They also require that plans conduct performance improvement projects that achieve, through ongoing measurement and intervention, demonstrable and sustained improvement in significant aspects of clinical care and non-clinical services that can be expected to affect health outcomes and member satisfaction. This approach to ensuring quality reflects the expansion in recent years of the problem-focused approach that was prevalent in the past to include a focus on systematic quality improvement as well.

We have worked closely with State Technical Advisory Groups (TAGs) in developing the managed care quality regulations and standards. Requirements under this regulation build on a variety of State and our efforts 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 that reduces duplicative 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 monitoring, and Federal oversight. This guidance emphasizes quality standards developed in conjunction with all system participants, such as managed care contractors, State regulators, Medicaid recipients or their representatives, and external review organizations.

We have built on efforts in other sectors in developing these quality assessment and performance improvement 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 Healthcare Accreditational Commission (AHAC), 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 agencies 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.

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

Regarding the new quality standards, we are interested in receiving comments concerning the cost or other impact of these provisions on State agencies and health plans.

K. Administration

1. Certifications and Program Integrity Protections

BBA sections 1902(a)(4) and (19) require that State agencies 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, State agencies, and HCFA.

Section 438.602 addresses the importance of reliable data that is submitted to State agencies. These data include enrollment information, encounter data, or other information that are used for payment determination. For the most part, State agencies reimburse MCOs on a capitated basis, and do not use claims or encounter data as a basis for payment. However, the collection of encounter, provider, and enrollment data will be most useful for State agencies in measuring quality performance and addressing various methodologies of rate setting and risk adjustment. The Medicaid provision of attesting to the validity of data presents an additional step in the process of data submission. MCOs have historically been working closely with State agencies when reporting Medicaid data to affirm that the data are accurate and complete. Submitting a certification of validity could take place in a variety of ways and will represent a varying degree of burden for health plans.

Section 438.606 requires MCOs to have effective operational capabilities to guard against fraud and abuse. This will result in reporting violations of law by

MCOs to the State agency. Providers and health plans have traditionally ensured compliance with Federal and State laws when providing and delivering health care to members. An example is compliance with National Association of Insurance Commissioners (NAIC) standards. However, additional resources and procedures will be necessary to have a systematic process for documenting violations and formally notifying the State agency of such instances.

The requirement of MCOs to certify the accuracy and completeness of provider contracts or other documents, as stated in § 438.608 is consistent with current practices. These demonstrations are evident in NCQA Accreditation procedures, Medicaid waiver reviews, and audits that are necessary for compliance with other relevant State and Federal laws. Depending on the MCO, new processes may be necessary to comply with this standard. This requirement may not necessarily result in new mechanisms or resources for MCOs, but may create the need for more coordination with additional State representatives in the review of provider contracts.

2. Change in Threshold from $100,000 to $1,000,000

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

L. Permitting Same Copayments in HMOs as in Fee-for-Service

Under section 4708(c) of the BBA, State agencies 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 realize some savings as a result. However, applying copayments in Medicaid populations may cause State agencies and MCOs to incur more overhead costs related to administering these fees. Factors contributing to these costs include copayments that are significantly lower for Medicaid beneficiaries than typical commercial copayments and difficulty in ensuring compliance with these payments, along with collection efforts that would inevitably be necessary for MCOs to obtain all fees due to them. Also, if State agencies take full advantage of this option, Medicaid managed care enrollees would incur additional costs to obtain health care services. As a result of these variables, it is difficult to predict how many State agencies will take advantage of this new option of permitting copayments in HMOs.

M. Six-month Guaranteed Eligibility

The legislation has expanded the States' option to guarantee up to 6 months eligibility in two ways. First, it expands the types of HMOs whose members may have guaranteed eligibility, in that now it 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 primary care case manager as defined in section 1905(t) of the Act. These changes are effective October 1, 1997. To the extent that State agencies choose this option, we expect MCEs in those States to support the use of this provision, as it affords healthplans with minimally acceptable assurance of membership for a specified period of time. Similarly, beneficiaries will gain from this coverage expansion and continuity of care will 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 [1]

[Dollars in millions]

	FY 1999	FY 2000	FY 2001	FY 2002	FY 2003
Federal	25	40	55	80	115
State	20	30	45	60	90
Total	45	70	100	140	205

[1] These estimates are rounded to the nearest $5 million.

The estimates of Federal costs are reflected in the current budget baseline. The estimates assume that half of the current Medicaid population is enrolled in managed care and that this proportion will increase to about two-thirds by 2003. We also assume that 15 percent of managed care enrollees are currently covered by guaranteed eligibility under rules in effect before to the BBA and that the effect of the expanded option under Section 4709 of the BBA will be to increase this rate to 20 percent initially and to 30 percent by 2003. The guaranteed eligibility provision is assumed to increase average enrollment by 3 percent in populations covered by the option. This assumption is based on computer simulations of enrollment and turnover in the Medicaid program. Per capita costs used for the estimate were taken from the President's FY 1999 budget projections and the costs for children take into account the interaction of this provision with the State option for 12 months of continuous eligibility under section 4731 of the BBA. The distribution between Federal and State costs is based on the average Federal share representing 57 percent of the total costs.

In States electing the 6-month guaranteed eligibility option, Medicaid beneficiaries will have access to increased continuity of care which should result in better health care management and improved clinical outcomes.

N. Conclusion

This BBA managed care regulation will affect HCFA, State agencies, MCOs, providers, and beneficiaries in different ways. The initial investments that are needed by State agencies and MCOs will result in improved and more consistent standards for the delivery of health care to Medicaid beneficiaries. Greater consumer safeguards will result from new quality improvement and

protection provisions. Consequently, long term savings will derive from more consistent standards across State agencies and MCOs, and increased opportunities for provider and beneficiary involvement in improved access, outcomes, and satisfaction. We solicit public comments on the costs that may be incurred by the above mentioned entities to the extent that they may be significantly economically affected by these provisions.

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.

42 CFR chapter IV would 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. Section 400.200 is amended to add the following definitions, in alphabetical order:

§ 400.200 General definitions.

* * * * *

HIO stands for health insuring organization.

* * * * *

MCE stands for managed care entity.

MCO stands for managed care organization.

* * * * *

PHP stands for prepaid health plan

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. In part 430 a new § 430.5 is added, to read as follows:

§ 430.5 Definitions.

As used in this subchapter, unless the context indicates otherwise—

Capitation payment means a payment the State agency makes periodically to a contract for each recipient enrolled under a contract for the provision of medical services under the State plan, regardless of whether the recipient receives services during the period covered by the fee.

Clinical laboratory means a facility that examines materials derived from the human body, for the purpose of providing information for the diagnosis, prevention or treatment of a disease or the assessment of a medical condition.

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.

Contractor means any entity that contracts with the State agency, under the State plan and in return for a payment, to process claims, to pay for or provide medical services, or to enhance the State agency's capability for effective administration of the program.

Federally qualified HMO means an HMO that has been determined by HCFA to be a qualified HMO under section 1310(d) of the PHS Act.

Health insuring organization means an entity that—

(1) Covers (through payments or arrangements with providers) services for recipients in exchange for a fixed payment amount; and

(2) Assumes risk for the cost of the services it covers.

Nonrisk contract means a contract under which the contractor—

(1) Is not at risk for costs incurred that do not exceed the upper limits on payments specified in § 447.362 of this chapter; and

(2) Is reimbursed based on the costs it actually incurs.

Prepaid health plan (PHP) means an entity that provides medical services to enrolled recipients, under contract with the State agency and on the basis of prepaid capitation payments, but does not have a comprehensive risk contract.

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 payment under the contract.

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, ''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 a 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 MCE enrollee who, while completing a minimum enrollment period, is deemed eligible only for services furnished by or through the MCE, may, as an exception to the deemed limitation, seek family planning services from any qualified provider.

(6) Section 1932(a) of the Act, as added by section 4701(a) of the Balanced Budget Act of 1997, permits a State to restrict the freedom of choice required by section 1902(a)(23), under specified circumstances, but not with respect to family planning services.

* * * * *

3. In § 431.55, the following sentence is added at the end of paragraph (c)(1)(i):

§ 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 PHP takes similar 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 individuals who—

(1) Are proposed to be transferred or discharged from nursing facilities; or

(2) Are adversely affected by the preadmission screening or the annual resident review required by section 1919(e)(7) of the Act.

5. In § 431.220(a) introductory text , paragraph introductory text is republished 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—

* * * * *

(5) Any MCO or PHP enrollee who is entitled to a hearing under subpart F of part 438 of this chapter.

* * * * *

PART 434—CONTRACTS

1. The authority citation for part 434 continues to read as follows:

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

2. In § 434.1, paragraph (a) is revised to read as follows:

§ 434.1 Basis and scope.

(a) *Statutory basis.* This part is based on section 1902(a)(4) of the Act, which requires that the State plan provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.

* * * * *

§ 434.2 [Amended].

3. In § 434.2, the definitions of ''capitation fee'', ''clinical laboratory'', ''contractor'', ''enrolled recipient'', ''Federally qualified HMO'', ''health insuring organization'', ''health maintenance organization (HMO)'', ''nonrisk'' ''prepaid health plan'' ''provisional status HMO'' and ''risk or underwriting risk'' are removed.

§ 434.6 [Amended]

4. In paragraph (a)(1), '' , 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.

Subpart F [Amended]

§ 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.* HCFA 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 introductory text is revised to read as follows:

§ 435.212 Individuals who would be ineligible if they were not enrolled in an MCE.

The State agency may provide that a recipient who is enrolled in an MCE 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 MCE.

If the State agency provides Medicaid to the categorically needy under § 435.212, it may provide Medicaid under the same rules to medically needy recipients who are enrolled in an MCE.

1. A new part 438 is added to chapter IV, to read as follows:

PART 438—MANAGED CARE PROVISIONS

Subpart A—General Provisions

Sec.

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. The application of the requirements of this part to PHPs that do not meet the statutory definition of MCO or a primary care case manager 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 MCE if that MCE still has a contract with the State.

(4) Section 1905(t) contains requirements that apply to primary care case managers.

(5) Section 1932—

(i) Provides that, with specified exceptions, a State may require Medicaid recipients to enroll in managed care entities;

(ii) Defines ''managed care entity (MCE)'' as ''an MCO or a primary care case manager'';

(iii) Establishes the rules that MCOs, primary care case managers, 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 ;

(iv) Establishes numerous protections for enrollees of MCEs;

(v) Requires States to develop a quality assessment and performance improvement strategy;

(vi) Specifies certain prohibitions aimed at the prevention of fraud and abuse;

(vii) Provides that a State may not enter into contracts with MCEs unless it has established intermediate sanctions that it may impose on an MCE that fails to comply with specified requirements; and (viii) Makes other minor changes in the Medicaid programs.

(b) *Scope.* This part sets forth requirements, prohibitions, and procedures for the provision of Medicaid services through managed care entities. 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—

Authorized representative means an individual authorized by an enrollee to act on his or her behalf in any dealings with an MCE or the State. The rules for appointment of representatives set forth in 20 CFR part 404, subpart R apply unless otherwise provided in this subpart.

Managed care entity (MCE) means—

(1) A Medicaid managed care organization (MCO) that has a comprehensive risk contract under section 1903(m) of the Act; or

(2) A primary care case manager.

Managed care organization (MCO) means—

(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) Is organized primarily for the purpose of providing health care services.

(ii) 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.

(iii) Meets the solvency standards of § 438.116.

Prepaid health plan (PHP) means an entity that provides medical services to enrolled recipients under contract with the State agency, and on the basis of prepaid capitation fees, but does not have a comprehensive risk contract.

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

Primary care case management means a system under which a primary care case manager 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 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, one of the following:

(1) A physician assistant.

(2) A nurse practitioner.

(3) A certified nurse-midwife.

Provider means—

(1) Any individual who is engaged in the delivery of health care services in a State and is licensed or certified by the State to engage in that activity in the State; and

(2) Any entity that is engaged in the delivery of health care services in a State and is licensed or certified by the State to deliver those services if licensing or certification is required by State law or regulation.

§ 438.6 Contract requirements.

(a) *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) Certain Community, Migrant, and Appalachian Health Centers identified in section 1902(m)(2)(G) of the Act. Unless they qualify for a total exemption under section 1902(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).

(b) *Capitation payments.* All risk contracts must specify—

(1) The actuarial basis for computation of the capitation payments; and

(2) That the capitation payments and any other payments provided for in the contract do not exceed the payment limits set forth in § 447.361 of this chapter.

(c) *Enrollment discrimination prohibited.* Contracts with MCEs must provide as follows:

(1) During open enrollment periods, the MCE 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 as provided under § 438.50 or under a waiver of freedom of choice under section 1115(a)(1) or section 1915(b) of the Act.

(3) The MCE will not, on the basis of health status or need for health services, discriminate against individuals eligible to enroll.

(d) *Services that may be covered.* An MCE contract may cover, for enrollees, services that are in addition to those covered under the State plan for recipients who are not enrollees.

(e) *Compliance with contracting rules.* All contracts must meet the requirements of this section.

(f) *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 relating to the entity's capacity to bear the risk of potential financial losses.

(g) *Physician incentive plans.* (1) MCO 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'', ''HCFA'', and ''Medicare beneficiaries'' must be read as references to ''MCO'', ''State agency'' and ''Medicaid recipients'', respectively.

(h) *Advance directives.* (1) MCO contracts must provide for compliance with the requirements of subpart I of part 489 of this chapter for maintaining written policies and procedures with respect to advance directives.

(2) The MCO must provide adult enrollees with oral and 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.

(i) *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.

(j) *Additional rules for contracts with primary care case managers.* A primary care case manager 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 terminate enrollment in accordance with § 438.56.

§ 438.8 Provisions that apply to PHPs.

The following requirements and options apply to PHPs, PHP contracts, and States with respect to PHPs, to the same extent that they apply to MCOs, MCO contracts, and States with respect to MCOs.

(a) The requirements of § 438.6, except those that pertain, respectively, to physician incentive plans, advance directives, and HIOs.

(b) The information requirements of § 438.10.

(c) The provision against provider discrimination in § 438.12.

(d) The requirements in subpart C of this part (enrollee protections).

(e) The requirements in subpart E of this part (quality) that are applicable to services furnished by the PHP.

(f) The requirements in subpart F of this part (grievance and appeals) except for HCFA denial of FFP under § 438.424(b).

(g) The requirements in § 438.56 (e) through (h) (enrollment and disenrollment) and § 438.58 (conflict of interest safeguards).

438.10 Information requirements.

(a) *Basic rules.* (1) Each State, MCE, and enrollment broker must, in furnishing information to enrollees and potential enrollees, meet the requirements that are applicable to it under this section.

(2) The provisions of paragraphs (b) and (c) of this section apply to all information furnished to enrollees and potential enrollees, such as enrollment notices, informational and instructional materials and the information specified in paragraphs (d) through (i) of this section.

(b) *Language.* The State must meet the following requirements:

(1) Establish a methodology for determining the prevalent language or languages in a geographic area.

(2) Make information available in the languages that predominate throughout the State, and require each MCE to make its information available in the languages that predominate in its particular service area.

(3) Make translation services available and require each MCE to make translation services available to meet the needs of all enrollees and potential enrollees.

(4) Provide instructions to enrollees and potential enrolees and require each MCE to provide instructions to its enrollees and potential enrollees on how to obtain information in the appropriate language and how to access translation services.

(c) *Format.* The material must—

(1) Use easily understood language and format; and

(2) Take into consideration the special needs of those who, for example, are visually impaired or have limited reading proficiency.

(d) *Provision of basic information.* (1) The information listed in paragraph (e) of this section must be provided as follows:

(i) To each enrollee, by the MCO or by the State if the State prohibits the MCO from providing it, within a reasonable time after it receives, from the State or the enrollment broker, notice of the recipient's enrollment.

(ii) To any potential enrollee who requests it, by the MCO, or by the State if the State prohibits MCOs from providing it.

(2) Once a year the MCO must notify its enrollees of their right to request and obtain the information listed in paragraph (e) of this section.

(e) *Basic information.* The following information must be provided as specified in paragraph (d) of this section.

(1) Kinds of benefits, and amount, duration, and scope of benefits available under the contract. There must be sufficient detail to ensure that enrollees receive the services to which they are entitled, including pharmaceuticals, mental health, and substance abuse services.

(2) Procedures for obtaining services, including authorization requirements.

(3) Names and locations of current network providers, including identification of those who are not accepting new patients.

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

(5) The extent to which enrollees may obtain services from out-of-network providers.

(6) The extent to which after-hours and emergency coverage are provided.

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

(8) Cost sharing, if any.

(9) The rights and responsibilities of enrollees, such as those set forth in §§ 438.56 and 438.320.

(10) Complaint, grievance, and fair hearing procedures required under § 438.414(b).

(11) Any appeal rights that the State chooses to make available to providers.

(f) *Additional information available upon request.* (1) The information specified in paragraph (f)(2) of this section must be provided, upon request, as follows:

(i) To each enrollee, by the MCO; and

(ii) To each potential enrollee, by the MCO, or by the State if the State prohibits the MCO from providing it.

(2) The following information must be provided in accordance with paragraph (f)(1) of this section:

(i) With respect to MCOs and health care facilities, their licensure, certification, and accreditation status.

(ii) With respect to health professionals, information that includes, but is not limited to, education and Board certification and recertification.

(g) *Additional information: Medicaid-covered benefits not provided under the MCE contract.* Before or during enrollment, the State must, directly or through the MCE, provide to Medicaid recipients information on the following:

(1) Any benefits to which they may be entitled under the Medicaid program, but that are not covered under the MCE contract.

(2) Specific instructions on where and how to obtain those benefits, including how transportation is provided.

(3) Cost sharing, if any.

(h) *Information that primary care case managers are required to provide.* Each primary care case manager must, upon request, provide information about the grievance procedures available to enrollees, including procedures for obtaining services during the appeals process.

(i) *Additional information: Mandatory MCE enrollment under section 1932 of the Act.*

(1) *Basic rule.* If the State plan provides for mandatory MCE enrollment under section 1932(a)(1)(A) of the Act, the State must provide the information specified in paragraph (i)(2) of this section, either directly or through the MCE—

(i) To potential enrollees whenever they request it, and at least once a year; and

(ii) Presented in a comparative, chart-like format.

(2) *Required information.* The information must include the following for each contracting MCE:

(i) The MCE's service area.

(ii) The benefits covered under the contract.

(iii) Any cost sharing imposed by the MCE.

(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.

(a) *General rules.* (1) An MCO may not discriminate with respect to 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.

(2) The MCO must contract with all health care professionals in the manner specified in § 438.314.

(b) *Construction.* Paragraph (a) of this section may not be construed to—

(1) Require the MCO to contract with providers beyond the number necessary to meet the needs of its enrollees;

(2) Preclude the MCO from using different reimbursement amounts for different specialties; or

(3) Preclude the MCO from establishing measures designed to

maintain quality of services and control costs, consistent with its responsibilities to enrollees.

Subpart B—State Responsibilities

§ 438.50 State plan and contract requirements: General rule.

A State plan that provides for requiring Medicaid recipients to enroll in managed care entities must—

(a) Specify the types of entities with which the State will contract under a mandatory enrollment program authorized by section 1932(a)(1)(A) of the Act, the payment method that will be used (whether fee-for-service or capitation), and whether the contract is a comprehensive risk contract; and

(b) Provide assurances that the State will meet all applicable requirements of—

(1) Section 1903(m) of the Act, with respect to MCOs;

(2) Section 1905(t) of the Act, with respect to primary care case managers and primary care case manager contracts;

(3) Section 1932(a)(1)(A) of the Act, which provides the option for States to limit freedom of choice by requiring recipients to receive their benefits through managed care entities; and

(4) This part, with respect to MCEs.

(c) Provide assurances that—

(1) All contracts will meet the applicable requirements of this part and of part 434 of this chapter;

(2) All MCO contracts will also meet the requirements of section 1903(m)(2) of the Act;

(3) All primary care case manager contracts will comply with the requirements of section 1905(t) of the Act; and

(4) All risk contracts will comply with the upper limit of payment restrictions imposed by § 447.361 of this chapter.

§ 438.52 Choice of managed care entities.

(a) *Terminology.* For purposes of this section, a State may define ''rural area'' as any of the following:

(1) Any area outside of an ''urban area'' as defined in § 412.62(f)(1)(ii) of this chapter.

(2) Any area not delineated as an ''urbanized area'' in the last census conducted by the Census Bureau, as described in § 491.5(c) of this chapter.

(3) Any area (except the whole State) under a definition proposed by a State and approved by HCFA or determined by HCFA (that may apply to one State or all States).

(b) *General requirement.* Except as specified in paragraphs (c) and (d) of this section, a State that requires Medicaid recipients to enroll in an MCE must give recipients a choice of at least two MCEs.

(c) *Exception for rural area residents.* For recipients who reside in a rural area, the State may, under a program authorized by section 1932(a) of the Act, or under a waiver under § 431.55 of this chapter, limit recipients to a single MCE, provided it permits the recipient—

(1) To choose from at least two physicians or case managers; and

(2) To obtain services from any other provider under the following circumstances:

(i) The service or type of provider is not available within the MCE network.

(ii) The provider is not part of the MCE network, but has an existing relationship with the recipient.

(iii) The only plan or provider available to the recipient does not, because of moral or religious objections, provide the service the enrollee seeks.

(iv) The State determines that other circumstances warrant out-of-network treatment.

(d) *Exception for certain health insuring organizations (HIOs).* The State may limit recipients to a single HIO if—

(1) The HIO is one of those described in section 1932(a)(3)(C) of the Act; and

(2) The recipient who enrolls in the HIO has a choice of at least two providers within the entity.

§ 438.56 Enrollment and disenrollment: Requirements and limitations.

(a) *Applicability.* (1) The provisions of paragraphs (b) through (d) of this section apply only to enrollment mandated under the authority of section 1932 of the Act.

(2) Paragraphs (a) and (e) through (h) apply under all MCE contracts, regardless of whether enrollment is mandated under section 1932, or voluntary, and under PHP contracts, as provided in § 438.8.

(b) *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 MCE:

(1) Recipients who are also eligible for Medicare.

(2) Indians who are members of Federally recognized tribes, except when the MCE is—

(i) The Indian Health Service; or

(ii) An Indian health 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.

(c) *Priority for enrollment.* Enrollment procedures must include a system under which recipients already enrolled in an MCE are given priority to continue that enrollment if the MCE does not have the capacity to accept all those seeking enrollment under the program.

(d) *Enrollment by default.* (1) For recipients who do not choose an MCE during their enrollment period, the State must have a default enrollment process for assigning those recipients to contracting MCEs.

(2) The process must seek to preserve existing individual 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 MCEs available to enroll them.

(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 general Medicaid population.

(e) *Disenrollment by the recipient: Timing.* (1) *General rule.* If the State chooses to restrict disenrollment, its contracts must provide that a recipient enrolled in an MCE is permitted to disenroll as follows:

(i) For cause, at any time.

(ii) Without cause, as follows:

(A) During the 90 days following the effective date of the individual's initial enrollment with the MCE. (If notice of enrollment to the recipient is delayed, the 90-day period may be extended to compensate for that delay.)

(B) At least once every 12 months thereafter.

(2) *Special rule for certain programs.* The provisions of paragraph (e)(1) of this section apply to changes among individual physicians or primary care case managers, for enrollees who—

(i) Reside in a rural area in which the State makes available only one MCE, as permitted under § 438.52(c); or

(ii) Reside in an area in which only one HIO is available, as permitted under § 438.52(d).

(f) *Procedures for disenrollment for cause.* (1) *Request for disenrollment.* (i) The enrollee must submit a written request to the State agency or, if the State permits MCEs to process disenrollments for cause, to the MCE.

(ii) When an MCE receives a request for disenrollment, it must promptly submit a copy to the State agency.

(2) *Action on enrollee's request.* (i) The MCE may approve the request if the State permits MCEs to process disenrollments for cause.

(ii) If the MCE approves the request, it must give the enrollee and the State agency written notice of the approval and of the effective date of disenrollment, which must be consistent with paragraph (f)(4) of this section.

(iii) If the MCE, for whatever reason, does not take action to approve the request, it must notify the State agency within a reasonable time-frame established by the State.

(iv) Upon receipt of the MCE's notice, the State agency determines whether there is good cause for disenrollment, based on the following:

(A) Reasons cited in the request, such as poor quality care, lack of access to necessary specialty services covered under the contract, or other reasons satisfactory to the State agency.

(B) Information provided by the MCE at the State agency's request.

(3) *Use of the MCE's grievance procedures.* (i) The State agency may require that the enrollee seek redress through the MCE's grievance system before making a determination on the enrollee's request, except when the request alleges that any delay would pose immediate jeopardy to the enrollee's health.

(ii) The grievance process, if used, must be completed in time to permit the disenrollment (if approved) to be effective no later than the first day of the second month after the month the enrollee makes the request.

(iii) If, as a result of the grievance process, the MCE approves disenrollment, the State agency is not required to make a determination.

(4) *State agency determination.* (i) If a State agency determination is required, the timing of that determination must be such as to permit disenrollment effective no later than the first day of the second month following the month in which the enrollee makes the request.

(ii) If the State agency fails to make a determination within the specified time frames, the request for disenrollment is considered approved.

(g) *Notice and appeals.* A State that restricts disenrollment under this section must take the following actions:

(1) Require MCEs to notify enrollees and potential enrollees of their disenrollment rights—

(i) At least 60 days before the start of each enrollment period; and

(ii) At least once a year.

(2) Establish an appeals process for enrollees dissatisfied with a State agency determination that there is not good cause for disenrollment.

(h) *Automatic reenrollment.* If the State plan so specifies, the contract must provide for automatic reenrollment of a recipient who is terminated from an MCE solely because he or she loses Medicaid eligibility for a period of two months or less.

§ 438.58 Conflict of interest safeguards.

(a) As a condition for contracting with MCOs 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 MCO contracts or the default enrollment process specified in § 438.56 of this chapter.

(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.

(a) *Basic rule.* The State agency must ensure that, except as provided in paragraph (b) of this section, no payment is made, for services not furnished through the MCO if the services were available under the MCO contract with the State agency.

(b) *Exception.* In accordance with § 438.114(c) and (d), emergency services and post-stabilization services are not subject to the limitation of paragraph (a) of this section.

§ 438.62 Continued service to recipients.

The State agency must arrange for Medicaid services to be provided without delay to any Medicaid enrollee of an MCO whose contract is terminated and for any Medicaid enrollee who is disenrolled from an MCO for any reason other than ineligibility for Medicaid.

§ 438.64 Computation of capitation payments.

The State agency must determine that capitation payments and any other payments provided for in the contract are computed on an actuarially sound basis.

§ 438.66 Monitoring procedures.

The State agency must have in effect procedures for monitoring the following aspects of the MCO's practices and procedures:

(a) Enrollment and termination practices.

(b) Implementation of grievance procedures.

(c) Violations subject to intermediate sanctions, as provided in subpart I of this part.

(d) Violations of the conditions for FFP, as set forth in subpart J of this part.

Subpart C—Enrollee Protections

§ 438.100 Benefits.

(a) Contracts with MCOs must specify the services that the entity is required to provide to Medicaid enrollees.

(b) If the contract does not cover all Medicaid services covered under the State plan, the State must make arrangements for furnishing those other services and give enrollees written instructions on how to obtain them.

§ 438.102 Enrollee-provider communications.

(a) *Practitioner defined.* As used in this subpart ''practitioner'' means a physician, as defined in section 1861(r) of the Act, or any of the following: a psychologist, physician assistant, physical or occupational therapist or therapist assistant, speech-language pathologist, audiologist, registered or licensed practical nurse (including nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, and certified nurse midwife), licensed or certified social worker, registered respiratory therapist and certified respiratory therapy technician.

(b) *General rule.* An MCO may not prohibit, or otherwise limit or restrict a participating practitioner (who is acting within the scope of his or her practice) from advising an enrollee who is the practitioner's patient, about the enrollee's health status or about medical care or treatment for the enrollee's condition or disease, regardless of whether the MCO provides benefits for the particular type of care or treatment.

(c) *Conscience protection.* The general rule in paragraph (b) of this section does not require the MCO to cover, furnish, or pay for a particular counseling or referral service if the MCO—

(1) Objects to the provision of that service on moral or religious grounds; and

(2) Makes written information on these policies available as follows:

(i) To the State, with its application for a Medicaid contract.

(ii) To prospective enrollees, before and during enrollment.

(iii) To current enrollees, within 90 days after adopting the policy with respect to any particular service.

(d) *Construction.* Nothing in paragraph (c) of this section may be construed to affect disclosure requirements under State law or under the Employee Retirement Income Security Act of 1974.

§ 438.104 Marketing activities.

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

Choice counseling means activities such as answering questions and providing information (in an unbiased manner) on available delivery system options, and advising on what factors to consider when choosing among them and in selecting a primary care provider.

Cold-call marketing means any unsolicited personal contact by the MCE with a potential enrollee for the purpose of influencing the individual to enroll in that particular MCE.

Enrollment activities means activities such as distributing, collecting, and processing enrollment materials and taking enrollments by phone or in person.

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

Marketing materials means materials that—

(1) Are produced in any medium, by or on behalf of an MCE;

(2) Are used by the MCE to communicate with individuals who are not its enrollees; and

(3) Can reasonably be interpreted as intended to influence the individuals to enroll or reenroll in that particular

MCE and *entity* include any of the entity's employees, affiliated providers, agents, or contractors.

Recipient and *potential recipient* include the recipient's authorized representative.

(b) *Requirements and prohibitions.* Each MCE contract must——

(1) Specify the methods by which the entity assures the State agency that marketing plans and materials are accurate and do not mislead, confuse, or defraud the recipients or the State agency.

(2) 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;

(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 of any other insurance: and

(v) Does not, directly or indirectly, engage in door-to-door, telephone, or other ''cold-call'' marketing activities.

(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 must provide that its Medicaid enrollees are not held liable for any of the following:

(a) The debts of the MCO, in the event of its insolvency.

(b) Services provided to the enrollee, for which—

(1) The State does not pay the MCO; or

(2) The State or the MCO does not pay the individual or health care provider that furnishes the services under a contractual, referral, or other arrangement.

(c) Payments for 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 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 447.58 of this chapter.

§ 438.110 Assurances of adequate capacity and services.

(a) *Basic rule.* Each MCO must give the State and HCFA assurances that it has the capacity to serve the expected enrollment in its service area in accordance with subpart E of this part.

(b) *Nature of assurances.* The MCO must submit documentation, as provided in paragraphs (c) and (d) of this section, to demonstrate that it—

(1) Offers an appropriate range of services, including access to preventive services, primary care services and specialty services for the anticipated number of enrollees for the service area; and

(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; and

(3) Meets the availability of services requirements of § 438.306.

(c) *Timing of documentation.* The MCO must submit the documentation described in paragraph (b) of this section at least every 2 years, and, specifically—

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

(2) At any time the State determines there has been a significant change in the MCO's delivery network or enrollee population.

(d) *State review and submission to HCFA.* After the State reviews the documentation, and after the MCO makes any changes required as a result of that review, the MCO must submit to HCFA assurances that include copies of—

(1) The documentation reviewed by the State; and

(2) The State's certification that the MCO has complied with the State's requirements for availability of services, as set forth in § 438.306.

§ 438.114 Emergency and post-stabilization services.

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

Emergency medical condition means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in—

(1) Serious jeopardy to the health of the individual or, in the case of a pregnant woman, the health of the woman or her unborn child;

(2) Serious impairment of bodily function; or

(3) Serious dysfunction of any bodily organ or part.

Emergency services means covered inpatient or outpatient services that are—

(1) Furnished by a provider qualified to furnish emergency services; and

(2) Needed to evaluate or stabilize an emergency medical condition.

Post-stabilization services means medically necessary non-emergency services furnished to an enrollee after he or she is stabilized following an emergency medical condition.

(b) *Disclosure requirements.* At the time of enrollment and at least annually thereafter, each MCE must provide, in clear, accurate, and standardized form, information that, at a minimum, describes or explains the following:

(1) What constitutes an emergency, and what constitutes post-stabilization services, 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 any emergency settings and other locations at which MCE physicians and hospitals provide emergency services and post-stabilization services covered under the contract.

(5) The fact that prior authorization is not required for emergency services.

(6) The fact that the provider must request authorization for post-stabilization services, but pre-authorization is not required if the MCE does not provide it within an hour after receiving a request for authorization or cannot be reached for authorization.

(c) *Coverage and payment: Post-stabilization services.* (1) The provider of post-stabilization services must request prior authorization for those services.

(2) Each MCE with a risk contract that covers post-stabilization services must pay for those services if—

(i) The services are pre-approved by the MCE; or

(ii) The services are not pre-approved because the MCE does not respond within 1 hour after receiving the provider's request, or cannot be contacted for approval.

(3) If services are covered under paragraph (c)(2) of this section, the MCE must continue to pay for the services until it contacts the provider and makes other arrangements.

(4) If post-stabilization services are not covered under an MCE risk contract, the State must pay for those services if they meet the conditions of paragraph (c)(2)(i) or (c)(2)(ii) of this section.

(5) If authorization by a primary care case manager is a condition for coverage of services, a primary care case manager may not deny authorization for post-stabilization services that meet the conditions of paragraph (c)(2)(ii) of this section.

(d) *Additional rules for emergency services.* (1) An MCO must pay for emergency services regardless of whether the entity that furnishes the services has a contract with the MCO.

(2) A primary care case manager 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 health care provider that furnishes the services; and

(ii) Pay for the emergency services if the manager's contract is a risk contract that covers those services.

(e) *Financial responsibility.* (1) An MCO may not deny payment for treatment obtained under either of the following circumstances:

(i) An enrollee had an emergency medical condition, including cases in which the absence of immediate medical attention would not have had the outcomes specified in paragraphs (1), (2), and (3) of the definition of ''emergency medical condition'' in this section.

(ii) A practitioner or other representative of the MCO instructs the enrollee to seek emergency services.

(2) The MCO is not responsible for services obtained outside the network unless they are emergency services or post-stabilization services that meet the requirement of paragraph (c)(2) of this section.

(f) *Stabilized condition.* The attending physician, or the practitioner actually treating the enrollee, determines when the enrollee is sufficiently stabilized for transfer or discharge, and that determination is binding on the MCO.

§ 438.116 Solvency standards.

(a) *Basic rule.* Each MCO must meet the solvency standards in paragraph (b) of this section, and must provide assurances satisfactory to the State showing that it has adequate provision against the risk of insolvency such as to ensure that its Medicaid enrollees will not be liable for the MCO's debts if it becomes insolvent.

(b) *State solvency standards requirement.* Except as provided in paragraph (c) of this section, an MCO satisfies the solvency requirements if it meets the solvency standards established by the State for private health maintenance organizations, or is licensed or certified by the State as a risk-bearing entity.

(c) *Exceptions to State solvency standards requirement.* The requirement of paragraph (b) of this section does not apply if the MCO—

(1) Does not provide both inpatient hospital services and physician services;

(2) Is a public entity;

(3) Is (or is controlled by) one or more Federally qualified health centers and meets the solvency standards established by the State for those centers;

(4) Has its solvency guaranteed by the State;

(5) Entered into its current contract before October 1998; or

(6) Had a contract under 1903(m) on August 5, 1997. (This exemption expires on August 5, 2000.)

Subpart D [Reserved]

Subpart E—Quality Assessment and Performance Improvement

§ 438.300 Scope.

This subpart implements section 1932(c)(1) and sets forth specifications for quality assessment and performance improvement strategies that States must implement to ensure the delivery of quality health care by MCOs. It also establishes standards that States and MCOs must meet.

§ 438.302 State responsibilities.

Each State contracting with an MCO must—

(a) Have a strategy for assessing and improving the quality of managed care services offered by the MCO;

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

(c) Conduct regular, periodic reviews to evaluate the effectiveness of the strategy, as often as the State considers appropriate, but at least every three years.

§ 438.304 Elements of State quality strategies.

At a minimum, State strategies must include the following—

(a) Contract provisions that incorporate the standards specified in this subpart.

(b) Procedures for assessing the quality and appropriateness of care and services furnished to all Medicaid enrollees under the contract. These procedures include, but are not limited to, continuous monitoring and evaluation of MCO compliance with the standards.

(c) Arranging for annual, external independent reviews of the quality outcomes and timeliness of, and access to services covered under each MCO contract.

(d) Appropriate use of intermediate sanctions that, at a minimum, meet the requirements of Subpart I of this part.

(e) An information system that is sufficient to support initial and ongoing operation and review of the State's quality strategy.

(f) Standards, at least as stringent as those in this subpart, for access to care, structure and operations, and quality measurement and improvement.

Access Standards

§ 438.306 Availability of services.

(a) *Basic rule.* Each State must ensure that all covered services are available and accessible to enrollees.

(b) *Choice of entities.* If a State limits freedom of choice, it must comply with

the requirements of § 438.52, which specifies the choices that the State must make available.

(c) *Services not covered by the MCO contract.* If an MCO contract does not cover all of the services covered under the State plan, the State must arrange for those services to be made available from other sources and instruct all enrollees on where and how to obtain them, including how transportation is provided.

(d) *Delivery network.* The State must ensure that each MCO complies with the requirements set forth in this paragraph.

(1) The MCO 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, the MCO must consider the following:

(i) The anticipated enrollment, with particular attention to pregnant women and children.

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

(iii) The numbers and types of providers required to furnish the contracted services.

(iv) The number of network providers who are not accepting new patients.

(v) The geographic location of providers and enrollees, considering distance, travel time, the means of transportation ordinarily used by enrollees, and whether the location provides physical access for enrollees with disabilities.

(2) The MCO provides female enrollees with direct access to a women's health specialist within the network for womens' routine and preventive health care services, notwithstanding that the MCO maintains a primary care provider for each enrollee.

(3) If seeking expansion of its service area, the MCO demonstrates that it has sufficient numbers and types of providers to meet the anticipated additional volume and types of services the added enrollee population may require.

(4) The MCO demonstrates that its providers are credentialed as required by § 438.314.

(5) When medically appropriate, the MCO makes services available 24 hours a day, 7 days a week. This applies, at a minimum, to —

(i) Emergency services and post-stabilization services; and

(ii) Non-emergency services that are required immediately because of an unforseen illness.

(6) The MCO ensures that its providers' hours of operation are convenient for enrollees and do not discriminate against Medicaid enrollees.

(e) *Provision of services.* The State must ensure that each MCO complies with the requirements of this paragraph.

(1) *Timely access.* The MCO must—

(i) Meet and require its providers to meet State standards established under § 438.304(f) for timely access to care and member services, taking into account the urgency of need for services;

(ii) Establish mechanisms to ensure compliance;

(iii) Monitor continuously to determine compliance; and

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

(2) *Initial assessment.* The MCO must provide initial assessments within the following time frames:

(i) For each enrollee, within 90 days of the effective date of enrollment.

(ii) For pregnant women and enrollees with complex and serious medical conditions, within a shorter period of time, as determined by the State.

(3) *Pregnancy and complex and serious medical conditions.* The MCO must have in effect State-approved procedures under which the MCO—

(i) Timely identifies and furnishes care to pregnant women;

(ii) Timely identifies individuals with complex and serious medical conditions, assesses those conditions and identifies appropriate medical procedures for monitoring or treating them; and

(iii) Implements a treatment plan that—

(A) Is appropriate to the conditions identified and assessed under paragraph (e)(3)(ii) of this section;

(B) Is for a specific period of time;

(C) Specifies an adequate number of direct access visits to specialists as required by the treatment plan; and

(D) Is updated periodically by the physician responsible for overall coordination of the enrollee's health care.

(4) *Cultural considerations.* The MCO ensures that services are provided in a culturally competent manner to all enrollees, including at least the language requirements of § 438.10.

§ 438.308 Continuity and coordination of care.

The State must ensure that each MCO meets the requirements of this section.

(a) *Primary care and over-all coordination.* This requires written policies that—

(1) Provide that each enrollee has an ongoing source of primary care appropriate to the enrollee's needs, and a health care practitioner who is formally designated as primarily responsible for coordinating the enrollee's overall health care; and

(2) Specify whether coordination is provided by the enrollee's primary care provider or by a different practitioner.

(b) *Coordination program.* Each MCO must ensure coordination of services internally and with services available from community organizations and other social programs.

(c) *Patient care information.* The MCO and its providers must have the information necessary for effective and continuous patient care and quality improvement, including procedures to ensure that—

(1) Each provider maintains, for Medicaid enrollees, health records that meet the requirements established by the MCO, taking into account professional standards; and

(2) There is appropriate and confidential exchange of information among providers.

(d) *Enrollee participation.* To ensure optimum enrollee participation, there must be procedures to ensure that providers—

(1) Inform enrollees of specific health conditions that require follow-up and, if appropriate, provide training in self-care; and

(2) Deal with factors that hinder enrollee compliance with prescribed treatments or regimens.

§ 438.310 Coverage and authorization of services.

(a) *Coverage.* Each contract must—

(1) Identify, define, and specify the amount, duration, and scope of each service that the MCO offers;

(2) Specify what constitutes ''medically necessary services'' to the extent they are described in the State plan; and

(3) Provide that the MCO furnishes the services in accordance with that provision.

(b) *Processing of requests.* Each contract must—

(1) Require that, in processing requests for initial and continuing authorization of services, the MCO and its subcontractors follow written policies and procedures that reflect current standards of medical practice;

(2) Specify the information required for authorization decisions and require that the MCO—

(i) Have in effect mechanisms to ensure consistent application of review criteria for authorization decisions;

(ii) Consult with the requesting provider when appropriate; and

(iii) Observe the time-frames specified in paragraph (d) of this section.

(c) *Notice of adverse action.* Each contract must provide that, within the time frames specified in paragraph (d) of this section, the MCO will give the requesting provider and the enrollee written notice, in accordance with § 438.404, of the following:

(1) Any decision to deny, limit, reduce, delay, or terminate a services, including specific reasons for the decision.

(2) The enrollee's right to file a grievance or request a State fair hearing, in accordance with subpart F of this part.

(d) *Time-frames.* Each contract must specify that the MCO will provide services as expeditiously as the enrollee's health condition requires and within State-established time-frames that may not exceed the following:

(1) Ordinarily, no later than 14 calendar days after receipt of the request for service, with a possible extension of up to 14 additional calendar days, if—

(i) The enrollee requests extension; or

(ii) The MCO justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.

(2) If the physician indicates, or the MCO determines that following the ordinary time-frame could seriously jeopardize the enrollee's life or health or ability to regain maximum function, no later than 72 hours after receipt of the request for service, with a possible extension of up to 14 additional calendar days if—

(i) The enrollee requests extension; or

(ii) The MCO 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

§ 438.314 Establishment of provider networks.

(a) The State must ensure that each MCO implements a documented selection and retention process that meets the requirements of this section.

(b) For each practitioner, including each practitioner who is a member of a contracting group that provides services to the MCO's Medicaid enrollees, the process must include procedures for the following:

(1) Initial credentialing that is based on a written application and site visits as appropriate, as well as primary source verification of licensure, disciplinary status, and eligibility for payment under Medicaid.

(2) Recredentialing that is accomplished—

(i) Within time-frames set by the State, but no less frequently than required by the State for private health maintenance organizations; and

(ii) Through a process that updates information obtained during initial credentialing and considers performance indicators, including those obtained through the following:

(A) The quality assessment and performance improvement program.

(B) The utilization management system.

(C) The grievance system.

(D) Enrollee satisfaction surveys.

(E) Other MCO activities, as specified by the State.

(3) Use of formal selection and retention criteria that, consistent with § 438.12 do not discriminate against particular practitioners, such as those who serve high risk populations, or specialize in conditions that require costly treatment.

(4) For each provider other than an individual practitioner, initial determination and periodic redetermination (at specified intervals determined by Federal and State credentialing cycles) to ensure that, at a minimum, the provider is licensed (if the State requires licensing to operate in the State) and in compliance with any other Federal or State requirements.

§ 438.318 Enrollee information.

(a) *General rule.* The requirements that States must meet under § 438.10 constitute part of the State's quality strategy.

(b) *Additional requirement.* (1) Each State or its contracted representative must also provide the information specified in paragraph (b)(2) of this section, for each contracting MCO throughout the State—

(i) To any potential enrollee who requests it; and

(ii) To all potential enrollees, when they first become eligible for Medicaid, are considering choice of MCOs under a voluntary program, or are first required to choose an MCO under a mandatory enrollment program; and

(iii) Within a time frame that enables them to use the information in choosing among available MCOs.

(2) *Required information.* Following is the information that the State must provide:

(i) Benefits covered.

(ii) Cost-sharing, if any.

(iii) Service area.

(iv) Names and locations of current network providers, including identification of those who are not accepting new patients.

(v) Benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those services, any cost sharing, and how transportation is provided.

§ 438.320 Enrollee rights.

(a) *General rule.* The State must ensure that each MCO has written policies regarding the enrollee rights specified in this section, complies with any other Federal and State laws that pertain to enrollee rights, and ensures that its staff and affiliated providers take into account those rights when furnishing services to enrollees.

(b) *Basic rights.* The State must ensure that each enrollee has the right to—

(1) Receive information in accordance with §§ 438.10 and 438.318.

(2) Be provided health care services in accordance with §§ 438.306 through 438.310.

(3) Be treated with respect and with due consideration for his or her dignity and privacy;

(4) Receive information on available treatment options and alternatives;

(5) Participate in decisions regarding his or her health care; and

(6) Have access to his or her medical records in accordance with applicable Federal and State laws.

(c) *Other statutory requirements.* The State must ensure that each MCO complies with any other Federal or State laws (such as the Civil Rights Act of 1964, the Age Discrimination Act of 1975, and the Americans with Disabilities Act) that pertain to enrollee rights.

§ 438.324 Confidentiality.

The State must ensure, consistent with the regulations in subpart F of part 431 of this chapter, that each MCO establishes and implements procedures to do the following:

(a) Maintain the records and any other information (in oral, written, or electronic format) in a timely and accurate manner.

(b) Safeguard the privacy of any information that identifies a particular enrollee by ensuring that—

(1) Original medical records are released only in accordance with Federal or State law, or court orders or subpoenas;

(2) Copies of records and information from the MCO are released only to authorized individuals; and

(3) Unauthorized individuals do not gain access to, or alter, patient records.

(c) Protect the confidentiality and privacy of minors, subject to applicable Federal and State law.

(d) Ensure that enrollees have timely access to the records and information that pertain to them.

(e) Abide by all Federal and State laws regarding confidentiality and disclosure of mental health records, medical records, other health information, and any information about an enrollee.

§ 438.326 Enrollment and disenrollment.

The State must ensure that each MCO complies with the enrollment and disenrollment requirements and limitations set forth in § 438.56.

§ 438.328 Grievance systems.

The State must ensure that each MCO has in effect a grievance system that meets the requirements of subpart F of this part.

§ 438.330 Subcontractual relationships and delegation.

(a) *General rule.* The State must ensure that each MCO oversees and is accountable for any functions and responsibilities that it delegates to any subcontractor, and meets the conditions of paragraph (b) of this section.

(b) *Specific conditions.* (1) Before any delegation, the MCO evaluates the prospective subcontractor's ability to perform the activities to be delegated.

(2) There is a written agreement that specifies the delegated activities and reporting responsibilities of the subcontractor and provides for revocation of the delegation or imposition of other sanctions if the subcontractor's performance is inadequate.

(3) The MCO monitors the subcontractor's performance on an ongoing basis and subjects it to formal review at least once a year.

(4) If the MCO identifies deficiencies or areas for improvement, the MCO and the subcontractor take corrective action.

Measurement and Improvement Standards

§ 438.336 Practice guidelines.

The State must ensure that each MCO develops (or adopts) and disseminates practice guidelines in accordance with this section.

(a) *Development of guidelines.* Guidelines——

(1) Are based on reasonable medical evidence or a consensus of health care professionals in the particular field;

(2) Consider the needs of the MCO's enrolles;

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

(4) Are reviewed and updated periodically.

(b) *Dissemination of guidelines.* The MCO disseminates the guidelines to all providers, to all enrollees as appropriate, and to individual enrollees when they request them.

(c) *Application of guidelines.* Decisions with respect to utilization management, enrollee education, coverage of services, and other areas to which the guidelines apply are consistent with the guidelines.

§ 438.340 Quality assessment and performance improvement program.

(a) *General rules.* (1) The State must require, through its contracts, that each MCO has an ongoing quality assessment and performance improvement program for the services it furnishes to its enrollees.

(2) Paragraphs (b) through (d) of this section set forth the basic elements, minimum performance levels, and performance improvement projects required for MCOs.

(b) *Basic elements of an MCO quality assessment and performance improvement program.* At a minimum, the State must require that the MCO——

(1) Achieve required minimum performance levels on standardized quality measures, in accordance with paragraph (c) of this section;

(2) 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 can be expected to have a favorable effect on health outcomes and enrollee satisfaction; and

(3) Have in effect mechanisms to detect both underutilization and overutilization of services.

(c) *Minimum performance levels.* (1) The MCO must meet the following requirements:

(i) Measure its performance, using standard measures required by the State, and report its performance to the State.

(ii) Achieve any minimum performance levels that the State establishes with respect to the standard measures.

(2) The State——

(i) May specify the standard measures in uniform data collection and reporting instruments; and

(ii) Must, in establishing minimum performance levels for the MCO—

(A) Consider data and trends for both the MCO and fee-for-service Medicaid in that State; and

(B) Establish the minimum performance levels prospectively upon contract initiation and renewal.

(d) *Performance improvement projects.* (1) Performance improvement projects are MCO initiatives 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 project must represent the entire population to which the measurement specified in paragraph (d)(1)(i) of this section is relevant.

(3) The State must establish MCO obligations for the number and distribution of projects among the required clinical and non-clinical areas specified in paragraphs (d)(4) and (d)(5) of this section, to ensure that the projects are representative of the entire spectrum of clinical and non-clinical areas associated with the MCO.

(4) Clinical areas include—

(i) Prevention and care of acute and chronic conditions;

(ii) High-volume services;

(iii) High-risk services; and

(iv) Continuity and coordination of care.

(5) Non-clinical areas include—

(i) Appeals, grievances, and complaints; and

(ii) Access to, and availability of, services.

(6) In addition to requiring that the MCO initiate its own performance improvement projects, the State may require that the MCO—

(i) Conduct particular performance improvement projects that are specific to the MCO; and

(ii) Participate annually in at least one Statewide performance improvement project.

(7) For each project, the MCO must assess its performance using quality indicators that are—

(i) Objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research; and

(ii) Capable of measuring outcomes such as changes in health status, functional status, and enrollee satisfaction, or valid proxies of these outcomes.

(8) Performance assessment on the selected indicators must be based on

systematic ongoing collection and analysis of valid and reliable data.

(9) The MCO's interventions must achieve improvement that is significant and sustained over time.

(10) The MCO must report the status and results of each project to the State as requested.

(e) *Program review by the State.* (1) The State must review, at least annually, the impact and effectiveness of the MCO's quality assessment and performance improvement program. The review must include—

(i) The MCO's performance on the standard measures on which it is required to report; and

(ii) The results of the MCO's performance improvement projects.

(2) The State may require that the MCO have in effect a process for its own evaluation of the impact and effectiveness of its quality assessment and performance improvement program.

§ 438.342 Health information systems.

(a) *General rule.* The State must ensure that each MCO maintains a health information system that collects, analyzes, integrates, and reports data and can achieve the objectives of this subpart. The system should provide information on areas including, but not limited to, utilization, grievances, disenrollments, and solvency.

(b) *Basic elements of a health information system.* The State must require, at a minimum, that the MCO 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 such 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 to HCFA, as required in this subpart, or upon request.

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 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.

Complaint means any oral or written communication, made by or on behalf of an enrollee, to any employee of the MCO or of its providers, or to the State, expressing dissatisfaction with any aspect of the MCO's or provider's operations, activities, or behavior, regardless of whether the communication requests any remedial action.

Enrollee means an enrollee or his or her authorized representative.

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

Grievance means a written communication, submitted by or on behalf of a Medicaid enrollee, expressing dissatisfaction with any aspect of the MCO's or provider's operations, activities, or behavior that pertains to—

(1) The availability, delivery, or quality of health care services, including utilization review decisions that are adverse to the enrollee;

(2) Payment, treatment, or reimbursement of claims for health care services; or

(3) Issues unresolved through the complaint process.

§ 438.402 General requirements.

(a) *The grievance system.* Each MCO must provide for a grievance system that includes a complaint process, a grievance process, and a link to the State's fair hearing system.

(b) *Complaint and grievance process requirements.* The MCO must—

(1) Base its complaint and grievance processes on written policies and procedures that, at a minimum, meet the conditions set forth in this subpart;

(2) Obtain the State's written approval of the complaint and grievance processes before implementation;

(3) Require that its governing body approve and be responsible for the effective operation of complaint and grievance processes; and

(4) Require that its governing body review and resolve complaints and grievances, unless it delegates this responsibility in writing to a grievance committee.

(c) *Grievance process requirements.* Each MCO grievance process must meet the following requirements:

(1) Consist of clearly explained steps that—

(i) Permit the enrollee to appeal to the MCO and to the State; and

(ii) Allow the enrollee a reasonable time to request grievance resolution and fair hearing. (The minimum time is 90 days from the date the MCO mails the notice of action, as provided under the fair hearing process at § 431.221 of this chapter.)

(2) Include, for each step, time frames that take into consideration the enrollee's health condition and provide for expedited resolution of grievances in accordance with § 438.410.

(3) Permit enrollees to appear before the MCO personnel responsible for resolving the grievance.

(4) Provide that, if the grievance resolution decision is wholly or partly adverse to the enrollee, the MCO submits the decision and all supporting documentation to the State as expeditiously as the enrollee's health condition requires but no later than the following:

(i) For a standard resolution, no later than 30 days after receipt of the grievance or the expiration of any extension.

(ii) For an expedited resolution, no later than 24 hours after reaching the decision.

(5) Not substitute for the State's fair hearing system.

(d) *State fair hearing.* The State must either permit the enrollee to request a State fair hearing on a grievance at any time, or provide for a State fair hearing following an MCO adverse decision on the grievance under paragraph (c)(4) of this section.

§ 438.404 Notice of intended action.

If an MCO intends to deny, limit, reduce, delay, or terminate a service or deny payment for a service, the MCO must give the enrollee timely written notice, within time-frames specified in § 438.310, to explain the following:

(a) The action the MCO intends to take.

(b) The reasons for the intended action.

(c) Any laws and rules that support the action.

(d) The enrollee's right to file a complaint or grievance with the MCO and to request a State fair hearing.

(e) The circumstances under which expedited grievance review is available and how to request it.

(f) How to file complaints, grievances, and State fair hearing requests.

(g) That if the enrollee files a grievance, he or she has a right to appear in person before the MCO personnel assigned to resolve the grievance.

(h) The circumstances under which benefits will continue pending resolution of the grievance or issuance of a State fair hearing decision.

(i) How to contact the designated office described in § 438.406(a).

(j) How to obtain copies of enrollee's records, not limited to medical records.

§ 438.406 Handling of complaints and grievances.

Each MCO must comply with the following requirements in handling complaints and grievances:

(a) Have an adequately staffed office that is designated as the central point for enrollee issues, including complaints and grievances.

(b) Acknowledge receipt of each complaint and grievance.

(c) Give enrollees any assistance they need in completing forms or taking other steps necessary to obtain resolution of the complaint or grievance at the MCO level.

(d) Conduct the grievance process using impartial individuals who were not involved in any previous level of review or decision making. In the case of a denial based on lack of medical necessity, the individual must be a physician with appropriate expertise in the field of medicine that encompasses the enrollee's condition or disease.

(e) Resolve all grievances in accordance § 438.408.

§ 438.408 Grievance resolution and notification.

(a) *Resolution.* The MCO must take the following actions and comply with the following requirements:

(1) Investigate the grievance.

(2) For a grievance that requires standard resolution, resolve the grievance as expeditiously as the enrollee's health condition requires, within time frames established by the State, but no later than 30 calendar days after it receives the grievance. The MCO may extend the 30-day time frame by up to 14 calendar days if—

(i) The enrollee requests the extension; or

(ii) The MCO justifies (upon request, to the State agency) a need for additional information and how the delay is in the interest of the enrollee.

(3) For a grievance that requires expedited resolution under § 438.410, resolve the grievance as expeditiously as the enrollee's health condition requires, within time frames established by the State, but no later than 72 hours after it receives the grievance. The MCO may extend the time frame by up to 14 calendar days if—

(i) The enrollee requests the extension; or

(ii) The MCO justifies (upon request, to the State agency) a need for additional information and how the delay is in the interest of the enrollee;

(4) Base the decision on the record of the case, including any MCO hearing provided under § 438.402(c)(3), and relevant program laws, regulations, and policies.

(b) *Notification.* (1) *Timing.* Within the time frames specified in paragraphs (a)(2) and (a)(3) of this section, the MCO must—

(i) Give the affected parties written notice of a standard resolution decision and oral and written notice of an expedited resolution decision; and

(ii) If the decision is wholly or partially adverse to the enrollee, submit the decision and all supporting documentation to the State as expeditiously as the enrollee's health condition requires, but no later than the following:

(A) For a standard resolution, no later than 30 days after it receives the grievance.

(B) For an expedited resolution, no later than 24 hours after it reaches the decision.

(2) *Content of notice.* The notice of grievance resolution must include the following:

(i) The name of the MCO contact for the grievance.

(ii) The results of the grievance process and the date it was completed.

(iii) A summary of the steps taken on behalf of the enrollee to resolve the issue.

(iv) A clear explanation of the right to a State fair hearing, if the enrollee is dissatisfied with the decision, and how to timely file for a fair hearing.

(v) For a grievance decision that is wholly or partly adverse to the enrollee, an explanation of the circumstances under which—

(A) Benefits will continue if the enrollee files a fair hearing request timely; and

(B) The enrollee may be required to pay the cost of any services furnished during the pendency of the appeal, if the final decision is adverse to him or her.

§ 438.410 Expedited resolution of grievances.

Each MCO must establish and maintain an expedited grievance review process under which the MCO—

(a) Provides an enrollee with expedited resolution of a grievance in response to a written request, or an oral request confirmed in writing within 24 hours, under the following circumstances:

(1) An enrollee makes the request, and the MCO determines that taking the time for a standard non-expedited resolution could seriously jeopardize the enrollee's life or health or the enrollee's ability to regain maximum function.

(2) A physician makes the request or supports an enrollee's request and indicates that taking the time for standard, non-expedited resolution could seriously jeopardize the enrollee's life or health or the enrollee's ability to regain maximum function.

(b) Issues the decision of the expedited resolution, including the information specified in § 438.408(b)—

(1) As expeditiously as the enrollee's health condition requires;

(2) Within the time frame established by the State agency, but no later than 72 hours after it receives the grievance, or the date of expiration of any extension specified in § 438.408(a)(3).

(c) Notifies the State of each decision that is wholly or partly adverse to the enrollee, and submits, for further review by the State, the records and documentation that support the decision—

(1) As expeditiously as the enrollee's health condition requires; but

(2) No later than 24 hours after the expedited decision,

(d) Continues the enrollee's benefits, pending final resolution, in accordance with § 438.420.

(e) Neither takes nor threatens to take any punitive action against a physician who requests an expedited resolution or supports an enrollee's request for expedited resolution.

(f) If it denies a request for expedited resolution of a grievance, takes the following actions:

(1) Automatically transfers the request to the time frame for standard resolution established under § 438.408(a)(2). The time frame begins with the day that the MCO receives the request for expedited resolution.

(2) Gives the enrollee prompt oral notice of the denial of the request and follows up, within 2 working days, with a written letter that —

(i) Explains that the MCO will process the request using the 30-day time frame for standard resolutions;

(ii) Informs the enrollee of the right to file a grievance if he or she disagrees with the MCO's decision not to expedite; and (iii) Provides instructions about the grievance process and its time frames.

§ 438.414 Information about the grievance system.

(a) *To whom information must be provided.* Each MCO must provide information about the grievance system, as required under § 438.10 and specified in paragraph (b) of this section to—

(1) Enrollees;

(2) Potential enrollees (as permitted by the State); and

(3) All providers, at the time of subcontracting.

(b) *Information content.* The information must explain the grievance system through a State-developed or State-approved description and must include the following:

(1) Specification of what constitutes grounds for a complaint, grievance, or State fair hearing request.

(2) An explanation of how to file complaints, grievances and State fair hearing requests, and the time frames for doing so.

(3) An explanation of the availability of assistance with the grievance process and State fair hearings.

(4) Toll-free numbers that the enrollee can use to register a complaint or complete a grievance form by telephone. The toll-free numbers must have adequate TTY and interpreter capability.

(5) The specific titles and telephone numbers of the persons who have responsibility for the proper functioning of the grievance process and the authority to require corrective action.

(6) Assurance that filing a grievance or requesting a State fair hearing will not negatively affect or impact the way the MCO and its providers, or the State agency treat the enrollee.

(7) Information on how to obtain care or services during the grievance and fair hearing processes as specified in § 438.420.

(c) *Aggregate information.* Upon request, the MCO must provide enrollees and potential enrollees with aggregate information, derived from the information collected under § 438.416(e), regarding the nature of enrollee grievances and their resolution.

§ 438.416 Recordkeeping and reporting requirements.

Each MCO must comply with the following requirements, and in so doing, must comply with the confidentiality requirements of § 438.324:

(a) Maintain a log of all complaints and grievances and their resolution.

(b) Track each grievance until its final resolution.

(c) Record any disenrollment and the reason for it, even if it occurs before the grievance process is completed.

(d) Retain the records of complaints, grievances (including their resolution) and disenrollments for three years, in a central location, and make them accessible to the State. If any litigation, claim negotiation, audit, or other action involving the documents or records is started before the expiration of the three-year period, the MCO must retain the records until completion of the action and resolution of issues which arise from it or until the end of the regular three-year period, whichever is later.

(e) As often as the State requests, but at least once a year, analyze the collected information and prepare and send to the State a summary that includes the following information:

(1) The number and nature of all complaints and grievances.

(2) The time frames within which they were resolved, and the decisions.

(3) A listing of all grievances that have not been resolved to the satisfaction of the affected enrollee.

(4) The number and nature of grievances for which the MCO provided expedited resolution, and the decisions.

(5) Any trends relating to a particular provider or a particular service.

§ 438.420 Continuation of benefits pending grievance resolution or State fair hearing decision.

(a) *Terminology.* (1) As used in this section, ''timely'', as it pertains to the filing of a grievance, or a request for expedited grievance resolution or State fair hearing, means filing—

(i) On or before the time limit specified by the State and communicated in the notice of intended action; or

(ii) Before the effective date of the MCO's proposed action, whichever is later.

(2) The State-specified time limit may not be less than the 5-day or 10-day time-frames specified in §§ 431.230 and 431.231 of this chapter for advance notice to Medicaid beneficiaries.

(b) *Basic rule.* If an enrollee timely files a grievance or requests expedited grievance resolution or a State fair hearing, the MCO must continue the enrollee's benefits until issuance of the final grievance decision or State fair hearing decision if the following conditions are met:

(1) The current level of services was ordered by the MCO treating physician or another MCO physician.

(2) The physician is authorized to order the services under the MCO contract.

(3) The enrollee requests continuation.

§ 438.421 Effectuation of reversed grievance resolutions.

(a) *Reversal by the MCO.* If the MCO reconsiders and reverses a grievance resolution decision to deny service, the MCO must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days after reversal.

(b) *Reversal by State fair hearing decision.* If an MCO grievance resolution decision to deny service is reversed by a State fair hearing decision, the MCO must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 calendar days after receipt of the State's notice of reversal.

§ 438.422 Monitoring of the grievance system.

(a) The records that MCOs are required to maintain and summarize under § 438.416 provide the basis for monitoring by the MCO and by the State.

(b) If the summaries required under paragraph (e) of § 438.416 reveal undesirable trends by a particular provider or involving a particular service, the MCO must conduct an in-depth review, report the results to the State, and take corrective action.

§ 438.424 Consequences of noncompliance.

If an MCO (or its providers) fails to comply with the provisions of this subpart—

(a) The State may terminate the MCO's contract, in accordance with § 438.718; and

(b) HCFA may deny FFP to the State, in accordance with §§ 438.802 and 438.804.

Subpart G—[Reserved]

Subpart H—Certifications and Program Integrity Protections

§ 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 will be determined, and services will be provided in a manner consistent with simplicity of administration and the best interests of the recipients.

§ 438.602 Certification of data that determine payment.

When State payments to MCOs are based on data submitted by the MCO—

(a) The data includes but is not limited to enrollment information, encounter data, and other information required by the State; and

(b) As a condition for receiving payment, the MCO must, concurrent with the submission of the data, attest to its accuracy, completeness, and truthfulness.

§ 438.606 Conditions necessary to contract as an MCO.

(a) Any entity seeking to contract as an MCO must have administrative and management arrangements or procedures designed to guard against fraud and abuse. Unless otherwise provided for by State law, the arrangements or procedures must include reporting to the State, and to HCFA or the OIG (or both) credible information on violations of law by the MCO or its subcontractors or enrollees.

(b) With respect to enrollees, this reporting requirement applies only to credible information on violations of law that pertain to enrollment in the plan, or the provision of, or payment for, health services.

§ 438.608 Certification for contracts and proposals.

MCOs must certify the accuracy, completeness, and truthfulness of information in contracts, requests for proposals, and other related documents specified by the State.

Subpart I—Sanctions

§ 438.700 Basis for imposition of sanctions.

(a) Each State that contracts with an MCO must establish intermediate sanctions, as specified in § 438.702, that it may impose if it makes a determination that an MCO acts or fails to act as follows:

(1) Fails substantially to provide medically necessary services that the MCO is required to provide, under law or under its contract with the State, to an enrollee covered under the contract.

(2) Imposes on enrollees premiums or charges that are in excess of the premiums or charges permitted under the Medicaid program.

(3) Acts to discriminate among enrollees on the basis of their health status or requirements 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 HCFA or to the State, or to an enrollee, potential enrollee, or health care provider.

(5) Fails to comply with the requirements for physician incentive plans, as set forth in § 422.208 of this chapter.

(6) Distributes directly, or indirectly through any agent or independent contractor, marketing materials that have not been approved by the State or contain false or materially misleading information.

(b) Each State that contracts with a primary care case manager may establish intermediate sanctions that it may impose if it determines that the case manager has distributed directly, or indirectly through any agent or independent contractor, marketing materials that have not been approved by the State or contain false or materially misleading information in violation of § 438.104(b).

§ 438.702 Types of intermediate sanctions.

(a) The types of intermediate sanctions that a State may impose under this subpart include any of 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 primary care case manager.)

(3) Granting enrollees of MCEs the right to terminate enrollment without cause. (The State must notify the affected recipients of their right to disenroll.)

(4) Suspension of all new enrollment, including default enrollment, after the date HCFA or the State notifies the MCE of a determination under § 438.700.

(5) Suspension of payment to the MCE for recipients enrolled after the date HCFA or the State notifies the MCE of a determination under § 438.700, and until HCFA or the State is satisfied that the reason for imposition of sanction no longer exists and is not likely to recur.

(b) The State may also impose the sanctions specified in paragraphs (a)(4) and (a)(5) of this section on entities that have been determined by the State or by HCFA to have committed violations as follows:

(1) On an MCO that has violated any of the requirements in section 1903)(m) of the Act or implementing regulations; and

(2) On an MCE that has violated any of the requirements in section 1932 of the Act or implementing regulations.

§ 438.704 Amounts of civil money penalties.

The limit on the amount of a civil money penalty the State may impose varies depending on the nature of the MCE's action or failure to act, as provided in this section.

(a) The limit is $25,000 for each determination of either of the following:

(1) A failure to act described in paragraph (a)(1), (a)(5), (a)(6), or (b) of § 438.700.

(2) A misrepresentation or falsification of information furnished to an enrollee, potential enrollee, or health care provider.

(b) The limit is $100,000 for each determination of either of the following:

(1) Discriminatory action as described in paragraph (a)(3) of § 438.700.

(2) A misrepresentation or falsification of information furnished to HCFA or to the State.

(c) The limit is $15,000 (subject to the $100,000 limit of paragraph (b) of this section) for each recipient the State determines was not enrolled because of the discriminatory practice determined under paragraph (b) of this section.

(d) For premiums or charges in excess of the amounts permitted under the Medicaid program, the limit is double the amount of the excess charges. The State must deduct from the penalty the amount of overcharge and return it to the affected enrollee.

§ 438.706 Special rules for temporary management.

(a) *Basis for 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 § 434.67(a) of this chapter, or that is contrary to any requirements of sections 1903(m) or 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) *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 Required imposition of temporary management for chronic substandard MCOs.

For an MCO that the State finds has repeatedly substantially failed to meet requirements in sections 1903(m) and 1932 of the Act and implementing regulations, the State must (regardless of any other sanctions that may be provided) impose temporary management and grant enrollees the right to terminate enrollment without cause, as described in § 438.702(a)(3).

§ 438.710 Notice of sanction; due process.

(a) *General rule.* Except as provided in paragraph (b) of this section, before imposing any of the sanctions specified in this subpart, the State must give the affected MCE timely written notice that explains——

(1) The basis and nature of the sanction; and

(2) Any other due process protections that the State elects to provide.

(b) *Exception.* The State may not delay imposition of temporary management during the time required for due process procedures, and may not provide a hearing before imposition of temporary management.

§ 438.718 Termination of an MCE contract.

A State has the authority to terminate an MCE's contract, and enroll that entity's enrollees in other MCEs or provide their Medicaid benefits through other options included in the State plan if the State determines that the MCE—

(a) Has failed substantially to carry out the terms of its contract; or

(b) Has failed to meet applicable requirements in sections 1932, 1903(m), or 1905(t) of the Act.

§ 438.720 Hearing on contract termination.

(a) *Requirement.* Before terminating an MCE contract under § 438.718, the State must provide the MCE a pre-termination hearing.

(b) *Procedure.* The State must—

(1) Within 30 days after reaching the determination to terminate, give the MCE written notice of its intent to terminate, the reason for termination, and the time and place of the hearing; and

(2) Provide the hearing not less than 30 nor more than 60 days after the notice, unless the State and the MCE reach written agreement on a different date.

(c) *Decision following a hearing.* (1) After the hearing, the State must give the MCE a written decision affirming or reversing the proposed determination to terminate the contract.

(2) If the hearing decision affirms the proposed determination to terminate, the State must indicate the date the termination is effective.

§ 438.722 Disenrollment during termination hearing process.

After a State has notified an MCE of its intention to terminate the MCE's contract, the State may——

(a) Give the MCE's enrollees written notice of the State's intent to terminate the MCE's contract; and

(b) Allow enrollees to disenroll immediately without cause.

§ 438.724 Notice to HCFA.

(a) The State must give the HCFA 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 the sanction; and

(2) Specify the affected MCE, the kind of sanction, and the reason for the State's decision to impose or lift the sanction.

§ 438.730 Sanction by HCFA.

(a) *Nature of sanction.* If the conditions of this section are met, HCFA may impose on an MCO the sanction of denial of payment for new enrollees, that is, for recipients enrolled after the effective date of the sanction.

(b) *Basis for sanction.* (1) A State agency may recommend that HCFA impose the denial of payment sanction on an MCO with a comprehensive risk contract if the MCO——

(i) Has failed to comply with the requirement of § 438.700(a)(1);

(ii) Has acted as specified in paragraph (a)(2), (a)(3), or (a)(4) of § 438.700.

(iii) Has failed to meet the physician incentive plan requirements specified in § 438.700(a)(5), or has failed to submit information on the incentive plan as required by § 417.479 of this chapter.

(2) The State agency's recommendation becomes HCFA's decision unless HCFA rejects it within 15 days.

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

(1) HCFA conveys the determination to the OIG for consideration of possible imposition of civil money penalties under part 1003 or 1005 of this title.

(2) 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 original 15-day period for an additional 15 days if, before the end of that 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 HCFA determines that the MCO's conduct poses a threat to an enrollee's health and safety.

(d) *Informal reconsideration.* (1) If the MCO submits a timely response to the notice of sanction, the State agency conducts an informal reconsideration that includes——

(i) Review of the evidence by an State agency official who did not participate in the original recommendation; and

(ii) A concise written decision setting forth the factual and legal basis for the decision.

(2) The State agency decision under paragraph (d)(1)(ii) of this section is forwarded to HCFA and becomes HCFA's decision unless HCFA reverses or modifies the decision with 15 days from date of receipt.

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

(e) *Effect of HCFA sanction.* HCFA's denial of payment for new enrollees automatically results in denial of State agency payments to the MCO for the same enrollees.

(f) *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 (c) of this section.

(2) If the MCO seeks reconsideration, the following rules apply: (i) Except as specified in paragraph (f)(2)(ii) of this section, the sanction is effective on the date specified in HCFA's reconsideration notice.

(ii) If HCFA, in consultation with the State agency, determines that the MCO's conduct poses a serious threat to an enrollee's health and safety, HCFA may make the sanction effective earlier than the date of HCFA's reconsideration decision under paragraph (d) of this section.

(g) *State plan requirement.* The State plan must provide that the State will monitor for violations of the actions or failures to act specified in this section and will implement the provisions of this section.

(h) *HCFA's role.* HCFA 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 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 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 HCFA 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 HCFA 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 such 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), 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 Medicaid participation under section 1128 or section 1128(a) of the Act.

(ii) Any entity that would provide those services through an excluded individual or entity.

§ 438.810 Expenditures for enrollment broker services.

State expenditures for the use of enrollment brokers are considered necessary for the proper and efficient operation of the State plan only if the following conditions are met:

(a) The broker is independent of any managed care entity or health care provider that furnishes services in the State in which the broker provides enrollment services.

(b) No person who is the owner, employee, or consultant of the broker or has any contract with the broker—

(1) Has any direct or indirect financial interest in any entity or health care provider that furnishes services in the State in which the broker provides enrollment services;

(2) Has been excluded from participation under title XVIII or XIX of the Act;

(3) Has been debarred by any Federal agency; or

(4) Has been, or is now, subject to civil money penalties under the Act.

(c) The initial contract or memorandum of agreement (MOA) for services performed by the broker has been reviewed and approved by HCFA before the effective date of the contract or MOA.

§ 438.812 Costs under risk and nonrisk contracts.

(a) Under a risk contract, the total amount the State agency pays for carrying out the contract provisions is a medical assistance cost.

(b) Under a nonrisk contract—

(1) The amount the State agency pays for the furnishing of medical services to eligible recipients is a medical assistance cost; and

(2) The amount the State agency pays for the contractor's performance of other functions is an administrative cost.

PART 440—SERVICES: GENERAL PROVISIONS

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

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

2. In subpart A, a new § 440.168 is added, to read as follows:

§ 440.168 Primary care case management services.

(a) Primary care case management services means case management related services that—

(1) Include location, coordination, and monitoring of primary health care services; and

(2) Are provided under a contract between the State and either of the following:

(i) A primary care case manager 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 a section 1915(b) or 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 managed care organizations.

(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 managed care organizations.

(b) *Definitions.* ''Claim'' and ''clean claim'' have the same meaning as those terms have in § 447.45.

(c) *Contract requirements.* (1) *Basic rule.* A contract with a managed care organization must provide that the organization will meet the requirements of § 447.45 (d)(2), (d)(3), (d)(5), and (d)(6).

(2) *Exception.* The managed care organization 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(b), the following changes are made:

a. In paragraph (b) introductory text, the parenthetical phrase is removed.

b. Paragraph (b)(6) is removed.

§ 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.

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

Dated: September 22, 1998.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Approved: September 23, 1998.

Donna E. Shalala,

Secretary.

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